Monday Research Poster Presentations

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

POSTER SESSION II: Poster Display Hours – 15:45 - 19:30
   Poster Author Discussion Hour – 18:30 - 19:30

POSTER SESSION I:

PCN: CANCER
PDB: DIABETES/ENDOCRINE DISORDERS
PUK: URINARY/KIDNEY DISORDERS

POSTER SESSION II:

PHS: HEALTH SERVICES
PIH: INDIVIDUAL'S HEALTH
PMS: MUSCULAR-SKELETAL DISORDERS
PSY: SYSTEMIC DISORDERS/CONDITIONS
## Research Poster Presentations – Session I

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**PCN1: LOWER ANTERIOR RESECTION SURGICAL COMPLICATIONS IN COLORECTAL CANCER PATIENTS: ASSOCIATION WITH LENGTH OF STAY, DISCHARGE TO INSTITUTIONAL CARE, AND 90-DAY READMISSION**

**Ammann EM**, Goldstein LJ, Johnston SS, Johnson & Johnson Co., New Brunswick, NJ, USA, Johnson & Johnson, Markham, ON, Canada

**OBJECTIVES:** Lower anterior resection (LAR) surgical complications are associated with substantial morbidity and economic burden. This study assessed the association between complications of particular importance in colorectal surgery—anastomotic leak (AL), bleeding, and infection—and hospital length of stay (LOS), discharge to institutional care, and 90-day readmission in patients who underwent LAR for colorectal cancer. **METHODS:** Patients who underwent LAR for colorectal cancer from 2008Q1-2015Q2 were identified with ICD-9-CM procedures and diagnoses recorded in the Optum Clinformatics Data Mart, a large U.S. database of health insurance claims. ICD-9-CM codes were used to identify patients diagnosed with AL, bleeding, and/or infection during the index LAR; patients with evidence of these complications present on admission or within 180d pre-index were excluded. Generalized linear models and Cox regression were used to separately identify the infection association between each complication and: LOS, discharge to institutional care (e.g., skilled nursing facility), and time-to 90-day readmission (all-cause; censoring at loss to follow-up), adjusting for patient demographics and baseline (180d pre-index) clinical characteristics. **RESULTS:** The study included 3,278 colorectal cancer patients who underwent LAR (median age 60y; 41% female; 69% privately insured; 88% elective admissions). During the index LAR, AL, bleeding, and infection were documented in 382 (11.7%), 384 (11.7%), and 211 (6.4%) patients, respectively. After covariate adjustment, each complication type was associated with increased LOS (adjusted differences: AL, 6.1 days, p<0.0001; bleeding, 3.3 days, p<0.0001; infection, 8.4 days, p<0.0001), higher odds of discharge to institutional care (ORs: 2.12, p=0.0006; 3.03, p<0.0001; 4.25; p<0.0001), and greater risk of 90-day readmission (HRs: 1.31, p=0.006; 1.35, p=0.002; 1.85; p<0.0001). **CONCLUSIONS:** This study provides contemporary real-world evidence on the burden of complications associated with LAR for colorectal cancer. Innovations in surgical care delivery and technology may reduce the risk and burden of these complications.

**PCN2: DETRIMENTAL IMPACT OF TOXICITY ON QUALITY OF LIFE IN HEPATOCELLULAR CARCINOMA PATIENTS TREATED WITH LENVATINIBOR SORAFENIB**

**Hudgens S**, Misurski D, Meier G, Clinical Outcomes Solutions, Tucson, AZ, USA, Eisai Inc., Woodcliff Lake, NJ, USA

**OBJECTIVES:** To determine whether adverse events (AE) were associated with statistically significant differences in overall health utility in patients with unresectable hepatocellular carcinoma (µHCC). **METHODS:** Data on the impact of AEs on the EQ-5D health utility index (HUI) were taken from a multicenter, randomized, open-label, non-inferiority Phase 3 study comparing lenvatinib (LEN) to sorafenib (SOR) as first-line µHCC systemic treatments. 954 patients were randomized to LEN (N=478) or SOR (N=476). The impact of each AE event during the stable treatment period (all post baseline assessments prior to disease progression) on the HUI score was presented using least squares mean (Adj Mean) estimates as a fixed effect relative to the score estimate of patients who did not present with the particular AE event. The statistical significance of the resulting estimate was determined via ANCOVA with alpha of 0.05. **RESULTS:** The adjusted HUI scores for Grade 3/4 and Any Grade asthenic conditions were statistically significant (Grade 3/4 Adj Mean = -0.108, p < 0.0001 and Any Grade Adj Mean = -0.026, p = 0.0008; respectively). Similarly, decreased appetite and weight decrease were significant for both the Grade 3/4 and Any Grade estimates (decreased appetite: Grade 3/4 Adj Mean = -0.078, p = 0.0023 and Any Grade Adj Mean = -0.052, p < 0.0001, respectively; weight decrease: Grade 3/4 Adj Mean = -0.053, p=0.0070 and Any Grade Adj Mean = -0.030, p = 0.0003, respectively). For Any AE, differences were significant for Grade 3/4 and Any Grade estimates (Grade 3/4 Adj Mean = -0.031, p = 0.0006 and Any Grade Adj Mean = -0.028, p = 0.0045, respectively). No additional events were significant for the Grade 3/4 or Any Grade models (p > 0.05). **CONCLUSIONS:** These data illustrate that
asthenic conditions, decreased appetite and weight decrease were the most common AEs that had a detrimental effect on HUI scores.

**PCN3: PATTERN OF CHEMOTHERAPY RELATED ADVERSE EFFECTS AMONG ADULT CANCER PATIENTS TREATED AT GONDAR UNIVERSITY REFERRAL HOSPITAL, ETHIOPIA: A CROSS SECTIONAL STUDY**

**Belachew sA**, Erku dA, Mekuria Ab, Gebresilassie BM, University of Gondar, Gondar, Ethiopia

Pattern of chemotherapy-related adverse effects among adult cancer patients treated at Gondar university Referral Hospital, Ethiopia: a cross-sectional study Adverse drug reactions (ADRs) are a global problem and constitute a major clinical problem in terms of human suffering. The high toxicity and narrow therapeutic index of chemotherapeutic agents makes oncology pharmacovigilance essential. This study was to assess the pattern of ADRs occurring in cancer patients treated with chemotherapy in a tertiary care teaching hospital in Ethiopia A cross-sectional study over a 2-year period from September 2013 to August 2015 was conducted on cancer patients undergoing chemotherapy at Gondar University Referral Hospital Oncology Center. Data were collected directly from patients and their medical case files. The reported ADRs were assessed for causality using the World Health Organization’s causality assessment scale and Naranjo’s algorithm. The severities of the reported reactions were also assessed using National Cancer Institute Common Terminology CTCAE version 4.0. The Pearson son’s chi-square test was employed to examine the association between two categorical variables. A total of 815 ADRs were identified per 203 patients included in the study. The most commonly occurring ADRs were nausea and vomiting (18.9%), infections (16.7%), neutropenia (14.7%), fever and/or chills (11.3%), and anemia (9.3%). Platinum compounds (31.4%) were the most frequent group of drugs causing ADRs. Of the reported ADRs, 65.8% were grades3–4 (severe level), 29.9% were grades 1–2 (mild level), and 4.3% were grade 5 (toxic level). Significant association was found between age, number of chemotherapeutic agents, as well as dose of chemotherapy with the occurrence of grades 3–5 toxicity. The high incidence of chemotherapy-related ADRs among cancer patients is of concern. Setting up an effective ADR monitoring and reporting system (onco-pharmacovigilance) and creating awareness among health care professionals regarding the importance of ADR reporting may help prevent the problem.

**PCN4: ASSESSMENT OF PATIENTS ADMITTED FOR DRUG-RELATED PROBLEMS IN CANCER CHEMOTHERAPY**

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**OBJECTIVES:** The main objective was to study the chemotherapy drug-related hospital admissions in a tertiary care teaching hospital and to estimate the cost involved in the management of DRP’s (Drug Related Problems) due to chemotherapy.METHODS: A prospective observational study was done over a period of 6 months. All patients admitted for supportive care management during the study period due to DRP were included in the study. Patients with chemotherapy drug-related admissions were prospectively identified from the patient’s medical records. The contribution of DRPs and cost incurred due to each hospitalization was assessed. Data were analyzed using SPSS ® 20.0 version.RESULTS: Out of 55 patients analyzed Drug-Related Problems (DRPs) were commonly observed in the age group of 51-60 years 25 (45.5%). The frequently occurring DRP was Adverse Drug Reactions 42 (76.4%) which was noticed more in females. Majority of the DRPs were caused by alkylating agents 8(14.5%) and the least by hormonal agents 8(14.5%). The mean length of hospitalization was found to be 9.6±6.5 days. Pharmacoeconomic evaluation for total direct medical cost and total direct non medical cost was performed. The total direct medical cost was found to be Rs. 31540 ± 42476. Medicine costs Rs16550± 25404 accounted for a major share of the total medical costs.CONCLUSIONS: Our study revealed DRPs is high in elderly patients and among patients with breast cancer. Adverse drug reactions were the predominantly identified problem among the DRPs and were reported to be high in females. Medicine charges accounted for a major share among direct medical cost. Direct non-medical charges such as transportation charges and food charges added on to the financial burden of patients with cancer. Pharmacist can provide better patient care by identifying and preventing DRPs and reducing drug-related morbidity and mortality.

**PCN5: COMPARATIVE EFFICACY AND SAFETY OF OLPARIB 400 MG CAPSULES BID AND NIRAPARIB 300 MG TABLETS QD AS MAINTENANCE TREATMENT AFTER RESPONSE TO CHEMOTHERAPY IN PATIENTS WITH PLATINUM-SENSITIVE RELAPSED NON-GERMLINE BRCA-MUTATED OVARIAN CANCER (PSROC)**

OBJECTIVES: Maintenance therapy with a poly(ADP-ribose) polymerase inhibitor (PARPi), following response to platinum-based chemotherapy, significantly extends progression-free survival (PFS) and time to first subsequent treatment or death (TFST) in germline BRCA-mutated (gBRCAm) platinum-sensitive relapsed ovarian cancer (PSROC). Statistically significant treatment benefit has also been observed in patients without a gBRCAm, suggesting sensitivity to PARPis in non-gBRCAm patients. Comparative efficacy and safety of different PARPis in non-gBRCAm is currently unknown. An indirect treatment comparison (ITC) of niraparib tablets and olaparib capsules, using data from ENGOT-OV16/NOVA and Study 19 (NCT00753545/S19) clinical studies, respectively, was conducted. METHODS: A Bayesian ITC was performed on efficacy and safety on the non-gBRCA data from NOVA (niraparib) and gBRCA wild-type data from S19 (olaparib). Efficacy analyses compared investigator (INV) and independent review committee (IRC) assessed PFS hazard ratios (HR) and TFST HR. Safety analyses included odds ratios (OR) of any grade ≥3 adverse event (AE), AEs leading to dose interruption, reduction, and discontinuation. RESULTS: HRs comparing olaparib and niraparib were 0.94 (95% credible interval 0.54–1.65) for investigator-assessed PFS, and 1.25 (0.67–2.30) for IRC PFS. TFST HR was 0.78 (0.47–1.30). No significant difference in efficacy between PARPi was observed. The corresponding ORs for AE were 0.34 (0.13–0.90), 0.54 (0.16–2.06), 0.16 (0.01–2.18) and 0.21 (0.04–1.21) for any grade ≥3 AE, and AE leading to dose interruption, discontinuation, and reduction, respectively. There was a significant reduction in the odds of any grade ≥3 AE. No significant difference in AE leading to dose interruption, reduction, and discontinuation. CONCLUSIONS: ITC shows no significant difference in efficacy between olaparib capsules and niraparib tablets as maintenance therapy in patients with non-gBRCAm PSROC following response to chemotherapy. Olaparib shows significantly reduced odds compared with niraparib for any grade ≥3 AE. No significant difference was observed in AEs leading to modification in drug administration.

PCN6: COMPARATIVE EFFICACY AND SAFETY OF OLAPARIB 300 MG TABLETS QD AS MAINTENANCE TREATMENT AFTER RESPONSE TO CHEMOTHERAPY IN PATIENTS WITH PLATINUM-SENSITIVE RELAPSED GERMLINE BRCA-MUTATED OVARIAN CANCER (PSROC)

Hettle R1, Sackeyfio A2, Gill J3, Siddiqui K3, Nussey F4, Friedlander M5,1PAREXEL International, London, UK, 2AstraZeneca, Cambridge, UK, 3PAREXEL International, Chandigarh, India, 4Edinburgh Cancer Centre, Western General Hospital, Edinburgh, UK, 5University of New South Wales Clinical School, New South Wales, Australia

OBJECTIVES: Maintenance therapy with a poly(ADP-ribose) polymerase inhibitor (PARPi), following response to platinum-based chemotherapy, significantly extends progression-free survival (PFS) and time to first subsequent treatment or death (TFST) in gBRCAm PSROC. The comparative efficacy and safety of different PARPis is currently unknown. An indirect treatment comparison (ITC) analysis of data from the ENGOT-OV16/NOVA and ENGOT-OV21/SOLO2 clinical studies was used to compare niraparib tablets with olaparib tablets. METHODS: A Bayesian ITC was performed on efficacy and safety data from NOVA (niraparib) and SOLO2 (olaparib). Efficacy data for gBRCAm patients in NOVA were compared with SOLO2. Efficacy analyses included comparing the hazard ratios (HR) of PFS, of investigator-assessed PFS (primary) and independent review committee (IRC)-assessed PFS of SOLO2 versus NOVA, and HR of TFST. Safety analyses included the odds ratio (OR) of any grade ≥3 adverse event (AE), and AEs leading to discontinuation, dose interruption, or dose reduction. RESULTS: PFS HRs comparing olaparib and niraparib were 1.11 (95% credible interval 0.67–1.83) for investigator-assessed PFS, and 0.93 (0.53–1.61) for IRC PFS. TFST HR was 0.90 (0.54–1.49). No significant difference in efficacy between PARPi was observed. The corresponding OR for AEs was 0.18 (0.07–0.47), 0.30 (0.11–0.79), 0.49 (0.01–6.91) and 0.13 (0.02–0.85) for any grade ≥3 AEs, AEs leading to dose interruption, discontinuation, or reduction, respectively. There was a significant reduction in the odds of any grade ≥3 AE and AEs leading to interruption or dose reduction with olaparib, compared with niraparib. CONCLUSIONS: ITC shows no significant difference in efficacy between olaparib tablets and niraparib tablets as maintenance therapy in patients with gBRCAm PSROC, following response to chemotherapy. Olaparib is predicted to have a superior safety profile versus niraparib, with reduced odds of grade ≥3 AEs, drug interruption, and dose reduction.

PCN7: COMPARATIVE EFFICACY AND SAFETY OF INTERVENTIONS FOR PREVENTING CHEMOTHERAPY INDUCED ORAL MUCOSITIS IN ADULT CANCER PATIENTS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

Kengkla K, Kaewpanan T, Kaewthong J, Ruankon S, Subthaweesin C, Saokaew S, University of Phayao, Muang, Phayao, Thailand

OBJECTIVES: To examine the comparative efficacy and safety of interventions for preventing chemotherapy induced oral mucositis (OM). METHODS: We searched PubMed, Embase, and the Cochrane Central systematically for the randomized control trials (RCTs) of interventions for preventing OM. Network meta-analysis (NMA) was performed to
estimate risk ratio (RR) and 95% confidence interval (CI) from both direct and indirect evidences. Primary outcome was any grade of OM. Secondary outcomes were mild-moderate OM, severe OM and adverse events, such as taste disturbance and gastrointestinal adverse events. This study was registered with PROSPERO, number CRD42016052489. RESULTS: A total of 29 RCTs with 2348 patients (median age, 56.1 years; 57.5% male) were included. Cryotherapy was associated with a significantly lower risk of OM than control (RR 0.51, 95% CI 0.38 to 0.68), and zinc sulfate (RR 0.47, 95% CI 0.23 to 0.97), but not significantly lower than sucralfate and palifermin. No significant differences were observed between cryotherapy and control for taste disturbance and gastrointestinal adverse events. However, palifermin was associated with the highest risk of taste disturbance. CONCLUSIONS: This NMA suggests that cryotherapy was the most effective intervention for preventing chemotherapy induced OM with a safety profile similar to control, but not significantly lower than sucralfate and palifermin. However, further large RCTs are needed to confirm these findings.

PCN8: COMPARATIVE EFFECTIVENESS OF NOVEL TREATMENTS FOR ADVANCED MELANOMA: A SYSTEMATIC LITERATURE REVIEW AND NETWORK META-ANALYSIS OF EFFECTIVENESS AND SAFETY OUTCOMES

Franken M1, Leeneman B2, Gheorghe M1, Buyukkaramikli N1, Gerrits J2, van der Helm I2, Uyl-De Groot C1, Versteegh M1, Haanen J1, van Baal P3, Erasmus University Rotterdam, Rotterdam, The Netherlands, 2Erasmus University, Rotterdam, The Netherlands, 3Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands

OBJECTIVES: There is a lack of comparative evidence of novel treatments for advanced melanoma. We synthesised effectiveness and safety evidence using a network meta-analysis (NMA). METHODS: A systematic literature review was performed in Embase, Medline, and Cochrane to retrieve effectiveness and safety evidence of randomised controlled phase-III trials (RCTs; time frame January 1, 2010 to March 1, 2017). Evidence on effectiveness (hazard ratio [HR] for progression-free survival [PFS]) and safety (relative risk [RR] for a grade ≥III adverse event [AE]) was synthesised by means of a Bayesian fixed-effect NMA. Reference treatment was dacarbazine. In accordance with RCTs, dacarbazine was pooled with temozolomide, paclitaxel, and paclitaxel in combination with carboplatin. RESULTS: Out of 1,100 citations, 25 phase-III RCTs were identified. Twenty-one (seventeen) treatments could be included in the effectiveness (safety) NMA. Dabrafenib plus trametinib was identified as most effective treatment, both in terms of HR for PFS (0.21 [95%CrI: 0.17-0.27]) and probability of being the best treatment (PBB: 61% of the simulations). Vemurafenib plus cobimetinib followed as second-best (PBB: 39%; HR PFS: 0.22 [95%CrI: 0.17-0.29]) and dabrafenib as third option (HR PFS: 0.32 [95%CrI: 0.23-0.42]). In case of no BRAF-mutation, nivolumab plus ipilimumab ranked best (PBB: 97%; HR PFS: 0.37 [95%CrI: 0.27-0.49]), followed by nivolumab (HR PFS: 0.50 [95%CrI:0.40-0.62]) and pembrolizumab (HR PFS 3-weekly: 0.51 [95%CrI:0.36-0.71]). Pembrolizumab was most favourable regarding safety (RR for AE 2-weekly [3-weekly]: 0.45 [0.59]; 95%CrI:0.25-0.72 [0.35-0.92]; PBB: 87% [11%]). Six treatments ranked better than dacarbazine, ten ranked lower. The four most effective treatments (HR for PFS) ranked lower than dacarbazine regarding safety. CONCLUSIONS: Until new evidence from RCTs becomes available, our study provides valuable insights into each novel treatment’s comparative effectiveness and safety. Dabrafenib plus trametinib seems the most effective treatment for advanced melanoma, closely followed by vemurafenib plus cobimetinib. Both treatments have, however, less favourable safety outcomes.

PCN9: A LONGITUDINAL INVESTIGATION OF THE RELATIONSHIPS BETWEEN PATIENT-REPORTED SYMPTOMS AND SURVIVAL AMONG PATIENTS WITH HR+/HER2- METASTATIC BREAST CANCER (MBC) TREATED WITH ABEMACICLIB IN THE PHASE 2 MONARCH 1 TRIAL

Houghton K1, Boye ME2, Price GL2, Stull DE1, Tolaney SM3,1RTI Health Solutions, Durham, NC, USA, 2Eli Lilly and Company, Indianapolis, IN, USA, 3Dana-Farber Cancer Institute, Boston, MA, USA

OBJECTIVES: In a phase 2 trial, abemaciclib demonstrated tumour responses in refractory HR+ HER2- mBC. The most common investigator-reported treatment emergent adverse events (TEAEs) were diarrhoea, fatigue, nausea, decreased appetite, and abdominal pain. Fatigue is known to play a central role in patient experience. We present an analysis of patient reports of these symptoms over the course of the trial, with fatigue as the central concept. We explicitly consider missing data, the relationships between symptoms, and the relationships with survival. METHODS: Data came from a single-arm, open-label study of 132 previously-treated patients with mBC. The EORTC QLQ-C30 v3 was administered at baseline and every 28 days thereafter. Domains for fatigue, pain, nausea and vomiting, appetite loss, and diarrhoea were analysed from baseline to visit 10 using extended pattern mixture modelling (ePMM). ePMM is a latent-variable longitudinal mixture model approach used to examine individual variability across all time points and identify subgroups; the subgroup identifier is regressed on missing data indicators at each time point. The final models assessed 1) the prediction of fatigue by the remaining symptoms, and 2) the prediction of overall survival (OS), and progression-free survival (PFS) by fatigue. RESULTS: Three fatigue
subgroups were identified: ‘no change’ (55%; n=73), ‘improvement’ (9%; n=12), ‘worsening then improvement’ (36%; n=47). Pain significantly predicted fatigue (P< 0.01) but the remaining TEAEs did not. Fatigue predicted OS and PFS: Patients in the ‘no change’ fatigue subgroup had significantly longer OS and PFS than those in the ‘worsening then improvement’ subgroup (P=0.01 and P = 0.001, respectively). CONCLUSIONS: Most patients reported no change in fatigue. Fatigue was predicted by changes in pain, and was predictive of changes in OS and PFS. Patient reports of symptom experience are informative and when modelled appropriately they can inform understanding of differential survival.

PCN10: EPIDEMIOLOGY OF BRAFV600-MUTATED METASTATIC MELANOMA IN EUROPE: A SYSTEMATIC REVIEW

Rahhal N1, Chalem Y1, Arkoub H2, Chollet J1, Bobrowska A3, Drane E3, Uchea C3, Wulund L3, Leonard S3,1Pierre Fabre SA, Boulogne-Billancourt, France, 2Pierre Fabre Medicament, Boulogne-Billancourt France, France, 3Costello Medical Consulting Ltd, Cambridge, UK

OBJECTIVES: Though ~50% of metastatic melanomas (MM) appear to carry the BRAFV600 mutation, making these patients eligible for targeted kinase inhibitor therapy, little is known about the epidemiology of this disease. We performed a systematic review of real-world evidence to assess the epidemiology of BRAFV600-mutated cutaneous MM in Europe. METHODS: MEDLINE, Embase and key oncology, dermatology and pharmacoeconomic conferences were searched, with reference lists of potentially relevant narrative and systematic reviews hand-searched. Eligible real-world studies included those published since 2005 reporting: BRAFV600 epidemiology, risk factors, natural history, or general prevalence of toxicities in cutaneous MM patients in the European Economic Area and Switzerland. RESULTS: We screened 1,448 records identified through database searches, 600 conference abstracts and 33 reviews. A total of 45 records reporting 43 unique studies were included. 40 studies reported MM epidemiology and 3 studies reported toxicity. 29–62% of MM was reported as BRAF-mutated, with 51–54% reported in countries with high MM incidence, e.g. Switzerland and Sweden. Many studies were single-centre with small sample sizes. V600E mutations were the majority (81–92%) of all V600 mutations, representing approximately one-third of overall MM. BRAFV600E was more common in younger patients, and did not differ from the general MM sex distribution. Studies reported conflicting results on whether the presence of a BRAFV600 mutation affected overall survival compared to patients with wildtype BRAF. There were no studies reporting ethnicity, comorbidities, or incidence of BRAFV600-mutated MM. CONCLUSIONS: Our finding that the BRAFV600 prevalence is around 50% is concordant with the literature. Our results also suggest that as much as one-third of MM is V600E-mutated, with the mutation more common in younger patients. However, real-world epidemiological evidence on incidence, comorbidities and toxicity associated with BRAF-mutated MM is still limited, despite the potentially large patient population.

PCN11: PATIENT CHARACTERISTICS, SKELETAL RELATED EVENTS (SRE) AND RENAL IMPAIRMENT (RI) IN PATIENTS WITH MULTIPLE MYELOMA (MM): A PATIENT CHART AUDIT IN EU5

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OBJECTIVES: This multicenter patient chart review aimed to understand the characteristics, bisphosphonate (BPs) treatment patterns, SREs and RI in newly diagnosed MM (NDMM) patients in 5 EU countries. METHODS: Medical records of MM patients were screened by oncologists, (onco-)hematologists and internists from France, Germany, Italy, Spain and the UK, with ≥3 years clinical experience and managing ≥15 MM patients/month. Data were collected in June-July (France, Italy, UK) and September-November (Germany, Spain) 2016 for patients whose disease progressed following a 1st, 2nd or 3rd line (L) of treatment within the previous 3 months. RESULTS: 391 physicians reviewed 813 patient charts of 1L patients (146, 175, 173, 141 and 173 in France, Germany, Italy, Spain and the UK respectively; weighted by MM incidence in each country). Mean [95% C.I.] age at diagnosis was 66 [65–66], 41% were female and 17%, 57%, 22% and 4% had an ECOG performance status score of 0, 1, 2 and 3+ respectively. Bone pain was the symptom ultimately leading to MM diagnosis in 63% of the patients, vertebral fractures in 23% and renal impairment in 23%. The majority of patients (74%) had at least 2 bone lesions and 51% had either mild, moderate or severe RI, at the initiation of 1L. 75% of all and 75% of RI patients received BPs during the entire 1L management (diagnosis to disease progression). 214 (26%) patients suffered from at least 1 new SRE during the follow-up (366 SREs overall), with a yearly SRE rate of 0.6, and 119 (15%) had SRE-related hospitalization. CONCLUSIONS: Bone pain, renal dysfunction and vertebral fractures were leading reasons for diagnosis of MM. 51% had an impaired kidney function at initiation of 1L treatment and one fourth of all patients were not treated with BPs, indicating an unmet need to prevent SREs in NDMM patients.
**PCN12: IMPACT OF DIFFERENT BASELINE DEFINITIONS ON THE INCIDENCE OF RELEVANT OUTCOMES ASSOCIATED WITH CANCER FOLLOWING AN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) DIAGNOSIS**

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**OBJECTIVES:** Administrative claims data pose the risk of misclassifying pre-existing conditions as incident outcomes after diagnosis, because they may first appear in data during the extensive post-diagnostic work-up. We describe the impact of baseline definitions on the incidence of relevant outcomes, comparing baseline periods of one year before (T0) vs. one year plus two weeks after (T14) diagnosis. **METHODS:** Adult patients with advanced NSCLC (stageIII/IV) were identified in 2006-2013 from two large Swedish databases and matched (1:4) with non-NSCLC subjects. We extracted all healthcare visits one year before (baseline) and after the cancer diagnosis. Incidence rate ratios (IRR) of Infections, Gastro-Intestinal, Cardiovascular, Metabolic and Musculoskeletal outcomes were estimated for T0 vs T14. Mortality rate ratios (IRR) were also estimated and results were stratified by healthcare visits during baseline (NV=none,1V=one,2+=many). **RESULTS:** Overall, 3,834 NSCLC patients (NV=4%,1V=9%,2+=87%) and 15,332 comparators (NV=24%,1V=17%,2+=59%) were included. The IRR for any outcome was 4.4(95%CI 4.2-4.6) in T0 and 3.8(95%CI 3.6-4.1) in T14, compared to the general population. The difference in IRR was biggest in the NV stratum (9.8 T0, 7.2 T14). The mortality IRR at T0 for patients with NV, 1V and 2V were 58.3(95%CI 48.3-70.4), 43.3(95%CI 37.5-50.1) and 25.2(95%CI 23.9-26.7), respectively. The rates remained constant across strata among NSCLC hence the difference was due to increased mortality in controls across strata. **CONCLUSIONS:** The definition of baseline affects marginally the IRRs of relevant outcomes, predominantly among patients without prior healthcare visits. In the general population higher incidence rate of outcomes is associated with more prior visits and poorer survival, but not among NSCLC patients. This confirms the validity of observed incident outcomes and the definition of the baseline ending at diagnosis.

**PCN13: ASSOCIATION BETWEEN SOCIOECONOMIC DEPRIVATION AND CANCER INCIDENCE AND OUTCOMES AMONG ENGLISH CCGS**


**OBJECTIVES:** It is well established that socioeconomic deprivation is associated with increased cancer incidence and poorer outcomes. In England, clinical commissioning group (CCG) funding is partly based on deprivation. The objective of this study was to assess the relationship between deprivation and the incidence and outcomes of breast, lung and colorectal cancers within CCG populations. **METHODS:** CCG-level data for breast, lung and colorectal cancers, along with index of multiple deprivation (IMD) scores, were extracted using NHS England’s Cancer and Tumours Focus Pack Tool. Pearson correlation coefficients were used to determine the relationship between IMD scores and breast, lung, and colorectal cancer incidence, one-year survival, early-stage detection (stage 1 or 2) and under-75 mortality rates. **RESULTS:** Data were available from 209 CCGs. The incidences of breast and lung cancers were positively correlated with IMD score (R=0.39 [p<0.001] and R=0.78 [p<0.001], respectively). Early-stage detection was also positively correlated with IMD score for all cancer types (R=0.19 [p<0.01], R=0.18 [p<0.01] and R=0.25 [p<0.001] for breast, colorectal and lung cancers, respectively). While colorectal cancer-related under-75 mortality was positively correlated with IMD score (R=0.28 [p<0.001]), no correlation was observed between breast and lung cancer mortality and IMD score (R=0.05 [p=0.50] and R=0.05 [p=0.50], respectively). There was also no correlation between IMD score and colorectal cancer incidence (R=0.08 [p=0.27]) or one-year survival for lung cancer (R=0.02 [P=0.73]). However, one-year survival was negatively correlated with IMD score for breast and colorectal cancers (R=0.37 [p<0.001] and R=0.46 [P<0.001], respectively). **CONCLUSIONS:** Despite the well-established link between deprivation and cancer incidence and poorer outcomes, CCG-level data do not always reflect this. Of note was the positive correlation between deprivation and early detection, which is unexpected given the lower uptake of cancer screening in more deprived areas. These data suggest that other factors exist within CCG populations that may affect outcomes.

**PCN14: NETWORK META-ANALYSIS OF TREATMENTS FOR UNRESECTABLE HEPATOCELLULAR CARCINOMA**

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**OBJECTIVES:** This study aimed to synthesize efficacy evidence via a systematic literature review and meta-analysis to enable the comparison of both lenvatinib (LEN) and sorafenib (SOR) to placebo in unresectable hepatocellular
PCN15: SECOND-LINE THERAPY IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Conduct a systematic literature review (SLR) of studies assessing clinical outcomes associated with pharmacological interventions in patients with locally advanced or metastatic urothelial cancer (UC) who have progressed during or after first line platinum-based chemotherapy. METHODS: Medline, EMBASE, and conference proceedings databases were searched (2001 – 2017) to capture overall response rate (ORR), progression-free survival (PFS), duration of response (DOR) and overall survival (OS) of systemic second-line therapy. 244 articles met the predefined inclusion criteria. Review of the 76 articles relating to second-line resulted in final data extraction from four randomized controlled clinical trials (RCTs) and thirty-eight single arm studies. RESULTS: ORR with cisplatin- and carboplatin-based regimens, vinflunine, and immuno-oncology therapies (IOs) (either single or combination regimens) ranged from 8% to 50% in RCTs and from 6% to 60% in single arm studies. Median PFS with chemotherapy ranged from 3.3 to 4.0 months in RCTs (n= 2), from 1.4 to 6.0 (n=15) in single arm studies, and from 1.1 to 4.1 (n=5) with IOs. Median OS with chemotherapy ranged from 5.3 to 13.6 months (n=23) and from 7.0 to 14.1 months (n=7) with IOs (OS from many IO studies not estimated or reported due to limited follow up). Median DOR ranged from 3.9 to 9.1 months (n= 16) with chemotherapy regimens, and was not estimable in IO studies (n=7), with >80% of responders having responses lasting ≥ 6 months. CONCLUSIONS: There was a large variability in outcomes observed by regimen, patient population and study design. The findings of this SLR suggest a high unmet need still exists for patients who have failed or progressed after first-line treatment. This highlights the need for new treatment options that can induce durable responses in these patients. Recently approved IOs seem promising for a patient population with historically limited treatment options.

PCN16: COMPARATIVE STUDY OF HEALTHCARE RESOURCE UTILIZATION (HRU) OUTCOMES BETWEEN CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) PATIENTS TREATED WITH IBRUTINIB VERSUS NON-IBRUTINIB TREATED PATIENTS

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OBJECTIVES: Ibrutinib is a novel targeted oral therapy approved for CLL. We aimed to compare real-world HRU of ibrutinib-treated CLL patients with others not on ibrutinib. METHODS: Newly diagnosed CLL patients initiating therapy between 01/01/2014-09/30/2016 were selected from the Inovalon Medical Outcomes Research for Effectiveness and Economics (MORE2) Registry payer claims and remittance dataset. HRU was assessed from the date of CLL onset to the date of the last administrative claim and reported as per-patient per-month (PPPM). RESULTS: Among the 2,342 CLL patients, 295 patients were treated with ibrutinib while 2,047 patients were not. Median age for all patients was 65 years; median follow-up was 359.87 days. More patients on ibrutinib were men (68.5% vs 57.8%, p-value <0.001), had commercial payer (39.1% vs 27.6%, p-value <0.001), lower inpatient costs (mean $813 vs $1,704, p-value <0.001), mean emergency room (ER) costs ($101 vs $177, p-value 0.007), and mean outpatient visits (3.74 vs 4.81, p-value 0.002) respectively. No statistically significant differences across length of stay, ER visits, office utilization and outpatient costs were observed. CONCLUSIONS: CLL patients on ibrutinib have experienced significant decreases in both inpatient and ER related costs compared to CLL patients not on ibrutinib. Longer follow up is needed to examine how these lower costs relate to outcomes.
PCN17: NEWLY DIAGNOSED MULTIPLE MYELOMA (NDMM) PATIENT PROFILES; FINDINGS FROM AN OBSERVATIONAL CHART REVIEW IN FRANCE, GERMANY, ITALY, SPAIN AND THE UNITED KINGDOM

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OBJECTIVES: To describe the characteristics of, and treatment outcomes in patients with specific profiles in the real-world NDMM setting. METHODS: The data presented were derived from a 2016 retrospective chart analysis of 813 patients whose disease had progressed after first line (1L). Patient profiles were constructed based on stem-cell transplant (SCT) eligibility, agents used in 1L, and time to progression (TTP). All analyses were descriptive. RESULTS: Of the 813 patients, 31% received a SCT and a bortezomib-based regimen (V). Of the 496 (61%) patients who did not receive a SCT, 71% received V, 22% received immunomodulator-based regimens (IMiD) and 7% received other regimens. Patients were then stratified by TTP (early [< 12 months] vs late [≥ 12 months]). Five profiles were identified accounting for 88% of the patients included. Profile 1a (P1a): SCT, V and late progression (26%); P1b: SCT, V and early progression (6%); P2a: non-SCT, V and late progression (26%); P2b: non-SCT, V and early progression (18%), and P3: non-SCT and IMiD (13%). The median TTP and complete response rates for profiles P1a, P1b, P2a, P2b and P3 were: 33.5 months and 51%; 10 months and 16%; 24 months and 26%; 6 months and 5%; and 17 months and 24%, respectively. The proportion of patients with revised International Staging System stage IV disease and the proportion of patients assessed for cytogenetic abnormalities with high-risk cytogenetics was higher in profile P1b than P1a (42% vs 22% and 25% vs 15%, respectively) and in profile P2b than P2a (46% vs 35% and 31% vs 19%, respectively). These differences may explain the differences observed in treatment outcomes. CONCLUSIONS: Achieving a prolonged TTP for all patients with NDMM continues to be a challenge. Understanding why patients progress early may inform subsequent treatment decisions and improve outcomes for patients with MM.

PCN18: MATCHING-ADJUSTED INDIRECT COMPARISON (MAIC) OF CRIZOTINIB WITH STANDARD OF CARE IN PROGRESSED NSCLC ALK+ PATIENTS BASED ON REAL-WORLD EVIDENCE (RWE) AND CLINICAL TRIAL DATA IN THE CZECH REPUBLIC

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OBJECTIVES: Non-small-cell-lung-carcinoma (NSCLC) markedly shortens and deteriorates life of patients. The aim of this analysis was to compare the relative effectiveness of crizotinib in progressed NSCLC ALK+ patients to Czech standard of care based on RWE and clinical trial data while adjusting for patients’ characteristic differences. METHODS: Patient characteristics and outcomes data were taken from RWE (NSCLC Registry TULUNG and Registry of Highly Innovative Drug VILP) in the Czech Republic and the PROFILE 1007 clinical trial. Patient-level data were available for crizotinib RWE only. Differences in patients’ characteristics in the crizotinib and pemetrexed arms were thus adjusted by MAIC approach. Age, sex, ECOG, smoking status, stage and histology types were included in the matching analysis. After matching, median overall survival (OS) and progression free survival (PFS) were estimated. RESULTS: There were 51 crizotinib patients in the Czech RWE arm receiving 2nd or later line crizotinib. Median follow-up of crizotinib RWE patients was 11.5 months. After matching, the patients’ characteristics were comparable. Naïve comparison of PFS and OS resulted in medians 5.8 and 15.3 months for crizotinib from RWE, 3.1 and 9.5 months for pemetrexed from RWE and 4.2 and 22.8 for pemetrexed from PROFILE 1007. After matching, the median PFS and OS of crizotinib from RWE changed to 4.8 and 14.2 months when adjusted to pemetrexed RWE and 6.2 and 27.2 months when adjusted to pemetrexed PROFILE 1007 data. Crizotinib increased PFS by 54% and 47% and OS by 49% and 19% when compared to pemetrexed RWE and pemetrexed PROFILE 1007 data, respectively. CONCLUSIONS: Treatment of progressed ALK+ NSCLC with crizotinib is associated with major prolongation of PFS and OS compared to pemetrexed in the Czech real-world setting after adjusting for the patients’ characteristic differences.

PCN19: ESTIMATION OF THE HEALTH BENEFIT ASSOCIATED WITH A POTENTIAL DENOSUMAB-INDUCED EXTENSION OF PROGRESSION FREE SURVIVAL IN MULTIPLE MYELOMA PATIENTS

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OBJECTIVES: The efficacy of Denosumab in the prevention of skeletal-related events in multiple myeloma (MM) patients, and its non-inferiority to Zoledronic Acid, was demonstrated in a randomized, double blind phase 3 trial (IMW 2017 and ASCO 2017). Preliminary analyses of trial survival data suggested that patients treated with
Denosumab may have a longer progression free survival (PFS) compared to patients treated with Zoledronic Acid (IMW 2017 and ASCO 2017). The objective of this study was to quantify the potential incremental health benefit associated with a Denosumab-induced extension of PFS, in MM patients. METHODS: Parametric statistical models were fitted on individual failure time data from the primary data analysis of the trial to extrapolate long-term trends for PFS. Multiple scenarios, based on the 5 best fitting parametric models (unrestricted exponential, Weibull, lognormal, log-logistic, and generalized gamma) were generated. A partitioned survival cohort model was used to calculate the quality-adjusted life gains associated with the extended PFS on top of anti-myeloma therapy. RESULTS: Model results showed that the delay in disease progression observed in the trial may translate into a lifetime health benefit equivalent to living between 1.5 and 2.3 extra months in perfect health, 1.9 and 2.8 extra months with the same quality of life as in the MM pre-progression state, and between 2.3 and 3.5 extra months with the same quality of life as in the MM post-progression state. CONCLUSIONS: In all MM patients, Denosumab use is potentially associated with a significant incremental health benefit, compared to Zoledronic Acid.

PCN20: MERKEL CELL CANCER: POOR RESPONSE TO CHEMOTHERAPY EXPOSES SIGNIFICANT UNMET NEED

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OBJECTIVES: Prior to the introduction of immuno-oncology agents for Merkel cell carcinoma (MCC), recommended treatment included surgery, radiation, and chemotherapy. This study aimed to analyze the effectiveness of chemotherapy for metastatic MCC treatment in real-world clinical practice. METHODS: Physicians in the Cardinal Health Oncology Provider Extended Network (OPEN™) completed an electronic case report form for adult patients diagnosed with metastatic MCC since 2000. Patients who received ipilimumab, nivolumab, and/or pembrolizumab were excluded. Information on clinical characteristics, treatments received, and response to treatment were collected. Response to treatment was determined based on pre- and post-treatment bi-dimensional sentinel lesion measurements in order to apply Response Evaluation Criteria In Solid Tumors (RECIST). Patient outcomes were stratified by line of therapy. RESULTS: Among the 44 patients identified who were initiated on first-line (1L) chemotherapy, the response rate (RR) was 40.9%. On average, patients were followed for 15.4 months (SD 15.6) after diagnosis. Median time to response for patients receiving 1L therapy was 3.2 months (range 1.3-13.4 months), and median duration of response (DOR) was 3.1 months (range 2.1-24.1 months). Median progression-free survival (PFS) for patients receiving 1L therapy was 5.1 months (95% CI 3.5-8.5 months). Among 23 patients who received second-line (2L) chemotherapy, the RR was 8.7% and median time to response was 1.8 months (range 1.8-1.9 months). Only 1/23 patients (4.3%) had a durable response, which lasted for 15.6 months. Median PFS for patients receiving 2L therapy was 4.0 months (95% CI 2.4-7.7 months). CONCLUSIONS: This study indicates RR to chemotherapy among metastatic MCC patients is limited, especially when used later than 1L therapy. Only a small proportion of patients receiving chemotherapy had a durable response. The results of this study further support the evaluation of the effectiveness of new immuno-oncology agents being investigated for treatment of metastatic MCC.

PCN21: SYSTEMATIC LITERATURE REVIEW AND INDIRECT COMPARISON OF GLASDEGIB PLUS LOW DOSE ARA-C VERSUS A HYPOMETHYLATING AGENT FOR ACUTE MYELOID LEUKEMIA PATIENTS INELIGIBLE FOR INTENSIVE CHEMOTHERAPY


OBJECTIVES: In a phase 2 randomized controlled study (RCT), glasdegib (GLAS) combined with Low Dose ARA-C (LDAC), showed significantly better overall survival (OS) vs LDAC alone in previously untreated acute myeloid leukemia (AML) patients ineligible for intensive chemotherapy (NIC). Hypomethylating agents (HMAs), azacitidine (AZA) and decitabine (DEC) are considered current standard of care in this population. Our objective was to conduct an indirect treatment comparison (ITC) comparing OS for GLAS+LDAC vs. AZA and DEC. METHODS: Embase, MEDLINE, Cochrane database, and conference abstracts (ASCO, ESMO, ASH) were systematically searched through 12/2016 for relevant RCTs of GLAS, AZA and DEC in NIC AML patients. Classical frequentist ITC using the Bucher method compared OS hazards ratios (HRs), 95% confidence intervals (CI) using LDAC as the common comparator. RESULTS: Four studies met inclusion criteria: two comparing AZA to LDAC: Fenaux 2010; Dombret 2015; one comparing DEC to LDAC: Kantarjian 2012, and one comparing GLAS+LDAC to LDAC: Cortes 2016. Fenaux 2010 study was excluded due to population differences: baseline median bone marrow blasts at 23% in Fenaux 2010 vs. 49% in Cortes 2016. The remaining AZA and DEC studies were generally comparable in patient baseline characteristics to the GLAS study: age and cytogenic risk: age 75/73/76 years old, poor cytogenic risk 34%/37%/39%, in AZA/DEC/GLAS+LDAC, respectively. In the ITC, with LDAC as the common comparator, GLAS+LDAC compared favorably with indirect HR for OS vs. AZA and DEC being 0.51 (0.35-0.75) and 0.57 (0.40-
0.82), respectively. **CONCLUSIONS:** Using ITC, treatment with GLAS+LDAC showed significantly better OS HR than AZA and DEC in previously untreated NIC AML patients. Limitations of current analysis include mixed IC & NIC population for the AZA trial, and mixed comparator arm of both LDAC and BSC for the DEC trial. Analyses using patient-level data matching baseline characteristics across studies may enable more robust ITC.

**PCN22: ANALYSIS OF RECENT APPROVALS OF IMMUNO-ONCOLOGY DRUGS ACROSS ENGLAND, SCOTLAND, GERMANY AND FRANCE**

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**OBJECTIVES:** Immuno-oncology (IO) is a rapidly evolving therapeutic area with promising clinical results. There are several hurdles that new IO drugs experience, such as failing to demonstrate overall survival and managing high budget impact. This research aims to explore recently appraised IO drugs in England, Scotland, Germany and France by their respective health technology assessment (HTA) bodies to identify key drivers behind their recommendations. **METHODS:** All publicly available appraisal reports from the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Agency (SMC), the Federal Joint Committee (G-BA) and the French National Authority for Health (HAS) between 1st January 2015 and 17th May 2017 for IO drugs were identified, from which clinical, health-economic outcomes and final decisions were extracted. **RESULTS:** Six IO technologies were assessed: 11 appraisals were completed by NICE, 15 by SMC, 14 by G-BA and 12 by HAS. Eight matched condition-intervention pairs were identified and recommended by HTA bodies. The decision was largely based on clinical effectiveness evidence (overall and progression-free survival) and the substantial unmet need addressed by the IO drug. Other factors contributed to the decision: patient access schemes and the views of patients’ representatives (SMC). For the economic assessment, significant differences of incremental cost-effectiveness ratios (ICERs) were found between several HTA bodies despite a similar final decision. The main reservations were related to the robustness of clinical and health economic analysis, the extrapolation methods of survival data and the justification of treatment costs. **CONCLUSIONS:** Based on the provided evidence, the European HTA bodies tend to evaluate IO drugs favourably, potentially due to the high unmet clinical need and other influencing schemes allowing expedited access. Some reservations/weaknesses were highlighted which may be used by pharmaceutical companies to improve the quality of future HTA submissions and increase chance of successful reimbursement.

**PCN23: EVALUATION OF THE CLINICAL EFFECTIVENESS OF AXITINIB, CABOZANTINIB, EVEROLIMUS, NIVOLUMAB, SUNITINIB AND BEST SUPPORTIVE CARE (BSC) IN PREVIOUSLY TREATED ADVANCED OR METASTATIC RENAL CELL CARCINOMA (AMRCC): A SYSTEMATIC REVIEW AND MIXED-TREATMENT COMPARISON (MTC)**


**OBJECTIVES:** Several therapies have recently been approved for routine commissioning in the UK National Health Service (NHS) for pre-treated amRCC, but comparative evidence to guide decisions between them is limited. This research evaluated the clinical effectiveness of axitinib, cabozantinib, everolimus, nivolumab, sunitinib and BSC for people with amRCC previously treated with vascular endothelial growth factor (VEGF)-targeted therapy. **METHODS:** Systematic review and MTC of randomised controlled trials (RCTs) and non-RCTs. Primary outcomes were overall survival (OS) and progression-free survival (PFS). Secondary outcomes were overall response rates (ORR), adverse effects (AEs), and health-related quality of life (HRQoL). MEDLINE, EMBASE, and The Cochrane Library were searched in January and June 2016 for RCTs and non-RCTs, respectively. Two or more reviewers abstracted study data and performed critical appraisals. Fixed-effect MTC was conducted for OS, PFS and ORR. Effect estimates included hazard ratio (HR) and odds ratio with 95% credible intervals (CrI). RCT data formed the primary analyses, with non-RCTs and studies at high risk of bias included in sensitivity analyses. HRQoL and AEs were summarised narratively. **RESULTS:** Four RCTs (n = 2,618) and eight non-RCTs (n = 1,526) were included. No suitable studies for sunitinib were identified. The inclusion of axitinib was limited to the sensitivity analyses. Results for PFS show a statistically significant benefit for cabozantinib vs everolimus (HR 0.51, 95% CrI: 0.41 to 0.63) and both treatments are more effective than BSC. OS results show a benefit for cabozantinib (HR 0.66, 95% CrI: 0.53 to 0.82) and nivolumab (HR 0.73, 95% CrI: 0.60 to 0.89) vs everolimus. Sensitivity analyses were consistent with the primary analyses. **CONCLUSIONS:** Evidence from RCTs suggest cabozantinib is likely to be the most effective treatment for PFS and OS, closely followed by nivolumab. All treatments appear to prolong PFS and OS compared with BSC although interpretation of some results is limited by heterogeneity.

**PCN24: COMPARING ITC RESULTS FROM LENVATINIB PLUS EVEROLIMUS FOR SECOND-LINE TREATMENT OF ADVANCED/METASTATIC RENAL CELL CARCINOMA: CROSSOVER VERSUS NO CROSSOVER**
OBJECTIVES: An indirect treatment comparison (ITC) involving lenvatinib plus everolimus (LEN+EVE) versus standard of care (SOC) therapy was conducted using networked data from HOPE 205, CHECKMATE-025, METEOR, AXIS and two crossover trials RECORD-1 and TARGET. Results showed superiority of LEN+EVE over EVE alone for overall survival in second-line treatment of advanced/metastatic renal cell carcinoma. No statistically significant differences in overall survival (OS) were found between LEN+EVE versus nivolumab (NIV), cabozantinib (CAB), axitinib (AXI), or placebo. METHODS: A subsequent analysis was conducted using intention to treat (ITT) data to evaluate the impact of crossover correction on OS estimates and additionally to uncover any potential bias due to its absence. Three ITC scenarios were analyzed: A) all comparators plus placebo versus EVE; B) all comparators versus placebo; and C) LEN+EVE versus all comparators. RESULTS: ITT data for Scenario “A” showed consistent variance in survival benefit versus crossover data by an average of 20%. OS estimates for AXI vs. EVE shifted from below null (0.98) to above null (1.27); and mortality risk (placebo vs. EVE) moved 51% further from null (1.15 vs. 1.67). IIT estimates for Scenarios “B” & “C” showed on average 9% and 14% differences in OS benefits respectively versus crossover. In Scenario “C” estimates for LEN+EVE versus Pazopanib (PAZ) or LEN+EVE versus Sunitinib (SUN) showed superiority with ITT data (0.82 or 0.75) but were inferior (1.2 or 1.09) with crossover. CONCLUSIONS: Selection bias was observed in naive approaches when comparing survival differences between crossover non-crossover data. Failure to account for this in clinical trials may have implications on the comparative effectiveness profile and also on the cost-effectiveness results and may lead to inconsistent resource allocation decisions.

PCN25: CLINICAL TRIAL SIMULATIONS BASED ON A META-ANALYSIS OF STUDIES IN PATIENTS WITH LOCALLY ADVANCED AND/OR METASTATIC ADENOCARCINOMA PANCREATIC CANCER RECEIVING GEMCITABINE (GEM) ALONE OR IN COMBINATION

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OBJECTIVES: To develop a model to: (1) describe median overall survival (mOS) in trials with locally advanced and/or metastatic adenocarcinoma pancreatic cancer treated with GEM alone and in combination; (2) simulate predictive distributions based on Von Hoff 2013 and assess the probability of the results in a future study; and (3) compare predictions based on mOS and overall survival hazard ratios (OS-HR). METHODS: A systematic review of randomized clinical trials with GEM alone or in combination was conducted. A linear mixed-effects model was fit to log-transformed mOS data, with an intercept reflecting GEM treatment alone, a between-trial random effect (n=30(0,0,2)) and residual error term (εij~N(0,σ2/Nij), i=study, j=treatment arm). Potential confounding or prognostic factors were tested as covariates. Drug-class combinations were simulated to produce model-based prediction distributions. RESULTS: Data consisted of 83 arms (40 studies;4813 patients) and first-line treatment across 21 drug-classes. The final model (abbreviated) is: LN(mOSij) = intercept+ θ1* platinumij + θ2* taxaneij + θ3*igf1r.inhibitorij+ ...+ θn * immunomodulatorij+ asian.study+ ηi+ εijwhere drug-class and asian.study are indicators (0 or 1). Estimated mOS for GEM was 6.6 months with 95% CI: 6.3, 7.0. The model mOS estimates for drug classes in combination with GEM were significantly better than GEM alone for: Hypoxia activated prodrug 8.9 (7.2, 11.2), Anti folates 8.5 (7.8, 9.3), Taxane 8.3 (7.6, 9.0) and Platinum 7.8 (7.2, 8.5). Simulations showed that the model predicts the Von Hoff study well and results related to drug classes for mOS and OS-HR were comparable. CONCLUSIONS: This meta-analysis is useful: (1) as a repository for data exploration of current randomized trials; (2) in characterizing typical endpoints for designing randomized clinical trials; (3) to guide a default product profile for pancreatic cancer therapies and; (4) for informing decisions during the drug development process. REFERENCES: 1Von Hoff DD et al. N Engl J Med.2013;369:1691–1703.

PCN26: EVALUATING THE CLINICAL EFFECTIVENESS OF TRASTUZUMAB EMTANSINE (T-DM1) VERSUS ALL OTHER TREATMENTS FOR PREVIOUSLY TREATED, UNRESECTABLE, HER2-POSITIVE METASTATIC BREAST CANCER (MBC): A MIXED TREATMENT COMPARISON (MTC)

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OBJECTIVES: T-DM1 is approved for the treatment of MBC in patients previously treated with trastuzumab+taxane. We compared the clinical effectiveness of T-DM1 with all other therapies in patients with previously treated, unresectable, HER2-positive locally advanced breast cancer (LABC) or MBC. METHODS: A systematic review was conducted that included all published data between January 1, 1998 and June 30, 2016. Eligible trials were controlled trials of pharmacological treatments for unresectable HER2-positive LABC or MBC that had progressed after

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PCN27: TIME TO CLINICALLY MEANINGFUL WORSENING IN HEPATOCELLULAR CARCINOMA PATIENTS TREATED WITH LENVATINIB OR SORAFENIB

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OBJECTIVES: To compare time to clinically meaningful worsening (TSW) in patients with unresectable hepatocellular carcinoma (μHCC) treated with lenvatinib (LEN) or sorafenib (SOR) using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and HCC-specific EORTC QLQ-HCC18 questionnaires. METHODS: This was a multicenter, randomized, open-label, non-inferiority Phase 3 study comparing lenvatinib (LEN) to sorafenib (SOR) as first-line μHCC systemic treatments. 954 patients were randomized to LEN (N=478) or SOR (N=476). Analyses on TSW, which is a within-subject analysis of meaningful change in terms of patient-reported deterioration, were conducted for these patient-reported measures including their domains and summary scores using published meaningful change thresholds which ranged from 6 to 12 points. Kaplan Meier curves were generated to characterize the divergence of the first TSW event occurring over time for each patient; median time and its 95% confidence interval (CI) was calculated with a prespecified significance level of 0.05. Unadjusted proportional hazard models were conducted to estimate the hazard ratio and its 95% CI. RESULTS: TSW was statistically significant favoring LEN for the QLQ-C30 domains of Role Functioning (2.0 versus 1.9 months in the LEN and SOR arms, respectively; p = 0.0098), Pain (2.0 versus 1.8 months, respectively; p = 0.0060), and Diarrhea (4.6 versus 2.7 months, respectively; p < 0.0001). In the QLQ-HCC18 results favored LEN for the domains of Body Image (2.8 versus 1.9 months, respectively; p = 0.0041) and Nutrition (4.1 versus 2.8 months, respectively; p = 0.0060). The p-values were calculated without multiplicity adjustment. CONCLUSIONS: Patients on SOR experienced a more rapid clinically meaningful deterioration in terms of Role Functioning, Nutrition (perhaps due to an increased severity of diarrhea), Pain (specifically affecting their daily lives) and Body Image.

PCN28: SYSTEMATIC LITERATURE REVIEW FOR TREATMENT OUTCOMES (INCLUDING IMMUNO-Oncology TREATMENT) AMONG PATIENTS WITH STAGE 3 UNRESECTABLE NON-SMALL CELL LUNG CANCER (NSCLC)

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OBJECTIVES: Immuno-oncology (IO) agents are being developed as a treatment option for patients with stage 3 unresectable NSCLC. This study aims to understand the comparative clinical efficacy of maintenance/consolidation therapies, including IO agents, for stage 3 NSCLC patients who have not progressed after completing chemoradiation therapy (CRT). METHODS: A systematic literature review of Medline, EMBASE and Cochrane Library was performed to identify randomised clinical trials (RCTs) satisfying the following criteria: 1) included adults with stage 3 unresectable NSCLC; 2) included at least one arm with concurrent CRT; 3) reported efficacy or safety outcomes; 4) published after 2002. RESULTS: Twenty-five RCTs were identified. Among them, five RCTs compared consolidation/maintenance therapy versus placebo post-CRT. Median progression-free survival (PFS) was 6.4–10.8 months in consolidation/maintenance arms, and 5.5–11.7 months in placebo arms. Median OS was 16.1–25.6 months in consolidation/maintenance arms, and 18.5–35.0 months in placebo arms (HR ranged from 0.88 to 1.59). Seven RCTs compared concurrent CRT regimens. These studies reported median PFS of 8.4–17.5 months and...
median OS of 13.5–30.0 months. Seven RCTs compared concurrent vs. sequential CRT. Median PFS was 6.7–17.0 months in concurrent arms and 9.0–12.1 months in sequential arms. Median OS was 12.7–24.3 months in concurrent arms and 12.9–18.4 months in sequential arms (HR ranged from 0.61 to 0.92). The remaining 6 RCTs compared other CRT regimens. Detailed network meta-analysis results including PFS outcomes from a phase 3 trial will be presented after primary clinical results are presented at ESMO 2017. **CONCLUSIONS:** Little evidence was found that chemotherapy agents as post-CRT consolidation therapy can improve survival outcomes. In addition, concurrent CRT showed improved efficacy vs sequential CRT, while the commonly used concurrent CRTs showed no clinically meaningful difference in treatment outcomes.

**PCN29: ESTIMATING THE IMPACT OF STRATEGIES FOR CERVICAL CANCER PREVENTION AND CONTROL IN INDONESIA USING MARKOV MODEL**

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**OBJECTIVES:** To estimate the impact of strategies for cervical cancer prevention and control in Indonesia. **METHODS:** An excel-based Markov model was used to simulate the effectivity of strategies for cervical cancer prevention and control in term of epidemiologic output which were incidence and mortality of cervical cancer diseases. The strategies included 17 scenarios which varied in combinations of intervention and interval for screenings. Model structure and probabilities were adopted from previous studies conducted in many other settings. Model was validated by comparing the model output versus observed data of cervical cancer in Indonesia including HPV prevalence, cervical cancer incidence and mortality, and distribution of cancer by state of cancer. Validation process employed qualitative approach using visual technique and quantitative approach using deviation value. Model calibration was conducted using “trial and error” to get model probabilities that resulted valid output. **RESULTS:** Based on valid model output, strategies of HPV vaccination resulted highest reduction of cervical cancer incidence and mortality, and followed by strategy of screening with Pap smear and VIA. Combination of strategies, shorter screening interval, and larger vaccination coverage rate would increase effectivity of strategy. Single strategy of HPV vaccination, screening with Pap smear, and screening with VIA yielded reduction of cervical cancer incidence by 36%, 12 – 17%, and 9 – 13%, respectively. Moreover they yielded reduction of cervical cancer mortality by 31%, 6 – 13%, and 2 – 7%, respectively. Strategy of HPV vaccination combined with VIA every 3 years for woman aged 30 – 45 years old and followed by Pap smear every 3 years for woman aged 48 – 63 years old was the most effective strategy. **CONCLUSIONS:** This model could then be used to estimate the lifetime costs and outcomes for cost effectiveness analysis of strategies for cervical cancer prevention and control in Indonesia.

**PCN30: CLINICAL COMPARISON OF FIRST-LINE PLATIN CHEMOTHERAPY REGIMENS IN PATIENTS WITH ADVANCED NONSQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) USING GERMAN REGISTRY DATA**

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**OBJECTIVES:** Lung cancer, one of the most frequent cancers worldwide, is a leading cause of mortality. Most patients are diagnosed in stages IIIB/IV where available therapy is mainly palliative. Aim of the analysis was to compare progression free survival (PFS) and overall survival (OS) of the most prevalent platinum-based chemotherapy regimens in NSCLC. **METHODS:** Data from the prospective, multicenter Tumor Registry Lung Cancer assessing oncology care in Germany was utilized. NSCLC patients staged IIIB/IV who received antineoplastic first-line treatment between 2010-2013 were identified. Patient and tumor characteristics, systemic therapies, PFS and OS of patients receiving one of the three most prevalent first-line platinum-based chemotherapies were descriptively compared using an unadjusted analysis, and an inverse probability of treatment weighting (IPTW) analysis adjusting for pre-defined parameters age, gender, stage, ECOG, and smoking status. **RESULTS:** In total, n=280 patients received either pemetrexed/platin (Pem/Plat, n=158), paclitaxel/platin (Pac/Plat, n=52) or vinorelbine/platin (Vin/Plat, n=70). Pac/Plat patients were older (65.94 vs. 63.6 Plm/Plat, 63.48 years Vin/Plat), and more often male (90% vs. <66% in Pem/Plat, Vin/Plat). ECOG 0 was more prevalent in Pem/Plat patients (34% vs. 21% Pac/Plat, 17% Vin/Plat). Only ~11% in each group presented with ECOG 2 or worse. In unadjusted analysis, median PFS/OS were comparable between Pac/Plat (5.7 [95% CI 3.9-8.2] / 11.5 [7.2-16.2]), Pem/Plat [6.4 [95% CI 4.2-6.6] / 11.3 [8.5-14.3]) and Vin/Plat (4.4 [95% CI 3.2-6.5] / 10.8 [7.0-16.0]). IPTW results differed slightly, however showed no
significant difference, Pac/Plat (8.1 [95% CI 4.2-9.1]) / 12.6 [7.2-22.4]), Pem/Plat (5.4 [95% CI 3.9-6.2]) / 10.2 [7.4-14.9]) and Vin/Plat (4.4 [95% CI 3.2-7.6]) / 8.1 [5.7-14.4]). Balancing diagnostics revealed limited balance between groups. CONCLUSIONS: No difference in PFS and OS was found between Pac/Plat, Pem/Plat, and Vin/Plat. Further research is warranted regarding imbalances between the respective groups.

**PCN31: OCCURRENCE OF SKELETAL-RELATED EVENTS (SRE) IN PATIENTS WITH SOLID TUMORS (ST) AND MULTIPLE MYELOMA (MM) IN GERMANY: EARLY VERSUS LATE INITIATION OF SRE PREVENTATIVE AGENTS (SPA)**

**Intorcia M**
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**OBJECTIVES:** In patients with ST and bone metastases (BM) or with MM, SREs are serious and common complications impacting life expectancy and quality of life. This exploratory and descriptive analysis estimated the time from diagnosis to occurrence of first and subsequent SRE in patients with early versus late treatment initiation with SPA.

**METHODS:** This was a retrospective analysis of a German sick-leave claims database (covering ~4 million patients) which includes data from 2007 to 2015. Patients with a diagnosis of ST coded with at least two outpatient or one inpatient diagnoses and newly diagnosed with BM after 07/2011 and patients newly diagnosed with MM after 07/2011, aged ≥18 years were included. All patients received either denosumab or bisphosphonates within 9 months from study inclusion. The study described the time from BM or MM diagnosis to occurrence of first and subsequent SRE in patients with early (≤3 months [m]) versus late (4-9m) treatment initiation with SPA.

**RESULTS:** A total of 1,144 patients were analyzed. 949 started treatment early and 195 late. Relevant baseline characteristics in early versus late initiators: mean age (70.1 versus 69.9 years), SRE present (25.7% versus 24.6%), osteoporosis (20.7% versus 12.8%), renal disease (17.1% versus 23.1%). The median (95% confidence interval) time to first SRE was 23m (16; 32) and 6m (3; 13) for the early and late initiators, respectively; the median time to second SRE was 41m (36; NA) and 21m (13; NA), respectively. A similar pattern was observed for the third SRE that did not reach median time.

**CONCLUSIONS:** In this exploratory, descriptive analysis, the median time to first and subsequent SRE was shorter for late versus early initiators. This suggests that patients initiating SPA earlier have lower SRE rates versus patients who may be initiating treatment later as a response to an SRE.

**PCN32: USE OF ABIRATERONE AND ENZALUTAMIDE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER IN ROUTINE CLINICAL PRACTICE**

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**OBJECTIVES:** To describe the results of abiraterone (AB) and enzalutamide (ENZ) treatment for metastatic Castration-Resistant Prostate cancer (mCRPC), the medication adherence and the monthly cost per patient.

**METHODS:** Prospective, descriptive, real world data based study including patients with mCRPC treated with abiraterone or enzalutamide. Initial registered variables: ECOG, Gleason, PSA levels. Follow-up variables: response evaluation criteria (RECIST), PSA levels, discontinuation and reason of discontinuation (progression, death, worst ECOG status, unacceptable toxicity, lack of adherence, patient decision, loss of follow-up). The number and cost of monthly dispensed containers was registered for each patient. All the data was extracted from the clinical practice registries: RPT-SAP® and Silicon®. The statistical data was obtained from SPSS® program.

**RESULTS:** A total of 37 patients were included: 17 of them received abiraterone and 20 enzalutamide. Nineteen have previously been treated with docetaxel (7 of AB and 12 of ENZ). Five of the 17 patients treated with abiraterone (29.4%) stopped the treatment. The reasons were: progression (100%) and worst ECOG status (40%). On the enzalutamide group, 9 of the 20 patients (45%) stopped the treatment because of: progression (88%), worst ECOG status (33%) and death (11%). The median of progression-free survival (PFS) for all the patients treated with abiraterone or enzalutamide was 20 months and the PFS after a year of treatment was 61%. No difference was found between drugs in monthly cost per patient: 3142±432€ (AB) and 3013±794€ (ENZ). The number of containers dispensed per patient was: 1.12±0.17 (AB) and 1.18±0.28 (ENZ).

**CONCLUSIONS:** Median PFS is slightly superior to which was found in clinical trials and medication adherence was excellent. Limitations of the study are: lack of data on concomitant treatments, adverse effects and patient related outcomes.

**PCN33: TREATMENT STRATEGIES AND OUTCOMES IN PATIENTS TREATED FOR RELapsed REFRACTORY MULTIPLE MYELOMA OVER 3 YEARS: PREMIERE STUDY**

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OBJECTIVES: The management of multiple myeloma (MM) has changed considerably yet real-world data on treatment patterns are scarce. The PREMIERE study estimated Progression Free Survival (PFS), Overall Survival (OS) and toxicity in patients with a first episode of Relapse/Refractory Multiple Myeloma (RRMM) in Spain. METHODS: Retrospective cohort chart review study of patients with RRMM over 3 years in 31 hematology centers. Patients ≥18 years with ≥1 prior lines of treatment (LOTs) for MM, starting a LOT for RRMM (index therapy, LOT1) were followed up. PFS and OS were described for LOT1 and subsequent LOTs (LOT2+), and by the most frequent treatment strategies (n >40) in LOT1 using Kaplan-Meier with estimation of the time to PFS and OS (median time-to-event in months), (Q1-Q3). RESULTS: Of 284 patients (median follow-up=20.1 months) 161 (56.7%) reached LOT2+. Progression occurred in 53.4% in LOT1, deaths in 24.7%. In LOT2+, deaths increasingly replaced progression: 49.7% progression in LOT2 to 21.4% in LOT5, vs 23.6% deaths in LOT2 to 64.3% in LOT5. Toxicity led to a change in LOT in approximately 10% in LOTs 1, 2 and 4. Longer PFS was observed in LOT1 vs LOT2+ (10.4 months, (8.7-12.6); 6.3 months, (4.4-8.2); p<0.05). OS was higher in LOT1 [Q1 and median not reached (NR), Q3=33.4 months vs 25.8 months (19.7-NR) in LOT2+; p=0.034]. Progression/mortality percentage by main treatment strategies in LOT1 was lower in patients with lenalidomide-dexamethasone at LOT1 (n=109) than in patients on bortezomib-dexamethasone (n=47), or chemotherapy (=41), but PFS and OS between LOT 1 and LOT2+ were not significantly different by LOT1 treatment strategies. CONCLUSIONS: Real-world data from a large follow-up study of patients treated for a first episode of RRMM in Spain showed poorer PFS and OS in LOT2+ than in LOT1. This highlights the need for more effective therapies and treatment strategies.

PCN34: COMPARING SURGICAL THERAPY AND HORMONAL THERAPY IN INCIDENCE OF CARDIOVASCULAR DISEASE AMONG PROSTATE CANCER PATIENTS IN KOREA


OBJECTIVES: Prostate cancer is one of the most common cancers in Korea, and it is necessary to generate evidence that can be used in clinical practice through comparison of short and long term effects between surgical therapy and hormonal therapy. The purpose of this study was to produce clinical evidence of the risk of cardiovascular disease in surgical therapy and hormonal therapy among patients with prostate cancer. METHODS: We linked three databases from 2002 to 2015; the Korea Central Cancer Registry, National Health Insurance Service claims data, and the cause of death data from Statistics Korea. Data were stratified into the stage of cancer, localized and regional, based on a subject age of 75 years, and propensity score matching was conducted based on the general clinical features of patients. The cumulative incidence risk ratio of cardiovascular disease within 5 year was calculated by using the Cox proportional hazards model. RESULTS: The cumulative incidence risk ratio of cardiovascular disease was 0.3665 in surgical therapy and 0.4949 in hormonal therapy. Compared to surgical therapy group, the hazard ratio of cardiovascular disease was 62% (HR=1.62, 95% CI 1.40-1.86; p<0.001) higher in hormonal therapy group. In patients who had localized prostate cancer with aged 75 or more, the hazard ratio of cardiovascular disease in hormonal therapy was 78% (HR=1.78, 95% CI 1.19-2.66; p=0.0048) higher than surgical therapy. Also, in comparison with surgical therapy, the hazard ratio of cardiovascular disease in patients who had localized prostate cancer with aged under 75 was 1.71 (HR=1.71, 95% CI 1.40-2.08; p<0.0001) in hormonal therapy. CONCLUSIONS: This study shows that the cumulative incidence risk ratio of cardiovascular disease within 5 year for hormonal therapy group was higher than surgical therapy group in South Korea. Our results could be used in determining the treatment direction of patients with prostate cancer.

PCN35: NEUTROPHIL-TO-LYMPHOCYTE RATIO (NLR) AS A PREDICTOR FOR RECURRENCE IN PATIENTS WITH STAGE III MELANOMA

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OBJECTIVES: Finding biomarkers that allow for the selection of appropriate patients for adjuvant treatment is a major priority. Neutrophil-to-lymphocyte ratio (NLR) is a strong predictor for overall survival and disease free survival (DFS) in many cancers. However, our study is the first investigation aiming to determine the predictive value of NLR on prognosis of patients with stage III melanoma. METHODS: This retrospective study utilized a cohort of patients with stage III melanoma treated at Huntsman Cancer Institute, University of Utah, from May 2002 to March 2016. A total of 108 patients had an absolute neutrophil count (ANC) and an absolute lymphocyte count (ALC) available at baseline. The optimal cutoff of NLR was determined by the significance of log-rank tests. A total of 108 univariate proportional Cox hazard models were fitted to find the optimal cutoff. DFS was assessed using the Kaplan–Meier
SAFETY AND EFFICACY OF OSIMERTINIB AS A THERAPY IN PATIENTS WITH EGFR T790M POSITIVE NON SMALL CELL LUNG CANCER PATIENTS: A SYSTEMATIC REVIEW

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OBJECTIVES: Lung cancer is the leading cause of cancer-related mortality worldwide, and Non-small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancers. In recent years, it has been well known that NSCLC patients with mutations of epidermal growth factor receptor (EGFR) response better to EGFR-tyrosine kinase inhibitor treatment. Osimertinib is a part of series of small-molecule inhibitors developed to target EGFR mutant forms that are resistant to first- and second-generation EGFR TKIs. METHODS: Clinical trials which included Osimertinib as an intervention for patients with EGFRm T790M advanced NSCLC, were identified in databases such as, Cochrane, and MEDLINE (via PubMed). No language and publication year restrictions were applied. Two researchers independently reviewed studies using the Cochrane methodology for systematic reviews. Outcomes of interest included progression-free survival (PFS), overall survival (OS), overall response rate (ORR), and safety. RESULTS: In total, 147 potentially relevant studies were screened. Three clinical trials involving 830 patients with EGFRm T790M advanced NSCLC were included. Two trials were single arm studies and 1 randomized controlled trial. Overall, 690 patients received Osimertinib and 140 received other drugs. The response rate was significantly better in the Osimertinib group (71%; 95% CI, 65 to 76) than in the platinum–pemetrexed group (31%; 95% CI, 24 to 40). Osimertinib provided a high objective response rate (ORR) and progression-free survival (PFS) in single arm studies. Overall, longer duration of progression-free survival was observed with Osimertinib. Very few patients were reported with adverse events of grade 3 or higher. CONCLUSIONS: Osimertinib is an important treatment option for patients with T790M-positive advanced non-small-cell lung cancer. Provides good clinical activity with minimal side-effects in patients with EGFRThr790Met-positive NSCLC. However, the results have to be interpreted cautiously due to limited number of trials available.
PCN38: TRASTUZUMAB AS A THERAPY VERSUS OTHER TREATMENT REGIMENS IN PATIENTS WITH HER2 POSITIVE BREAST CANCER: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: Breast cancer is the second most common cause of death for women behind lung cancer, and overexpression of HER2 found in approximately 15-20% of all breast cancers. Trastuzumab is a recombinant monoclonal antibody against HER2, has clinical activity in advanced breast cancer that overexpresses HER2. METHODS: Clinical trials which included Trastuzumab as an intervention for patients with HER2 positive Breast cancer were identified from 2011 to 2017 in databases such as, Cochrane, and MEDLINE (via PubMed). No language restrictions were applied. Two researchers independently reviewed studies using the Cochrane methodology for systematic reviews. Outcomes of interest included progression-free survival (PFS), Disease free survival (DFS), overall survival (OS), overall response rate (ORR), and safety. RESULTS: A total of 105 potentially relevant studies were screened. Five clinical trials involving 7768 patients with HER2 positive Breast cancer were included. Overall 1892 patients were received Trastuzumab. The combination of Trastuzumab with Pertuzumab plus Docetaxel significantly prolonged progression-free survival, with no increase in cardiac toxic effects when used as first-line treatment for HER2-positive metastatic breast cancer. The addition of 1 year of adjuvant trastuzumab significantly improved disease-free and overall survival among women with HER2-positive breast cancer. The addition of trastuzumab to paclitaxel after doxorubicin and cyclophosphamide in early-stage HER2-positive breast cancer results in a substantial and durable improvement in survival as a result of a sustained marked reduction in cancer recurrence. Adjuvant trastuzumab improves RFS of patients treated with TX-CEF or T-CEF. Very few patients had cardiac failure. CONCLUSIONS: Trastuzumab is an important treatment option for patients with HER2 positive Breast cancer. Trastuzumab improved overall survival and progression-free survival in HER2-positive women with metastatic breast cancer. Provides good survival benefit with minimal adverse events. However, the results have to be interpreted cautiously due to limited number of trials available.

PCN39: INTENSITY MODULATED RADIATION THERAPY IN MALIGNANT PLEURAL MESOTHELIOMA; A PILOT FOR TREATMENT OUTCOMES AND COST-EFFECTIVE EXPECTATIONS

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OBJECTIVES: The study aims to test the effect of Intensity Modulated Radiation Therapy (IMRT) on unresectable Malignant Pleural Mesothelioma (MPM) patients who exhausted the standard treatment modalities. A control group scheduled for supportive care will be compared to the test group in terms of median overall survival (OAS), median progression free survival (PFS), quality of life (QOL) and health economic perspectives. METHODS: 24 eligible patients were randomized (1:1) to either best supportive care versus IMRT to the tumor volume. Radiotherapy group were treated with either step and shoot or rapid arc method. QOL of patients in both groups was assessed by European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire QLQ-30 and QLQ-LC. Tumor progression was monitored by serial CT scans. Assessment was done at enrollment and after 4 months. Incremental cost-effectiveness ratio (ICER) was calculated for IMRT versus best supportive care. The output data of the ICER were total costs, median OAS, median PFS for each treatment modality. RESULTS: No significant statistical difference in the median OAS between both groups. (11 vs. 13 months respectively. P=0.117) while radiotherapy group showed a highly significant statistical improvement of the PFS (7.5 vs. 4.3 months respectively. P=0.009). The radiotherapy group demonstrated a significant deterioration in their final QOL scores compared to the baseline. IMRT had an incremental cost of 43,935 L.E per patient with an incremental effectiveness of 4 months of progression free survival, providing an ICER of 10,984 L.E. CONCLUSIONS: IMRT in MPM with intact lung is detrimental and not cost effective.

PCN40: TREATMENT PATTERNS IN NON-SMALL CELL LUNG CANCER IN FRANCE

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OBJECTIVES: To examine real-world treatment patterns and clinical characteristics of French patients with advanced (stage IIIb/IV) non-small cell lung cancer (NSCLC) METHODS: Data were extracted from case report forms (CRFs) collected from physicians in France for patients with cancer in active phase in 2015. CRFs were extrapolated nationally using projection coefficients based on hospital activity level and type. This study was limited to treated, advanced NSCLC patients not participating in clinical trials. RESULTS: Patients (n=39,188) were predominantly male (69.3%), mean age of 64.2 years, on first line treatment (63.3%), and with an Eastern Cooperative Oncology Group
(ECOG) score of 1 (61.1%). Regardless of treatment line, patients were overwhelmingly treated with Chemotherapy/Targeted therapy/Immunotherapy (82.6%) without any other parallel treatment (e.g. surgery, radiotherapy). Platinum(s) were prescribed in combination with at least one other product, typically with Pemetrexed (33.6%). Platinum combinations were preferred for first line (84.1%); while monotherapies were preferred for second and third+ line treatments (docetaxel = 32.3% and nivolumab = 24.9%, respectively). Among patients receiving monotherapy in any line, 30.5% patients experienced 3+ toxicities, with no toxicity reported in 73.4% of nivolumab patients. For combination therapy patients in any line, 38.1% experienced 3+ toxicities, with no toxicity reported in 37.9% of platinum-pemetrexed patients. Complete remission was reported in 2.7% of first line patients, 11.2% of second line patients and 2.3% of third+ line patients. Disease progression increased by treatment line, from 4.4% in first line to 13.6% in second line to 26.9% in third+ line. Due to ongoing treatment, response was not evaluated in 32.0% of patients. CONCLUSIONS: Given the toxicities and incomplete response associated with current treatments, there is still a need for safer, more effective treatment options in advanced NSCLC. The recent introduction of immunotherapies is promising.

**PCN41: ESTIMATING THE NUMBER OF RELAPSED AND REFRACTORY INDOLENT LYMPHOMA PATIENTS ACROSS EUROPE, WHO ARE EXPECTED TO INITIATE A NEW LINE OF THERAPY (LOT)**

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**OBJECTIVES:** Follicular lymphomas (FL) constitute the second most common sub-type of non-Hodgkin lymphoma (NHL), and marginal zone lymphomas (MZL) the third. The introduction of rituximab around 15 years ago has led to a substantial increase in survival for patients with indolent NHLs. With a median overall survival of approximately 14 years and a median first-line progression-free survival of between 2–4 years for most rituximab-based regimens, more patients may require second- and third-line therapies. There is currently limited literature reporting estimates of the number of these patients. METHODS: We created a model to estimate the number of patients in the EU28 with relapsed and/or refractory FL and MZL requiring a new (LOT) treatment in a given year. Population data from the World Bank, epidemiological data from GLOBOCAN and the literature, and efficacy data from published randomised controlled trials and observational studies, were used to populate the model. Market research data was used to determine the market shares of FL and MZL treatments. The model tracked both prevalent and incident patients between 2017 and 2022. RESULTS: Across the EU28, the model projects that over the 5-year period, 63,804 FL and 25,560 MZL patients will require a second LOT. Of these, 58,439 FL and 18,606 MZL patients will have relapsed on, or be refractory to, a prior rituximab containing regimen. An estimated 41,936 FL and 15,331 MZL patients will require a third LOT between 2017 and 2022. Of these, 41,443 FL and 14,369 MZL will have been previously treated with a rituximab containing regimen. CONCLUSIONS: We predict a growing number of patients eligible for second- and third-line therapies in FL and MZL. With improved outcomes from first line therapies, greater consideration must now be given to the relapsed/refractory setting, to consolidate gains in patient survival.

**PCN42: TREATMENT PATTERNS IN HEAD & NECK SQUAMOUS CELL CANCER IN FRANCE: ARTISTE STUDY ON CANCEROLOGY PATIENT CHARTS**

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**OBJECTIVES:** With the advent of new immunotherapies for recurrent/metastatic (R/M) head and neck squamous cell cancers (HNSCCs), the current study examined real-world treatment patterns in HNSCC by relevant demographic/clinical factors to understand current standard of care and inform the potential role/utilization of the new therapies. METHODS: Patient characteristics, clinical profiles, and current antitumor treatments were reported from case report forms collected by physicians in the cross-sectional Kantar Health French Cancrology database. Corresponding data were extrapolated to the whole of France using projection coefficients based on hospital activity level and type of hospital. Analyses focused on representative 2015 data for patients with primary R/M HNSCC. RESULTS: Patients (n=8,579) were predominantly male (79%), receiving 1st line treatment (88%), having oropharynx tumor (26%), and with mean age of 61 years. Most patients who underwent 1st-line treatment had Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 (80%), and were treated with chemotherapy or targeted therapy alone (68%). Other treatment options included combining chemotherapy/targeted therapy with surgery and/or radiation. Cetuximab was the predominate regimen prescribed as 1st line monotherapy. Similarly for all locations, combination therapies involving platinum/5FU/cetuximab/taxane were preferred to monotherapy in 1st line. The majority (66%) of patients received a regimen with a cycle length of 3 weeks. Across all lines, toxicities occurred to more than three quarters of patients; diarrhea, leucopenia, skin rash, nausea/vomit, and/or mucositis were the most occurring toxicities, each affecting ≥20% patients with varying severity. Among patients with tumor response evaluated/specified (n=5,182), 11% and 11% had a completely and partial remission, respectively.
respectively. **CONCLUSIONS:** Chemotherapy/targeted therapy alone is the most commonly used regimen for HNSCC, with a variety of combinations used more often than monotherapy. Current treatment options for HNSCC remain limited for all lines, especially 2nd line. Immunotherapies are expected to fill part of this unmet need.

**PCN43: ORAL ESTROGEN THERAPY IS ASSOCIATED WITH REDUCED RISK OF HEPATITIS B VIRUS–RELATED HEPATOMA IN TAIWANESE POSTMENOPAUSAL WOMEN**

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**OBJECTIVES:** It is noticed that the incidence of hepatoma in females was generally lower compared to males. The sex differences have been attributed to estrogen. However, information on the incidence of HCC in postmenopausal women receiving estrogen is still lacking. We aimed to evaluate the relationship between HT and the HCC risk in postmenopausal women with HBV, and also investigate the cumulative incidences of HCC. **METHODS:** We used the Large Health Insurance Dataset (LHID) in Taiwanese National Health Insurance claims databases to establish research cohorts. The clinical dataset consist 3 million adult patients from 1997 to 2012. We excluded male, aged 50 years younger, and any previous cancer, then established two cohorts (HT and non-HT users) in postmenopausal women which are aged≥50 years between 1 January 1997 and 31 December 2012 and diagnosis with HBV. 3,333 postmenopausal women with HBV for at least 90 days HT (HT group) and 10,458 untreated postmenopausal women with HBV (non-HT group), who never received HT or less than 90 days were matched 1:4 based on propensity scores. A cohort study (n=14,713) was conducted among this population to estimate the association between the 10-year cumulated incidence of HCC and exposure to HT by Cox’s proportion hazard model, and multivariable analyses using conditional logistic regression were executed after adjusting for hazard ratios (HR) and competing mortality. **RESULTS:** Insurance claim data presents that the treated cohort had a significantly lower 10 years incidence of HCC (3.05%; 95% confidence interval [CI], 1.54% - 4.55%) than non-treated cohort (5.65%; 95% CI, 4.64%-6.65%; P <0.05). Hormone therapy was associated with a reduced risk of HCC, with an adjusted hazard ratio of 0.58 (95%CI, 0.38-0.9; P<0.05) after adjusting for other confounders and competing mortality. Cirrhosis modified this association. **CONCLUSIONS:** We highlight emerging evidence that HT therapy was associated with a decreased risk of HCC among postmenopausal women with HBV.

**PCN44: CHARACTERISTICS AND TREATMENT PATTERNS IN PATIENTS TREATED FOR RELAPSED REFRACTORY MULTIPLE MYELOMA OVER 3 YEARS: PREMIERE STUDY**

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**OBJECTIVES:** The management of multiple myeloma (MM) has changed considerably yet real-world data on treatment patterns are scarce. The PREMIERE study explored patient characteristics and treatment patterns in patients treated for a first episode of Relapse/Refractory Multiple Myeloma (RRMM) in Spain. **METHODS:** Retrospective cohort chart review study of patients treated for RRMM over 3 years in 31 hematology centers in Spain. Patients ≥18 years with ≥1 prior line of therapy (LOT) for MM, starting a LOT (index therapy, LOT1) due to relapsing or refractory disease were followed up to the earlier of loss to follow-up, enrollment into a clinical trial, end of follow-up, or death. Patient characteristics at index and treatment patterns are described. **RESULTS:** A total of 284 patients, 53.9% male, with a mean age of 68 years at index were followed for a median 20.1 (Q1-Q3=7.9-34.1) months. Average disease duration at index was 2.5 years, 72.3% patients with relapsed disease, and 83.1% with only one LOT before index. Prior treatments included: corticosteroids (97.5%), chemotherapy (70.4%, mainly with melphalan), proteasome inhibitors (PIs) (75.7%, mainly bortezomib), immunomodulators (9.2%, all lenalidomide), stem cell transplant (29.6%) and radiotherapy (16.2%). LOT1 treatments were: immunomodulators (42.3%), PIs (17.3%), chemotherapies (14.4%), and combinations (24.6%). The maximum number of LOTs after index was seven: 284 (100%) LOT1, 56.7% LOT2, 29.9% LOT3, 13.4% LOT4. Lenalidomide + dexamethasone was the most frequent treatment regimen in LOTs 1 (38.4%) and 2 (25.5%), followed by bortezomib + dexamethasone (16.6% and 14.3%), whereas chemotherapy regimens were increasingly used in LOT3 (30.6%) and beyond (≥30% in subsequent LOTs), progressively replacing all other treatment strategies. **CONCLUSIONS:** This study provides data of recent treatment patterns in RRMM, contributing to a better understanding of the added value of new treatments.

**PCN45: EPIDEMIOLOGY OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER IN THE US, EUROPE AND JAPAN**

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**OBJECTIVES:** The primary objective of this study was to estimate the annual number of patients with locally
advanced or metastatic urothelial cancer (UC) and those treated with systemic chemotherapy in the US, Europe and Japan. METHODS: A structured literature search in the English language (2001 to 2017) was conducted in Medline, EMBASE, conference proceedings and other secondary data sources. Out of 43 articles identified, twelve reported data on incidence and three on the prevalence of UC. Seven Real-World (RW) studies provided insight into treatment patterns. The incidence of UC was derived from SEER (2016) for the US and Globocan (2012) for EU-28 and Japan. The number of patients with locally advanced or metastatic UC was determined based on the stage distribution at diagnosis. RESULTS: The crude incidence rate of UC reported for the US, EU-28 and Japan was 25.7, 25.7 and 18.6 per 100,000 (83,662; 129,977; and 23,567 patients). The incidence of locally advanced or metastatic UC was 3.8, 3.8 and 2.8 per 100,000 (12,494; 19,411 and 3,520 patients), respectively. Based on the findings of the RW studies, approximately 35% (range: 30% - 62%) of this patient population was ineligible for systemic first line chemotherapy (due to impaired renal function, poor performance status [ECOG PS >1], existing comorbidities and other reasons). Of those who received first line chemotherapy, only 50% (range 30% - 55%) received second line chemotherapy. The 5-year survival in this patient group is approximately 5%. CONCLUSIONS: A large proportion of patients with advanced or metastatic UC are not receiving systemic therapy. There is an urgent need for newer and alternate treatment options that are both effective and well tolerated. Data on the epidemiology of locally advanced or metastatic UC is scarce. More population-based studies would elucidate the global epidemiology of this disease.

PCN46: A SYSTEMATIC LITERATURE REVIEW OF UK EPIDEMIOLOGY OF BRCA1 AND BRCA2-MUTATED LOCALLY ADVANCED OR METASTATIC OVARIAN CANCER

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OBJECTIVES: In the United Kingdom (UK), ovarian cancer (OC) is the fifth most common cancer and the fourth most common cause of cancer death among women. BRCA-mutations have been recognized as important factors in OC diagnosis and treatment. Therefore, this systematic literature review (SLR) explored the epidemiology of BRCA-mutated OC in the UK. METHODS: Following PRISMA guidelines, MEDLINE and Embase were systematically searched for English publications between 2007 and February 2017. The latest OC data in England were also targeted (Office for National Statistics, 2015). RESULTS: In 2015, 5,771 new cases and 3,325 deaths of OC were registered in England, making it the third most common female cancer. Of 1025 publications screened in the SLR, eight studies were included. A retrospective case review in North Wales showed high (47%) recurrence rates. Another study in recurrent OC showed that most of these recurrences were platinum-sensitive. Two studies reporting data specifically on BRCA-mutation carriers showed that these patients had a worse prognosis compared with those without BRCA-mutations. More specifically, a higher proportion of carriers with BRCA mutations presented with later stages of OC (77%) and had a significantly higher proportion of visceral metastasis (74% vs. 16% of those without mutations). Tumor and disease characteristics associated with BRCA-mutated OC were more comparable with those of high-grade rather than low-grade serous carcinoma. Among BRCA-mutated OC cases, BRCA1-mutations were more commonly reported (>60%) and associated with younger age at diagnosis than BRCA2 (median 50 vs. 58 years). Although more BRCA1-mutation carriers had advanced OC (70% vs. 24%), no significant survival differences were found between BRCA1 and BRCA2-mutation carriers. CONCLUSIONS: To our knowledge, this is the first SLR on the epidemiology of BRCA-mutated OC in the UK. The limited evidence found suggests that BRCA-mutations may have distinct clinical and prognostic features that necessitate targeted disease management.

PCN47: ESTIMATING POPULATION TRENDS IN COLORECTAL CANCER STRATIFIED BY STAGE, LINE OF THERAPY, AND HIGH MICROSATELLITE INSTABILITY IN THE UNITED STATES FROM 2017 TO 2021

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OBJECTIVES: Estimate 5-year future incidence/prevalence of colorectal cancer (CRC) in the United States (US) by age, gender and stage. Among CRC patients with metastatic CRC (mCRC) or recurrent CRC, estimate the population distribution across different lines of systemic therapy (LOTs), stratified by high level of microsatellite instability (MSI-H). METHODS: Colon and rectal cancer age-adjusted incidence rates were calculated from the SEER-18 cancer registries, using first matching record for patients age ≥ 20 years diagnosed from 2004-2014. Estimated incidence/prevalence was calculated by multiplying tumor-, gender-, stage-, and age-specific incidence rates/prevalence proportions by corresponding gender- and age-specific US population estimates for 2017-2021. Trend analyses of historical annual incidence rates (2004-2014) were used to generate average annual percent change to adjust the estimated CRC incidence counts. Estimates for 5-year recurrence rates were applied to prevalent CRC estimates. Combined incident mCRC (stage IV) and recurrent CRC estimates were stratified by LOTs and MSI-H. RESULTS: Total 2017 US CRC estimates were 132,192; decreasing to 128,826 by 2021. Between 2017
and 2021, CRC incidence declines for both males and females. However, the greatest increase in incident CRC is expected for individuals ages 20-49. Stage I CRC estimates exhibit a decreasing 5-year trend (32,687 to 30,727), while mCRC estimates show an increase (29,593 to 30,232). Combined mCRC and recurrent CRC will increase from 66,730 in 2017 to 70,512 in 2021, across all LOTs and for MSI-H CRC. Notably, number of combined mCRC and recurrent CRC 3rd-line treated patients will increase from 10,574 to 11,223 over 5 years, and those treated by 3rd-line with MSI-H will increase from 529 to 561.

**CONCLUSIONS:** Over the next 5 years, it is estimated that mCRC, recurrent CRC, and use of all LOTs will increase, despite overall decreases in CRC incidence. This confirms the need for availability of new therapies for late stage disease.

**PCN48: INCIDENCE OF NON-SMALL-CELL LUNG CANCER AND BURDEN OF EGFR MUTATIONS: A 10-YEAR GLOBAL FORECAST**

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**OBJECTIVES:** To estimate the incidence of Non-Small Cell Lung Cancer (NSCLC) globally between 2016 and 2026 and the estimated prevalence of EGFR mutations in this population. Oncogenic mutations have attracted more attention as carriers are eligible for targeted treatments and disease outcome can be modified based on the presence of specific mutations. **METHODS:** To estimate the incidence of NSCLC we analyzed country-specific cancer registries for lung cancer (C34) and NSCLC histology data (IARC, 2013). We reviewed the peer-reviewed literature for population-based studies estimating the prevalence of EGFR mutations in patients diagnosed with NSCLC. The ten-year forecast for incidence incorporated risk factors such as economic development, smoking, screening and demographic changes related to aging and population growth. When country-specific data were unavailable, a risk-factor and GDP-based model was used to extrapolate data from a proxy country. The prevalence of EGFR mutation was assumed to be constant over the forecast period. **RESULTS:** In 2016, the incidence of NSCLC varied widely, ranging from 3 to 57 per 100,000 in Africa and North America respectively, with approximately 2 million cases diagnosed globally. Over the next ten years, we expect approximately 25% increase in incident NSCLC cases worldwide. Africa and low-income Asia Pacific countries are expected to grow around 40% due to demographic change and other risk factors. The prevalence of EGFR mutation ranged from 19-41%, with approximately 668 thousand NSCLC patients with EGFR mutations worldwide, in 2016. **CONCLUSIONS:** The incidence of NSCLC will continue to increase over the next ten years due to an increase in risk factors, population growth, and aging. Further analyses estimating the increase in NSCLC incidence that is attributable to modifiable risk factors and assessing the prevalence of other oncogenic mutations with targeted-therapy potential is indicated.

**PCN49: USE OF ANTIPSYCHOTICS AND THE RISK OF COLORECTAL CANCER: A CASE-CONTROL STUDY USING DATA FROM THE LINKED NETHERLANDS CANCER REGISTRY AND PHARMO DATABASE NETWORK POPULATION**

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**OBJECTIVES:** The carcinogenetic effects of antipsychotics is unclear and may vary between different types of antipsychotics. Therefore, this study examines the association between the use of different types of antipsychotics and the risk of colorectal cancer (CRC) using data from the linkage between the Netherlands Cancer Registry (NCR) and Out-patient Pharmacy Database of the PHARMO Database Network. **METHODS:** Patients who were newly diagnosed with CRC between 1998-2014 were selected. The date of diagnosis was defined as index date. Each patient was matched to four controls based on gender, birth year and year of start enrolment in the PHARMO Database Network. Matched controls received the same index date as their matched case. Cases and controls were not allowed to have a diagnosis of cancer before index date. The association between the use of antipsychotics (either typical, atypical or lithium) before index date and risk of CRC was estimated using conditional logistic regression. **RESULTS:** A total of 29,490 CRC cases and 117,960 controls were identified. The use of any antipsychotic before index date was slightly higher among controls compared to CRC cases [3% vs. 2%] resulted in an odds ratio (OR) of 0.64 (95% CI 0.59-0.70) for CRC. Stratification by typical or atypical antipsychotics yielded almost the same OR. A different OR was seen for lithium: 1.17 (95% CI: 0.94-1.45) and increased with long term use (≥5 years: 1.60 (95% CI: 1.12-2.31). Also, the OR of lithium differed between tumour sites: [proximal colon: 1.09 (95% CI: 0.78-1.53); distal colon: 1.44 (95% CI: 1.00-2.06) and rectum: 1.04 (95% CI: 0.65-1.65]), which was not seen for atypical or typical antipsychotics. **CONCLUSIONS:** Overall, no association was seen between the use of antipsychotics and the risk of CRC. However, an increased risk of CRC was seen with long term lithium use and differed between specific tumour sites.
PCN50: UNDERSTANDING MORTALITY IN MULTIPLE MYELOMA (MM): FINDINGS FROM AN OBSERVATIONAL CHART REVIEW OF DECEASED PATIENTS IN THE UK, FRANCE, GERMANY, ITALY AND SPAIN

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OBJECTIVES: To be the first study to evaluate data from deceased patients with MM in Europe, and describe patient characteristics, treatment patterns and outcomes before their deaths. METHODS: This retrospective, descriptive study analysed 2016 chart data from patients in France, Italy, Germany, Spain and the UK who died during the 3 months before study initiation. RESULTS: Of 789 cases extracted, one-quarter (24%) of the patients died during or following first-line treatment (1L), and 21%, 21%, 15% and 12% died at 2L, 3L, 4L and 5L, respectively; 6% had never been treated. Overall, only 37% of patients were receiving active drug treatment when they died, 51% of individuals died during a treatment-free interval while receiving palliative care and 12% died during a treatment-free interval while further treatment was being planned. In contrast, of deaths defined as unexpected (not due to MM; 49% of all deaths), 76% occurred during active treatment. The highest proportion of unexpected deaths was in patients at 1L (66%), with the proportion decreasing by treatment line to 45% at 5L. Patients who survived to later treatment lines were younger at diagnosis and had less severe disease than those who died at early lines. Disease progression was increasingly dominant as the cause of death as treatment line increased (50% of deaths at 1L vs 84% at 5L), while renal failure and infection were responsible for considerably more deaths at 1L than at 5L. CONCLUSIONS: Death during early treatment lines is often not due to MM and commonly occurs during active treatment. In patients who survive to later lines, death is more typically related to the impact of disease progression. Understanding factors associated with death in MM could help increase the proportion of patients who reach later lines and inform new treatment approaches for improving patient survival.

PCN51: CONTRASTING IMPROVING RATES OF CANCER SURVIVAL IN THE CONTEXT OF LIFE YEARS LOST COMPARED TO THE GENERAL POPULATION


OBJECTIVES: In recent years, UK life expectancy (LE) has increased, as has the incidence of many common cancers. In 2014, approximately 357,000 new cases of cancer were identified in the UK, with half of all cases diagnosed in patients aged 70 or over. The therapeutic landscape associated with cancer treatment is rapidly evolving and significant increases in survival have been observed. This study aimed to quantify the improvement in survival associated with common cancer types between 1971 and 2010, relative to the general population. METHODS: Published survival rates, stratified by decade, for 21 common cancers were extrapolated with piecewise exponential models using 1-year, 5-year and 10-year survival estimates, assuming a minimum annual survival hazard equivalent to that of the general population. A partitioned survival model was used to compare cancer survival estimates with published age- and sex-adjusted general population LE estimates; mean per-patient life years (LYs) lost were derived. RESULTS: Between 1971 and 2010, estimated age-adjusted cancer LE increased from 6.7 to 12.7 years across evaluated cancers while the age-adjusted general population LE increased from 17.2 to 22.9 years over the same period. Mean LYs lost to cancer in 1971 were 10.6, decreasing to 10.2 in 2010 driven by 62% (n=13) of evaluated cancers. In 2010, 43% of evaluated cancers exhibited a >10-year difference in LE compared to that of the general population (brain cancer was associated with a 29.4-year reduction), whilst 19% exhibited LE differences of <5 years, notably, prostate cancer and melanoma with LY differences of 0.4 and 1.7, respectively. CONCLUSIONS: Generally, LYs lost due to cancer have decreased in recent decades. However, this study highlights that there are still significant areas of unmet need, with several cancers seeing only marginal LE improvements.

PCN52: BASELINE POPULATION CHARACTERISTICS AND THE ASSOCIATION BETWEEN PROGRESSION-FREE SURVIVAL AND OVERALL SURVIVAL IN ADVANCED NON-SMALL CELL LUNG CANCER PATIENTS

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OBJECTIVES: We aimed to identify baseline population characteristics that may affect the association between progression-free survival (PFS) and overall survival (OS) in advanced non-small cell lung cancer (NSCLC) patients. METHODS: Based on a previously conducted systematic literature review, we used data from 928 individual
PCN53: THE VALIDITY OF OBJECTIVE RESPONSE RATE AS A SURROGATE FOR PROGRESSION-FREE AND OVERALL SURVIVAL IN THE EVALUATION OF FIRST-LINE CHEMOTHERAPY FOR ADVANCED NON-SMALL CELL LUNG CANCER

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OBJECTIVES: In oncology, objective response rate (ORR) may be used as a surrogate for progression-free survival (PFS) or overall survival (OS). A recent analysis examined correlations between ORR, PFS, and OS across all lines of therapy for advanced non-small cell lung cancer (aNSCLC) based on data from 14 randomized clinical trials (RCTs) that were submitted to the Food and Drug Administration. The objective of our study was to estimate the relationship between ORR, PFS, and OS using a more comprehensive evidence base, focusing on the first-line aNSCLC setting. METHODS: A systematic literature review of RCTs of chemotherapy doublet–containing regimens used as first-line therapies for aNSCLC in the pre-immunotherapy era was conducted. Weighted linear regression models were fit and R² calculated to estimate associations between ORR and OS or PFS using relative treatment effect measures (ORR: odds ratio; PFS/OS: hazard ratio). Additionally, models were fit using experimental arm estimates (ORR: proportion; PFS/OS: median) to address dilution of treatment effect for OS arising from crossover. Sensitivity analyses explored the impact of trial characteristics on estimated associations. RESULTS: Forty eligible RCTs (2003-2015) were identified from 9783 abstracts. Included RCTs enrolled treatment-naïve patients with stage IIIb/IV or recurrent aNSCLC. ORR and PFS were significantly correlated (treatment effect, all arms: R²=0.63 [95% confidence interval (CI): 0.37, 0.89]; experimental arms: R²=0.48 [95% CI: 0.16, 0.80]). Using experimental arm data alone, ORR and OS were correlated (R²=0.49; 95% CI: 0.17, 0.80), but no association was detected using treatment effect data from all arms. Sensitivity analyses supported the main findings. CONCLUSIONS: Based on RCTs of chemotherapy in first-line aNSCLC, correlations were identified between ORR and PFS, and between ORR and median OS in the absence of crossover. These findings corroborate previously established analyses and may support the use of ORR as a surrogate for clinical outcomes in early regulatory decision-making.

PCN54: ESTIMATING SURVIVAL AFTER RADICAL PROSTATECTOMY IN PROSTATE CANCER; A PROPENSITY-SCORE MATCHING METHOD

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OBJECTIVES: Prostate cancer (PC) is one of the first most common malignancy in men and the second most common leading source of cancer deaths in Europe. The majority of the patients undergoing radical prostatectomy (RP) are under the age of 70 years. In this study we examined overall survival of patients with RP and compared to an age-matched general population of patients with PC. METHODS: We performed a retrospective cohort study from 2002 to 2013 using the database of the Hungarian National Health Insurance Found Administration which comprises longitudinal claims data for the whole population. Patients with PC were selected through a multi-step process based on international classification codes of PC and having either androgen-deprivation therapy or radical prostatectomy or radiotherapy. RP patients were matched 1:1 to general PC controls with no RP via propensity score matching to balance age and presence of bone metastasis. We compared overall survival using Kaplan-Meier method and Cox regression model. RESULTS: Altogether 50,392 men with prostate cancer were identified during the whole study period and 5,590 of them had RP. In patients with and without RP, mean (SD) age was 60.5 (6.1) and 71.9 (8.5) years and 221 (4.0%) and 3,170 (7.1%) patients had bone metastasis, respectively. In the matched control sample
(n=5,590), mean age was 60.5 (6.0) years and 231 (4.1%) patients had bone metastasis. Our results showed that RP had better survival benefit (Log-rank p<0.001) and improved overall 3-year (95.3% vs. 75.5%, p<0.001) and 5-year survival rates (89.8% vs. 63.9%, p < 0.001) compared to the matched sample. In multivariate analysis, RP patients showed lower (HR: 0.20; 95% CI: 0.18-0.22) and patients with bone metastasis showed higher (HR: 1.86; 95% CI: 1.61-2.16) overall mortality risk. **CONCLUSIONS:** Our results showed that patients underwent RP had longer overall survival in PC.

**PCN55: OVERALL SURVIVAL IN PATIENTS WITH METASTATIC UROTHELIAL CANCER BY FIRST-LINE THERAPY**

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**OBJECTIVES:** Currently, cisplatin-based chemotherapy is the preferred first line therapy (1L) for patients with metastatic urothelial cancer (mUC). However, most patients diagnosed with mUC have comorbidities and impaired functional status that limit its use. Few studies have described the overall survival (OS) of patients with mUC treated in real-world practice with non-cisplatin-based regimens. This study describes the treatment patterns and OS of patients diagnosed with mUC in the Veterans Affairs (VA) practice setting who received 1L non-cisplatin regimens consistent with the National Comprehensive Cancer Network (NCCN) v2.2015 guidelines for mUC. **METHODS:** The VA Corporate Data Warehouse (01/2006-05/2017) was used to identify adults diagnosed with mUC (based on ICD9/10 diagnosis codes) who received 1L non-cisplatin regimens per guidelines. Median survival time from 1L initiation and 2-year OS rates were estimated from Kaplan-Meier analyses. **RESULTS:** The study included 1,749 adults with mUC treated with 1L non-cisplatin containing regimens (median age 70 years; 99% males). Of these, 766 (43.8%) received 1L carboplatin-based regimens and 983 (56.2%) received non-carboplatin-based regimens. Among those treated with carboplatin-based regimens, carboplatin and gemcitabine was the most common regimen (321 [41.9%]); among those treated with non-carboplatin regimens, single agent gemcitabine was the most common regimen (134 [13.6%]). The median survival time was 11.8 months (95% CI 11.2; 12.3) overall, 9.9 (8.8; 10.1) for patients treated with carboplatin-based regimens (any), 9.5 (8.6; 10.3) for those treated with carboplatin and gemcitabine, and 14.5 (13.4; 15.4) for those treated with non-carboplatin based regimens. The corresponding 2-year OS rates were 29.9% (27.6; 32.2), 23.8% (20.6; 27.1), 20.4% (15.9; 25.4), and 34.6% (31.4; 37.8), respectively. **CONCLUSIONS:** Survival estimates among "real-world" mUC patients in the VA practice setting who do not receive cisplatin-based treatments are suboptimal. New treatments are needed to address this unmet need.

**PCN56: THE NOVEL GENERATION AND VALIDATION OF SURVIVAL CURVES IN ONCOLOGY UTILIZING ELECTRONIC MEDICAL RECORDS LINKED TO POINT OF SERVICE CLAIMS DATA**

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**OBJECTIVES:** Survival is an important endpoint in outcomes research. Identifying mortality utilizing EMR and claims data is challenging, as they lack reliable mortality records. We describe a method of generating survival curves by linking EMR to claims data, and initial validation of a mortality proxy. **METHODS:** Using the QuintilesIMS Oncology EMR, we identified patients with stage III/IV gastric, glioblastoma (GBM), head and neck, melanoma or lung cancers (NSCLC and SCLC). The first systematic treatment between 1/1/2014 and 6/30/2015 was the index date. Using a HIPAA-compliant encrypted ID, patients were linked to QuintilesIMS longitudinal prescription data (LRx), a consistent HEM/ONC panel of outpatient medical claims (Dx), and a consumer panel death index incorporating the SSDMF. The last observed claim in LRx/Dx followed by ≥6 months of no activity defined the mortality proxy. Validation of the proxy was determined through agreement the month and year of death within the death index. Survival time from index was estimated using Kaplan Meier analysis. **RESULTS:** A total of 11,010 patients were evaluated, 4,895 linked to LRx/Dx data, and 2,912 (60%) met the death proxy; of these, 1,076 (37%) linked to the consumer panel, with 376 having month/year of death. When compared to the LRx/Dx claims proxy, 100% agreed on death, with 295 (78%) agreeing exactly on month/year of death, 112 (16%) agreeing +/-1 month, 12 (3%) agreeing +/-2 months, and 7 (2%) had agreement of >2 months. The 12 month survival from index treatment in the study population was 56% for gastric cancer, 46% for GBM, 61% for head and neck cancer, 62% for melanoma, 43% for NSCLC, and 33% for SCLC. **CONCLUSIONS:** A death proxy using linked LRx/Dx claims in stage III/IV cancer patients correlated accurately with a consumer death index, and with further validation may serve as a useful tool in outcomes research studies.
PCN57: SURVIVAL RATES IN PRIMARY HEPATIC CARCINOMA PATIENTS WITH CIRRHOSIS IN SOUTH KOREA: A RETROSPECTIVE ANALYSIS OF 68,328 PATIENTS IN THE NATIONAL CANCER REGISTRY

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OBJECTIVES: Early detection of primary hepatic carcinoma (PHC) patients with cirrhosis is critical to enhance PHC patients’ survival rates because cirrhosis is a major risk factor to develop PHC and limiting factors to select treatment approaches. The study aimed to support the importance to detect PHC with cirrhosis early through determining current survival rates in PHC patients with cirrhosis according to their characteristics. METHODS: A retrospective analysis was performed on 68,328 PHC patients with cirrhosis in the national cancer registry from 2005 to 2015 linked to the Korea national health insurance claims database. The survival rates and median survival durations of the patients were analyzed regarding their sex, age, surveillance, epidemiology, and end results (SEER) stage and type of PHC at diagnosis. RESULTS: There were differences of survival rates depending on their characteristics including SEER stage. The 5-year survival rates of hepatocellular carcinoma (HCC) patients aged 20-49 years were 54% (95% CI, 53-56%) for localized stage, 19% (95% CI, 18-20%) for regional stage and 4% (95% CI, 3-5%) for distant stage. If LCC patients aged over 75 years were for localized stage, their 5-year survival rate was 25% (95% CI, 23-27%) but they were for distant stage, their 5-year survival rate was 2% (95% CI, 1-3%). The overall median survival duration of HCC was 4.66 years (95% CI, 4.56-4.77) for localized stage but it was 0.33 years (95% CI, 0.32-0.35) for distant stage. This trend was observed consistently in other PHC groups regardless of sex or types of PHC at diagnosis. CONCLUSIONS: Early detection of PHC would improve the survival rate of adults with cirrhosis irrespectively of their sex, age and type of PHC at diagnosis. The future studies would need to impact early detection of PHC with cirrhosis.

PCN58: PREDICTING OUTCOMES FROM MULTIPLE UNCONTROLLED HISTORICAL STUDIES OF TREATMENT OF PHYSICIAN’S CHOICE: PROGRESSION-FREE SURVIVAL AND OVERALL SURVIVAL IN UNTREATED METASTATIC MERKEL CELL CARCINOMA

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OBJECTIVES: Metastatic Merkel cell carcinoma (mMCC) is an ultra-rare skin cancer with a poor prognosis. With no licensed treatments available for mMCC, there been a lack of standardisation in care, with outcomes poorly understood. The aim of this study was to estimate progression-free survival (PFS) and overall survival (OS) outcomes from multiple studies of treatment of physician’s choice (TPC), most of which included platinum-based chemotherapy regimens. METHODS: Literature searches were conducted to identify studies of Stage IV mMCC patients receiving TPC. Data were identified and analysed using regression techniques and visual inspection of Kaplan-Meier plots. Kaplan-Meier data from identified studies were digitised, analysed and standardised (where potentially prognostic factors were imbalanced). Extracted data were synthesised and analysed using appropriate methods such as pooling, inverse variance meta-analysis, or meta-analysis of curve parameters. RESULTS: Analysis of individual patient data from 67 patients from one study indicated that no characteristic, including age, gender, immunosuppression, disease stage at diagnosis or Eastern Cooperative Oncology Group (ECOG) performance status, was identified to have a prognostic effect on PFS or OS. Two further studies reported data for PFS, five for OS, with no randomised-controlled trials identified. As no prognostic factors were identified and outcomes were similar between studies, literature-based data were digitised and pooled. Fitting parametric curves to pooled data gave a median (mean) PFS of 4.3 (10.5) months and OS of 10.9 (18.0) months among patients with mMCC receiving first-line TPC using the generalised gamma and log-logistic curves, which provided the best fit. CONCLUSIONS: Outcomes in mMCC are poor, with no observed patient characteristic identified as prognostic of PFS and OS. Similarly, outcomes between the uncontrolled studies were surprisingly homogeneous, despite differences in patient characteristics and treatment regimens. These TPC data help to put into context the results of emerging immuno-oncology therapies for mMCC.

PCN59: MATCHING ADJUSTED INDIRECT COMPARISON OF SUNITINIB AND EVEROLIMUS FOR THE TREATMENT OF PancreATIC NEUROEndOCRINE Tumours (PNETs)

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OBJECTIVES: The relative effectiveness of sunitinib and everolimus to treat pNET patients has been assessed using matching adjusted indirect comparison (MAIC) based on the RADIANT-3 everolimus trial. We performed an analysis using updated OS data for both treatments using individual patient data (IPD) from sunitinib’s trial (A6181111), offering an opportunity to assess robustness of results to IPD source. METHODS: Analyses included Bucher-type comparisons using hazard ratios (HRs) for progression-free survival (PFS) and overall survival (OS) vs. best standard of care (BSC), and a MAIC matching on all baseline characteristics available from both studies. An anchored MAIC was performed for PFS, applying balancing weights in A6181111 to derive an adjusted HR for sunitinib vs BSC. The ratio of this and the HR for everolimus yielded a HR for sunitinib vs. everolimus. An unanchored MAIC was performed for OS since survival in the BSC arms may be contaminated differentially by crossover. A Cox model was fit the weighted OS data for sunitinib and virtual IPD for death/censoring times for everolimus derived from its published OS curve. RESULTS: The effective sample size after matching was 43 (original N=86) for sunitinib and 31 (original N=85) for BSC. The unadjusted PFS HR for sunitinib vs everolimus was 1.20 (0.72-2.01), and 0.85 (0.39-1.89) after adjustment. Similarly, an unmatched OS comparison yielded 1.03(0.75-1.42); this reduced to 0.82 (0.53-1.27) after matching. CONCLUSIONS: Like the prior MAIC, analyses demonstrate comparable PFS and OS with sunitinib and everolimus, but produced point estimates that differ in direction. For PFS, this is attributable to baseline imbalances in A6181111 favouring BSC that are adjusted for in the current analysis; for OS, the direction may reflect changes in updated survival data. Limitations include uncertainty due to the small size of the sunitinib trial, and possible residual confounding in OS comparisons. DISCLOSURE: This research was sponsored by Pfizer.

CANCER - Cost Studies

PCN60: FINANCIAL IMPACT OF INTRODUCING SC TRASTUZUMAB (HERCEPTIN) VERSUS CURRENTLY USED IV TRASTUZUMAB (HERCEPTIN) ON THE BUDGETS OF DIFFERENT HOSPITALS ACROSS KINGDOM OF SAUDI ARABIA (KSA)

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OBJECTIVES: Trastuzumab is the standard of care in HER2+ve breast cancer (BC) treatment. It is usually administered as intravenous (IV) infusion. This study investigated economic implications of using subcutaneous (SC) trastuzumab compared to IV formulation in KSA for early BC (EBC). METHODS: A budget impact model was developed to estimate financial impact of introducing fixed dose trastuzumab SC for treatment of HER2+ve EBC in KSA. Clinical and cost inputs were obtained through discussion with medical oncologists and hematologists. Base case scenario evaluated impact of replacing IV formulation by SC in 100% patients in 1st year itself and impact of gradual replacement of IV formulation by SC in up to 75% patients (SC adoption in Year 1: 25%; Year 2: 50%; Year 3: 75%). Two hypothetical scenarios evaluated impact of reduction in non-drug cost (by 25% and 50% in scenario 1 and 2 respectively) based on increased awareness and higher use of SC trastuzumab in local treatment centers. RESULTS: Introduction of trastuzumab SC vials across different hospitals in KSA is expected to lead to cost savings by decreasing total cost by 1.6% to 3.1%. For the scenario considering gradual replacement, reduction in total budget across KSA for Year 1, ranged from 0.4%-0.8%; for Year 2, ranged from 0.8%-1.6% and for Year 3, ranged from 1.2%-2.3%. In hypothetical scenarios, the reduction in total cost ranged from 7.2% to 9.4% and 12.4% to 16.6% in scenarios 1 and 2 respectively. Fixed dose SC formulation led to lower drug cost due to elimination of vial wastage. Lower monitoring time and ability to administer at local treatment center lowered non-drug cost compared to IV formulation given at major hospitals. CONCLUSIONS: Trastuzumab SC reduces the overall treatment cost as compared to trastuzumab IV due to less hospitalization and travel costs thus decreasing the budgetary impact in KSA.

PCN61: BUDGET IMPACT ANALYSIS OF DABRAFENIB AND TRAMETINIB COMBINATION THERAPY IN THE TREATMENT OF BRAF V600E-MUTANT ADVANCED NON-SMALL CELL LUNG CANCER IN THE UNITED STATES

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OBJECTIVES: To estimate the budget impact of dabrafenib + trametinib (TAFMEK) market entry for patients with BRAF V600E-mutant advanced non-small cell lung cancer (NSCLC) from a US third-party payer’s perspective. METHODS: Costs of treatment (drug and drug administration), monitoring, adverse events (AEs), progression, terminal care, and BRAF testing were estimated over three years under the scenarios with and without
TAFMEK entry. Published epidemiology data were used to estimate the targeted population size. BRAF test rate was assumed to increase by 5%, 15% and 20%, respectively, for the first three years with TAFMEK entry. Existing first-line treatments included bevacizumab combination therapy, platinum doublet, pembrolizumab, and best supportive care (BSC). Treatments in the second-line included bevacizumab combination therapy, docetaxel, erlotinib, pemetrexed, platinum doublet, nivolumab, pembrolizumab, and BSC. Model inputs were collected from published trials, drug labels, public data sources, and assumptions. All costs were estimated in 2016 USD. RESULTS: In a hypothetical plan with 1 million members, an estimated 5.3, 6.6 and 7.2 patients in the overall population (first- and second-line) would be diagnosed with BRAF V600 mutant-advanced NSCLC in Year 1, 2, and 3 with TAFMEK entry, respectively. In Year 1, TAFMEK increased treatment costs in the overall population by $0.0142, monitoring costs by $0.0002, and BRAF test costs by $0.0011 per member per month (PMPM), but decreased AE costs by $0.0001 and progression and terminal care costs by $0.0017 PMPM, resulting in a net increase of the total budget of $0.0137 PMPM. The budget impact was $0.0304 and $0.0369 PMPM in Year 2 and Year 3, respectively. CONCLUSIONS: TAFMEK entry for BRAF V600E-mutant advanced NSCLC is expected to increase treatment, monitoring and BRAF test costs, which are partially offset by reductions in AE costs and progression and terminal care costs. The estimated total budget impact to US payers was modest.

**PCN62: BUDGET IMPACT MODEL OF COBIMETINIB IN COMBINATION WITH VEMURAFENIB FOR THE TREATMENT OF PREVIOUSLY TREATED BRAF V600-MUTATION POSITIVE PATIENTS WITH MALIGNANT MELANOMA IN GREECE**

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OBJECTIVES: To estimate costs and budget impact of establishing cobimetinib plus vemurafenib (cobimetinib) as a first-line treatment option for post-malignant melanoma with HR+/HER2+ metastatic breast cancer in the US. METHODS: A budget impact model with a commercial US third-party payer perspective calculated the incremental cost of introducing cobimetinib over 3 years in patients with HR+/HER2+ breast cancer (74%) eligible for treatment (100%). Two scenarios compared relevant treatments for this population excluding or including cobimetinib. Market shares were derived from market research and uptake assumptions (cobimetinib was assumed only to displace other CDK-based therapies). Treatment duration was based on median time to treatment discontinuation (assumed the same for ribociclib and palbociclib+letrozole) and median progression-free survival (all other comparators) based on clinical trial data. Acquisition costs represented the lowest wholesale acquisition costs within Medi-Span Price Rx® while considering co-payment. The model also included costs of drug administration, monitoring, health state (progression-free and post-progression), subsequent treatment, and relevant serious (≥Grade 3) adverse events based upon Medicare payments. RESULTS: Assuming 1 million insured members, the calculated number of patients eligible for treatment was 263. The introduction of cobimetinib resulted in $3.01 M cumulative total savings over three years, attributed to reduced costs (drug acquisition ($2.72 M), subsequent treatment ($96 K), and adverse events ($82 K)). Savings per year increased over the time horizon with increased market share of cobimetinib: $125 K, $1.04 M, and $1.85 M in Years 1-3, respectively ($0.01, $0.09, and $0.15 incremental cost savings per member per month, respectively). The introduction of cobimetinib resulted in a cumulative incremental cost saving of $318.11 per member treated per year. CONCLUSIONS: The introduction of cobimetinib as a first-line treatment option for post-malignant melanoma with HR+/HER2+ advanced or metastatic breast cancer in the US offers a cost-saving option with reduced drug acquisition, adverse event, and subsequent treatment costs for US commercial payers.

**PCN63: BUDGET IMPACT MODEL OF COBIMETINIB IN COMBINATION WITH VEMURAFENIB FOR PREVIOUSLY UNTREATED BRAF V600-MUTATION POSITIVE PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC MELANOMA**

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OBJECTIVES: Metastatic melanoma is one of the most aggressive forms of cancer, affecting over 150,000 new patients annually worldwide. The WHO estimates that 66,000 patients worldwide die from malignant melanoma every year. The objective of this study is to estimate the potential budget impact of Cobimetinib plus Vemurafenib over a three-year time horizon from a third-party payer perspective in Greece. METHODS: A budget impact model is adapted to the Greek context to assess the budgetary consequences of the addition of Cobimetinib plus Vemurafenib for the treatment of previously untreated BRAF V600-mutated metastatic melanoma. The model estimates the expected costs of alternative treatment approaches after the launch of Cobimetinib plus Vemurafenib and compares these costs with a counterfactual situation without Cobimetinib plus Vemurafenib combination therapy.
Epidemiological, clinical and resource use data were obtained from published literature and expert interviews. Once the eligible population has been determined, the anticipated market uptake of Cobimetinib, as well as the market share estimates of all comparator regimens have been assumed. An expert panel of oncologists provided resource use data and externally validated the model inputs. Cost parameters were derived from official sources (National Medicines Agency-EOF, Ministry of Health, Social Insurance Fund-EOPYY) in Greece. **RESULTS:** Under the assumption of a gradual increase of the market share of Cobimetinib and Vemurafenib up to 39.5% in the third year since launch the total budget impact is estimated at €387,346 in the first, €945,984 in the second, and €973,924 in the third year since launch. Over the entire three-year period the estimated budget impact amounts to €2,307,254.

The results are sensitive to the prices of Cobimetinib and Vemurafenib and the evolution of market shares. **CONCLUSIONS:** The use of Cobimetinib plus Vemurafenib for the treatment of metastatic melanoma presents a reasonable budget impact for the third party payer in Greece.

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**PCN64: BUDGET IMPACT ANALYSIS OF FIRST-LINE CERITINIB IN THE TREATMENT OF ALK+ METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) IN THE UNITED STATES**

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**OBJECTIVES:** Ceritinib (Zykadia\textsuperscript{®}) is now approved for first-line (1L) treatment of ALK+ metastatic NSCLC in the US. This analysis estimated the budget impact of adding ceritinib to a US payer formulary for the 1L treatment of ALK+ metastatic NSCLC. **METHODS:** Costs of treatment (drug and drug administration), drug monitoring, radiotherapy/radiosurgery, adverse events (AEs) reported in ≥50% of the patients in relevant clinical trials, progression, terminal care were estimated over 3 years under the scenarios with and without ceritinib in 1L. The analysis assumed these treatment options across the 1L to third-line (3L): alectinib, ceritinib, brigatinib, crizotinib, docetaxel, pemetrexed, platinum doublet, nivolumab, pembrolizumab, best supportive care. Ceritinib 1L was projected to reach an average market share of 6.2% (Year 1), 14.1% (Year 2), and 16.8% (Year 3) and assumed to take market share from other treatments. Model inputs were estimated based on published trials, drug labels, public data sources, and assumptions. All costs were estimated in 2016 US$ and results were tested for robustness in sensitivity analyses. **RESULTS:** In a hypothetical plan with 1 million members, an estimated 26, 30, and 30 ALK+ metastatic NSCLC patients would be eligible for treatment across 1L to 3L. The estimated budget impact of adding (vs. not adding) ceritinib 1L to such US payer plan was estimated to result in plan total savings of $4,597 (Year 1), $17,601 (Year 2), $28,913 (Year 3), with per member per month (PMPM) savings ranging from 0.0004 (Year 1) to 0.0024 (Year 3), and per patient per year savings ranging from $290 (Year 1) to $1,353 (Year 3). Results were robust based on sensitivity analyses. **CONCLUSIONS:** Adding ceritinib 1L treatment for ALK+ metastatic NSCLC to a US payer formulary is estimated to yield modest savings to a US payer over the first 3 years.

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**PCN65: ECONOMIC BURDEN ASSOCIATED WITH SKELETAL-RELATED EVENTS IN PATIENTS WITH BONE METASTASES IN COLOMBIA**

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**OBJECTIVES:** Skeletal-related events (SREs) are associated with a high expenditure of healthcare resources. This study aims to provide an estimation of the cost per SRE in patients with Bone Metastases (BM) secondary to breast cancer, prostate cancer, and other solid tumors. Additionally, the budget’s impact of denosumab in the prevention of SREs in patients with BM was estimated from the Colombian healthcare system’s perspective. **METHODS:** The SRE management costs (vertebral fracture (VF), non-vertebral fracture (NVF), radiation to bone (RB), surgery to bone (SB) and spinal cord compression (SCC)) were estimated through a Delphi panel. A budget impact model was adapted combining epidemiological data and eligibility for treatment with denosumab (6% of eligible patients with denosumab in the first year and 46% in the fifth year). Evidence collected in clinical trials was used to estimate the denosumab clinical effect vs zoledronic acid. A 5 years’ time horizon was projected. The model included the following costs: medicines, administration, monitoring, and SRE management. Deterministic sensitivity analysis was conducted. **RESULTS:** The average cost per each SREs across all tumors was $26,190.680 COP for VF, $20,440.198 COP for NVF, $9,880.520 for RB, $26,190.680 for SB and $26,287.988 for SCC. The total annual Budget Impact to 5 years with the introduction of denosumab was $1,209,382,032 COP for breast cancer, $1,135,095,230 COP for other solid tumors, and a saving of $195,431,756 COP for Prostate Cancer. The deterministic sensitivity analysis indicated that the results were sensitive to the drug costs, 21 day window, and zoledronic acid patient management cost. **CONCLUSIONS:** SREs add substantial costs to the management of patients with bone metastases. The use of denosumab would lead to avoid SRE, to reduce health consequences and their treatment cost for the Colombian Healthcare System.
PCN66: BUDGET IMPACT ANALYSIS OF TRIFLURIDINE AND TIPIRACL HYDROCHLORIDE IN THE TREATMENT OF METASTATIC COLORECTAL CANCER IN GREECE

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OBJECTIVES: To evaluate the economic consequences following the introduction of trifluridine and tipiracil hydrochloride (FTD/TPI) in the Greek market for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with, or are not considered candidates for available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents and anti-epidermal growth factor receptor agents. METHODS: A budget impact model was adapted from a third-party payer perspective (EOPYY) over a 5-year time horizon (2017-2021) to estimate the financial impact of FTD/TPI taking market shares from regorafenib. Based on local experts, regorafenib is a treatment alternative to FTD/TPI. In the scenario that FTD/TPI is not on the Greek market, it was assumed that all patients were treated with regorafenib instead of best supportive care. The number of eligible patients was estimated from local experts and published literature, the projected uptake of FTD/TPI was provided by Servier Hellas, the progression free survival and overall survival was obtained from relevant published studies and the healthcare resource unit costs as retrieved from officially published sources (prices for 2017 in euros) were considered as input in the analysis. The model measured outcome was incremental budget impact from the introduction of FTD/TPI as a treatment option in the patients with mCRC. RESULTS: Over the 5-year horizon, the total number of eligible Greek patients was 368 and the number of patients who received FTD/TPI was 74, 130, 183, 199, 205 in years 1 to 5, respectively. The introduction of FTD/TPI led to annual cost savings versus regorafenib of €30,788, €73,414, €115,531, €133,413 and €141,462 from years 1 to 5, respectively, resulting in a total 5-year cost savings of €494,609. CONCLUSIONS: The results suggest that the introduction of FTD/TPI in the treatment of patients with mCRC may be considered over the next 5 years for the Greek payer.

PCN67: BUDGET IMPACT OF ATEZOLIZUMAB FOR THE TREATMENT OF 2ND LINE NON-SMALL CELL LUNG CANCER (NSCLC) AFTER FAILURE WITH PLATINUM CONTAINING CHEMOTHERAPY IN GREECE

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OBJECTIVES: Lung cancer is the leading cause of death from cancer, Greece is the EU country with the highest incidence of lung cancer under the age of 45. Non-small Cell Lung Cancer (NSCLC) accounts for approximately 85% of all lung cancer cases. The purpose of this analysis was to estimate the potential budgetary impact of introducing Atezolizumab as a 2nd line treatment for NSCLC patients in Greece, after failure with platinum-containing chemotherapy. METHODS: The analysis was based on a budget impact model considering the market shares and price of Atezolizumab as a 2nd line treatment approach in NSCLC patients. Published literature was the source of data used regarding the clinical effectiveness of each intervention. The model was populated with epidemiological and clinical effectiveness data from the literature and Greek-specific inputs on health resource use, based on an expert panel of 10 oncologists. The analysis follows a third party payer perspective (Greek Social Insurance). RESULTS: The Incremental Annual Budget Impact of the gradual introduction of Atezolizumab (first year market shares 5% and fifth year 27%) as a 2nd line treatment for NSCLC patients is projected to be €1,483,155, €3,377,747, €4,328,746, €4,421,391 and €5,016,492 for year one to five respectively. The uptake of Atezolizumab is estimated to result in an incremental cumulative budget impact of €18,627,531 for the five year time horizon of the analysis. The analysis is sensitive to the price of Atezolizumab (and its comparators) and the projected market shares. CONCLUSIONS: Based on the available epidemiological data for Greece, 2,504 patients with NSCLC move to 2nd line treatment after the failure of platinum containing chemotherapy making them eligible for Atezolizumab. Owing to the projected market shares for Atezolizumab the budgetary impact of its gradual uptake is of moderate size.

PCN68: BUDGET IMPACT OF ALECTINIB IN THE TREATMENT OF NAÏVE ANAPLASTIC LYMPHOMA KINASE-POSITIVE (ALK+) ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) IN GREECE

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OBJECTIVES: Lung cancer poses a considerable disease and economic burden on healthcare systems globally. Alectinib, a highly selective, CNS-active anaplastic lymphoma kinase (ALK) inhibitor is a new treatment option for 5% of Non-Small Cell Lung Cancer (NSCLC) patients who carry mutations associated with ALK. The objective of this
analysis is to estimate the potential budgetary impact of the introduction of Alectinib as a 1st line treatment approach in ALK+ NSCLC patients in the Greek healthcare setting. **METHODS:** The analysis was based on a budget impact model considering the market shares and price of Alectinib as a 1st line treatment approach in ALK+ NSCLC patients compared to Crizotinib. Ceritinib and chemotherapy. The model was populated with epidemiological and clinical effectiveness data from the literature and Greek-specific inputs on health resource use, based on an expert panel of 10 oncologists. The analysis followed a third party payer perspective (Greek Social Insurance). **RESULTS:** 109 patients are estimated to be the ALK+ NSCLC in Greece per year. The gradual introduction of Alectinib as a treatment for naïve ALK+ NSCLC patients (first year market share 3%, fifth year 60%) is projected to result in an annual incremental budget impact of €71,371, €454,469, €1,245,170, €2,699,802 and €4,161,658 for year one to five respectively, compared to the “world without” scenario. The cumulative budget impact (€6,632,470 for the five year time horizon of the analysis) is sensitive to the price of Alectinib (and its comparators) and the projected market shares. **CONCLUSIONS:** Based on the available epidemiological data for Greece, 5100 patients are diagnosed with NSCLC, of which 109 are eligible for treatment with an ALK inhibitor such as Alectinib. Owing mostly to the small number of patients, the budget impact of the introduction of Alectinib is reasonable.

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**PCN69: TO DETERMINE THE FINANCIAL IMPACT OF INTRODUCING SC RITUXIMAB (MABTHERA) VS. CURRENTLY USED IV RITUXIMAB (MABthera) ON THE BUDGETS OF DIFFERENT HOSPITALS ACROSS THE KINGDOM OF SAUDI ARABIA (KSA)**

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**OBJECTIVES:** Rituximab is the standard of care in Non-Hodgkin’s lymphoma (NHL) treatment. It is usually administered as intravenous (IV) infusion. This study investigated the economic implications of using rituximab subcutaneous (SC) compared to IV formulation in KSA for NHL. **METHODS:** A budget impact model was developed to estimate the financial impact of introducing fixed dose rituximab SC compared to IV formulation for the treatment of NHL, on budgets of different hospitals in KSA over three years. Clinical and cost inputs were obtained through discussion with medical oncologists and hematologists. Global Budget Impact model of rituximab was adopted reflecting the local treatment practice. The model compared both drug and non-drug costs for the two formulations. It also assessed the impact of gradual replacement of IV with SC in up to 75% of patients (SC adoption in Year 1: 25%; Year 2: 50%; Year 3: 75%). **RESULTS:** The introduction of rituximab SC vials across different hospitals in KSA is expected to lead to cost saving by decreasing total cost of treatment by 6.5% to 17.6%. Reduction in both drug cost (ranging from 8.57% to 15%) and non-drug cost (includes central access, administration, consultation and travel cost; ranging from 4.1% to 22.4%) occurred. Fixed dose SC formulation led to lower drug cost due to elimination of vial wastage. Although both formulations were administered in day care clinic/office, SC formulation required less monitoring and administration time, decreasing the overall cost. For the scenario considering gradual replacement of IV by SC, reduction in total budget across KSA for Year 1, ranged from 1.6% to 4.4%; for Year 2, ranged from 3.3% to 8.8% and for Year 3, ranged from 4.9% to 13.2%. **CONCLUSIONS:** Rituximab SC reduces the overall treatment cost as compared to Rituximab IV thus decreasing the budgetary impact in KSA.

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**PCN70: BUDGET IMPACT ANALYSIS OF AVELUMAB IN PATIENTS WITH METASTATIC MERKEL CELL CARCINOMA IN THE US**

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**OBJECTIVES:** The aim of this research was to estimate the budget impact of avelumab (BAVENCIO®) as a treatment option for patients with previously treated (2L+) and untreated (1L) metastatic Merkel cell carcinoma (mMCC) in the United States of America (US). **METHODS:** A budget impact model with a five-year horizon was developed. Comparators were pembrolizumab and chemotherapies recommended for use in the eligible population. It is anticipated that avelumab and pembrolizumab, both immune-oncology agents (IOs), are expected to partially replace chemotherapies (chemotherapy share 1L: 47% to 35%; 2L+: 62% to 60%). Duration of treatment was estimated based on the clinical study results for avelumab (JAVELIN Merkel 200); an observational study of patients with mMCC treated with chemotherapies, and evidence from a single arm study for pembrolizumab (NCT02267603). Costs included drug acquisition and administration, monitoring, adverse events, and transport costs. All inputs were validated by practicing clinician opinion. **RESULTS:** Considering a hypothetical health plan with 100 million members in 2017, 294 patients were estimated to have mMCC, with mMCC confirmed in an estimated 77 patients eligible for treatment with avelumab as 1L treatment and 23 as 2L treatment. The budget impact of avelumab was estimated to be US$0.0006 per member per year (PMPY) in Y1. Over 5 years the total budget impact was estimated to be US$0.013 PMPY. A slower uptake of IO agents (e.g. if their market share remained at 53% in 1L and 38% in 2L+)
would result in a 5-year budget impact of US$0.011 PMPY. On the contrary, if IO agents completely replaced chemotherapies the impact would be US$0.022 PMPY. **CONCLUSIONS**: MCC is a rare condition with a poor prognosis and patients stand to benefit greatly from new innovative immunotherapies. The addition of avelumab as a treatment option would likely result in a very modest increase in healthcare expenditure.

**PCN71: FINANCIAL CONSEQUENCES OF THE PERFORMANCE OF A PD-L1 TEST TO SELECT PATIENTS RECEIVING SECOND AND THIRD LINE TREATMENTS FOR NON-SMALL CELL LUNG CANCER IN ITALY**

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**OBJECTIVES:** the objective of the analysis is to assess the financial consequences of a therapeutic strategy aimed at selecting patients eligible to receive immune-oncological therapies to maximize clinical outcomes for the treatment of Non-Small Cell Lung Cancer (NSCLC) in Italy. **METHODS:** a budget impact analysis was performed implementing a therapeutic algorithm for the treatment of NSCLC, based on a previous analysis performed by Prof. Paz Ares, the ESMO 2016 guidelines and Italian real clinical practice. Two scenarios were implemented considering patients’ pathway from second to third line treatments: a base case scenario in which patients do not perform a PD-L1 test and a comparative scenario in which such test is performed. The second scenario is characterized by a selection of the patients for whom the clinical benefits of the administration of immune-oncological treatments would be maximized thanks to a PD-L1 test (on the base of clinical trials results). The costs considered were direct medical costs (referred to 2017) related to oncological treatments, treatments’ administration and PD-L1 test. **RESULTS:** the target population consists of 9,216 patients starting a second line treatment. The cost to treat the population considered in second and third line of treatment is estimated to be 137.1 million € in the base case scenario and 98.2 million € in the comparative scenario, with a – 38.9 million € impact on the budget of the Italian National Health Service. **CONCLUSIONS:** the selection of patients who might benefit more from an immune-oncological treatment through a selection with PD-L1 test, would lead to a decrease of the cost to treat second line NSCLC patients in Italy, with a decrease of almost 39 million € for the Italian National Health Service, as a consequence of an increase in the appropriateness of treatment.

**PCN72: PREDICTING THE FUTURE COSTS OF CANCER BASED ON REGISTER DATA AND INNOVATION TRENDS**

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**OBJECTIVES:** the rising financial burden of cancer on health-care systems worldwide has led to the increased demand for evidence-based research on which to base planning and budget decisions. Models are well fit to predict future incidence and prevalence of cancer and health care costs in order to aid health care managers in allocating resources. Based on real world register data, statistical predictions and clinical expertise we develop a prediction model for future costs of cancer in the period from 2017 to 2034. **METHODS:** The health predictions is based on NORCAN (Cancer Registry of Norwegian). The treatment predictions are based on cancer stage, first/second/third/fourth line treatment, drug costs and administration costs. Health care utilization, productivity losses are based on register data while QALY gains were taken from the scientific literature. We decompose the key cost drivers and predict their future development. We use clinical experts to predict the consequences of innovations and how the future care delivery will take place. **RESULTS:** The cancer related costs of the health care, except nursing and care services are estimated at NOK 15 billion in 2014 (US$1.00=NOK8.50). Here, specialist health care comprised nearly 90 percent of the total costs. The costs of anti-cancer drugs were NOK 1,7 billion, with an annual growth of 26 percent (real price adjusted). Total societal costs (excluding value of lost life years) were estimated to NOK 40 billion. The value of life years lost were estimated to nearly NOK 100 billion. The prediction model will predict the future cost development for the key components. **CONCLUSIONS:** Use of register data and prediction model can assist policy makers in preparing for future cancer challenges and more efficient cancer care.

**PCN73: HEALTHCARE COSTS ASSOCIATED WITH CERVICAL CANCER, PRECANCEROUS LESIONS, AND GENITAL WARTS TREATMENT IN TAIWAN**

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**OBJECTIVES:** Although cervical cancer is the most prevalent cancer for women in Taiwan, its cost implications to the health system in Taiwan have yet to be thoroughly explored. From the perspective of the health payer, this study aims to investigate the healthcare costs associated with cervical cancer, precancerous lesions and genital warts (GW) treatment in Taiwan. **METHODS:** Three patient groups were identified as follows. First, a total of 15,511 new
cases of low-grade cervical intraepithelial neoplasia (CIN1) and 3,294 cases of high-grade CIN (CIN2/3) in 2012 were identified from the linked biopsy dataset and pap smear test dataset. Second, a total of 3,418 new cases of GW in 2012 were obtained from the National Health Insurance (NHI) claims database. Third, a total of 4,685 new cases of invasive cervical cancer (ICC) in 2008-2011 were identified from Taiwan cancer registry dataset. Inpatient and outpatient claims associated with treatment of the three patient groups covering 1 year after CIN1, CIN2/3 and GW diagnosis, and 5 years after ICC diagnosis, respectively, were retrieved from the NHI claims database. Per-patient-per-year measurement was used in combination with the bootstrapping method to take into account the issues of skewedness and censoredness at death when estimating the healthcare costs. RESULTS: The average total costs were NT$2,961.81 for CIN1 and NT$11,244.56 for CIN2/3. The average total costs for the first through the fifth year after ICC diagnosis were NT$375,226.84, NT$81,088.77, NT$353,021.78, NT$38,878.88, and NT$28,160.51, respectively. The average total costs for GW patients were NT$8,677.02. CONCLUSIONS: Healthcare costs associated with treatment of cervical cancer and precancerous lesions resulted in considerable costs to the healthcare system in Taiwan.

PCN74: THE ECONOMIC IMPACT OF SWITCHING TO HERCEPTIN (TRASTUZUMAB) BIOSIMILAR FOR THE TREATMENT OF METASTATIC BREAST CANCER FROM A UK PAYER PERSPECTIVE

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OBJECTIVES: Herceptin (trastuzumab) is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) as a monotherapy for the treatment of those patients who have received at least two chemotherapy regimens for their metastatic disease. Currently, there are four Herceptin biosimilars under review by the EMA. The aim of the study was to evaluate the economic impact of switching to the Herceptin biosimilar product in patients with MBC from a UK payer perspective. METHODS: A one-year budget impact model was created in Microsoft Excel to calculate the number of patients in the UK who can receive the biosimilar for MBC. Incident and prevalent populations were both eligible to receive the biosimilar, with a 50% uptake among incident patients, and 25% uptake among prevalent patients. MBC incidence and prevalence rates, and population and treatment characteristics were taken from available literature. Only drug costs were included as the same efficacy and safety was assumed for trastuzumab and the biosimilar. Trastuzumab cost was obtained from the British National Formulary; a 20% discount was assumed with the biosimilar. Patients were assumed to be on treatment without breaks in the base-case scenario. RESULTS: Among the 25,809 patients estimated to be on treatment for MBC, 6,999 (25%) were predicted to receive the biosimilar, resulting in a cost reduction of £89,088,725 (5%). When additional patients who had stopped and restarted treatment with the biosimilar were also accounted for, similar savings were estimated. CONCLUSIONS: The results from this economic assessment suggest that the introduction of the biosimilar could lead to considerable savings in the UK. These findings should be evaluated in light of actual treatment and prescribing patterns, and patient preferences.

PCN75: PHARMACOECONOMIC ASPECTS OF VARIOUS STRATEGIES OF VESSEL SEALING AND REDUCTION OF POSTOPERATIVE COMPLICATIONS OF INGUINAL LYMPH NODES DISSECTION IN PATIENTS WITH GYNECOLOGIC CANCERS

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OBJECTIVES: Pharmacoeconomic evaluation of various strategies of vessel sealing for the prevention of postoperative complications of inguinal lymph nodes dissection (ILND) in Russian patients with gynecologic cancers. METHODS: A modeling of outcomes and costs of intraoperative application of TachoComb hemostatic sponge and standard technologies of final hemostasis was conducted based on clinical study by A. Buda et al. with consideration of the frequency of complications after ILND. TachoComb (as new strategy) and traditional methods of lympho- and hemostasis included into territorial programs of state guarantees (TPSG) were evaluated in groups of 100 patients. Public health care costs were determined; cost-effectiveness ratio (CER) and budget impact were analyzed. The study considered costs of in-patient treatment according to TPSG, and additional costs of TachoComb. The main measure of effectiveness was the share of patients without ILND complications (lymphocele, cellulitis, disruption and infections of postoperative wound, lymphedema). The frequency of complications of ILND corresponded with the study by A. Buda et al. The length of stay in hospital (LOS) in cases with complications was assessed by expert gynecologic oncologists. RESULTS: The LOS was 10 days in cases without complications, and 26 days with complications. Considering the frequency of complications, a hospital received from TPSG 4,500.58 RUB per patient daily in TachoComb group, and 2,979.25 RUB in the traditional care group. CER values were 50,766.49 to 55,180.96 in the TachoComb group, and 57,689.19 to 60,654.44 in the traditional care group (maximal value in lymphocele and minimal in wound infections). The sensitivity analysis considered the changes in costs of
vessel sealing depending on the frequency of lymphocele, which required drainage, and confirmed the benefit of TachoComb. CONCLUSIONS: The TachoComb definitely has advantages in respect of budget impact due to reduced LOS, better outcomes and cost-effectiveness ratio for the frequency of ILND complications.

**PCN76: COST-EFFECTIVENESS AND BUDGET IMPACT OF NEW THERAPIES FOR METASTATIC MELANOMA IN ITALY**

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**OBJECTIVES:** About 232,000 new cases of melanoma are diagnosed worldwide each year, according to the WHO. More recent research led to the development of new therapies for metastatic melanoma such as targeted therapy (inhibition of BRAF or MEK genes) and checkpoint inhibitor immunotherapy. Both therapies prolong progression-free and overall survival compared with chemotherapy. The aim of this research was to compare combined targeted therapy and checkpoint inhibitor immunotherapy cost-effectiveness, through cost-effectiveness analysis (CEA) and budget impact analysis (BIA) for the Italian context over a period of three years. **METHODS:** The cost-effectiveness analysis was conducted by adjustment of clinical efficacy results of Norwegian HTA Report on Metastatic Melanoma to Italian setting. We used the therapeutic strategy of one Italian region, Emilia-Romagna, to estimate BRAF + mutation in Italian population, while lifetime treatment costs were estimated from progression free survival of randomized clinical trial. The Italian budget impact regards both drug as treating adverse events costs over a three years period. **RESULTS:** Incremental cost-effectiveness ratio (ICER) resulted respectively 62707, 175879, 31137 and 20161 €/QALY for dabrafenib+ trametinib, vemurafenib + cobimetinib, nivolumab and pembrolizumab. The cost-effectiveness analysis showed that targeted therapy was not cost-effective, despite clinical efficacy was superior than checkpoint inhibitor immunotherapy. BIA showed that combined targeted therapy compared to checkpoint inhibitor immunotherapy requires nearly 200% additional resources for metastatic melanomas BRAF+ in all three years considered. The cost of treating adverse drug events (ADEs) does not significantly affect overall expenditure, but it resulted also significantly lower for patients receiving checkpoint inhibitor immunotherapy. **CONCLUSIONS:** Recent therapies for metastatic melanoma improve clinical outcomes but have a significant impact on health systems’ budgets. Economic evaluations may help decision-maker to understand the value of new therapies of metastatic melanoma and to allocate health systems’ budgets maximizing the clinical value.

**PCN77: PUBLICATION TIMING AND DATA UTILISATION IN COST-EFFECTIVENESS ANALYSES IN NON-SMALL CELL LUNG CANCER – A LITERATURE ANALYSIS ON PUBLICATION TIMING**

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**OBJECTIVES:** Peer-reviewed cost-effectiveness analysis (CEA) publications provide vital information for health economic value-based decisions, therefore timely publication of CEA is essential. A literature analysis of CEA publications in non-small cell lung cancer (NSCLC) treatment in North America (NA) and Europe (EU) was performed to assess the timing of CEA publication date (CDP), relative to drug approval date (DD) and clinical/real-world data (for CEA model input) publication date (CRD). **METHODS:** An EMBASE literature analysis from January 2005-March 2017 was conducted with the following key criteria: "original articles", "English", "human", "non-small cell lung cancer", "cost-effectiveness analyses". Information extracted from the eligible publications included: CDP, CRD, country, drug, and type of economic evaluation. DDs were retrieved from regulatory bodies’ websites and news reports. To determine publication timing CDP – CRD and CDP – DD were calculated, and descriptive statistics used to evaluate the timings. **RESULTS:** Fifty-two eligible publications were identified: 22 from NA (Canada: 18%, America: 68.2%) and 30 from EU, which consisted of publications from 7 countries, with France having the most (36.7%) publications. Across all publications, mean CDP – DD delay was 3.75 years (NA: 3.7 years, EU: 3.8 years) and mean CDP – CRD delay was 2.1 years (NA and EU: 2.1 years), and only 25% used real-world data. Most common types of economic evaluations were cost-utility analysis (44.2%), CEA (11%), direct cost (13.5%), and budget impact model (7.7%). Fourteen of the 24 NSCLC treatment drugs had at least 1 CEA publication; erlotinib had the most (48%) publications. **CONCLUSIONS:** As peer-reviewed CEA publications are slow in timing, have an incomplete coverage of drugs, and limited coverage of EU countries, publication timing and availability could be improved to support a faster and better informed appraisal for NSCLC medication. Furthermore, CEA publications could benefit from using more (local) real-world data as input for CEA models.

**PCN78: AN ECONOMIC EVALUATION MODEL FOR FOLLICULAR LYMPHOMA (FL): PREDICTING TREATMENT COST, LIFE EXPECTANCY AND QUALITY-ADJUSTED LIFE YEAR OF DIFFERENT SCENARIOS USING UK POPULATION BASED OBSERVATIONAL DATA**

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OBJECTIVES: Follicular lymphoma (FL) is the commonest indolent lymphoma, with ~1,860 new cases diagnosed each year in the UK. Clinical management ranges from immediate treatment with chemotherapy and/or radiotherapy, to observation ("watch-and-wait"); initiating treatment if/when symptoms develop. Previous studies have focussed on clinical trial data for specific drugs, meaning that their findings cannot be extrapolated to the general patient-population. Based on a population-based patient-cohort, the objective of this study was to develop a generic and flexible decision model to reflect real-world practice and predict cost, survival and quality-adjusted life years (QALY) for different scenarios. METHODS: Patients newly diagnosed 2004-11 with FL in the UK’s population-based Haematological Malignancy Research Network (www.hmrn.org) were followed until 2015 (n=740). Mapped treatment pathways, QALYs, and cost information, were incorporated into a discrete event simulation that reflected patient heterogeneity, including age and treatment options. Two scenarios based on latest NICE guidelines (www.nice.org.uk/guidance/ng52 and TA226) were conducted. RESULTS: The annual cost of treating FL across the UK was around ~£55 million. The predicted mean cost and QALY per patient from diagnosis to death were £24,872 and 9.72 for those treated with curative intent (69%), £5,296 and 8.21 for those managed by “watch-and-wait” throughout (29%), and £6,165 and 0.1 for those who only received palliative care (2%). Scenario analyses demonstrated that the cost of introducing frontline and maintenance rituximab to all patients would be ~£5.7 and £6.7 million/year respectively, but the potential saving based on the improved outcomes could be in the region of £6-10 million (induction) and £14-18 million (maintenance) a year. CONCLUSIONS: This is the first modelling study to use ‘real-world’ evidence to predict costs of entire FL treatment pathways and permit scenario analyses at any part of the pathway. Future application of the model could support healthcare policy-making and the introduction of new drugs such as biosimilars.

PCN79: THE COST STUDY OF CETUXIMAB AND PANITUMUMAB IN THE FIRST-LINE TREATMENT OF MCRC IN THE CZECH REPUBLIC

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OBJECTIVES: The EGFR antibodies cetuximab and panitumumab are reimbursed in the Czech Republic in combination with chemotherapy or alone for the treatment of WT RAS patients with metastatic colorectal cancer (mCRC). However, the high cost is a potentially limiting factor. The aim of this analysis was comparison of costs in treatment with cetuximab or panitumumab in the first-line treatment of mCRC. METHODS: The costs and effectiveness of cetuximab and panitumumab in the real clinical practice were retrospectively evaluated in the National comprehensive cancer center from the perspective of healthcare payer. Cost data (examination, medication, hospitalization) were collected since the initiation of cetuximab/panitumumab treatment to any tumour response (RECIST criteria) and/or to death. Mean follow-up was 21 and 17 months for all patients treated with cetuximab and panitumumab respectively. Costs were converted to EUR (€1= CZK 26.23). RESULTS: In total 22 (73%men, mean age 60) and 29 (66%mnen, mean age 58) WT KRAS patients with mCRC were treated with cetuximab and panitumumab respectively. Costs were converted to EUR (€1= CZK 26.23). RESULTS: In total 22 (73%men, mean age 60) and 29 (66%mnen, mean age 58) WT KRAS patients with mCRC were treated with cetuximab and panitumumab respectively. Costs were converted to EUR (€1= CZK 26.23). RESULTS: In total 22 (73%men, mean age 60) and 29 (66%mnen, mean age 58) WT KRAS patients with mCRC were treated with cetuximab and panitumumab respectively. The costs and effectiveness of cetuximab and panitumumab in the first-line treatment between 11/2011 and 07/2016. The treatment was mostly discontinued in both evaluated groups due to PD (cetuximab 59.1%; panitumumab 55.2%). The mean costs per progression-free survival (median 10.7 and 8.1 months) were EUR 36,762.7 and EUR 38,247.4 (CZK 964,286.80 and CZK 1,003,229.13) for cetuximab and panitumumab respectively. During our follow-up period 55% patients died in cetuximab group; 41% patients in panitumumab group. The median overall survival was 17.3 and 12.1 months and the mean costs since initiation of treatment to death were EUR 48,978.7 and EUR 48,977.7 (CZK 1,284,712.1 and CZK 1,284,685.1) per patient treated with cetuximab and panitumumab respectively. CONCLUSIONS: The reimbursement of EGFR antibodies were the main cost driver observed in both evaluated groups. Drugs made up more than 71% (cetuximab) and 77% (panitumumab) of total costs to PD.

PCN80: IDENTIFICATION OF GENERIC CANCER MEDICINES THAT HAVE UNDERGONE MOMENTOUS PRICE RISES IN THE NHS IN ENGLAND

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OBJECTIVES: Over the last 40 years, the rising trend in cheaper generic medicines has enabled the national health service (NHS) to save billions of pounds which have been used to fund new and innovative medicines. However, recent incidents suggest new practices in the pricing of generic medicines may be underway, as evidenced by the recent opening of a formal investigation by the European Commission (May 2017) against a pharmaceutical company regarding alleged cases of unfair and significant price increases for generic cancer medicines. We seek to understand if similar pricing practices are taking place widely in generic cancer medicines and in other areas of high demand such as anti-hypertensives, statins and antacids. METHODS: Medicines of interest were categorised as generic cancer medicines and associated supportive care medicines. Price and formulation data was obtained from
the British National Formulary (BNF). The timeframe of interest was from September 2010 to May 2017. Longitudinal price changes were compared and trends were identified for the different categories of medicines. RESULTS: Substantial price rises were seen in a number of generic cancer medicines, with some prices increasing between 100% and 1,314% between 2010 and 2017. The highest price increase observed was that of busulfan for the treatment of leukaemia, which rose from 21p per 2mg tablet in 2010 to £2.76 in 2017. CONCLUSIONS: Although substantial price rises were seen in a small group of cancer medicines, a similar pattern was not seen across all cancer medicines or treatment categories analysed. Our research suggests that there may exit small monopolistic situations within the generic market in England.

PCN81: COST COMPARISON OF TREATMENT CHOICES FOR ADVANCED NON-SMALL CELL LUNG CANCER: AN OBSERVATIONAL STUDY

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**OBJECTIVES:** Pharmacotherapy has improved survival for non-small cell lung cancer (NSCLC) but is limited by financial burden in resource poor settings. National list of essential medicines (NLEM) and drug price control in India intend to reduce this burden. This study was planned to compare costs among advanced NSCLC patients who get essential vs non-essential medicines. **METHODS:** Patients diagnosed with advanced NSCLC from July 2016 to January 2017 were enrolled in this prospective, observational study. Data on demography, quality of life and estimate of treatment related costs (direct and indirect) was collected. Group A patients received essential medicines (NLEM) and group B received medicines outside NLEM. Indian costs were converted to USD (per patient per month) and data is expressed as mean±SD/ median (range). **RESULTS:** Forty advanced NSCLC patients (age 55.4±10.5 years; 33% females; 38% nonsmokers; 25% local residents) were enrolled. Median treatment duration was 2.75 (0.33–14) months in group A (n=16) and 6.5 (0.5–72) months in group B (n=24). Average cost incurred was 750.1 (235–5304) in group A and 541.1 (40–4258) in group B. Cost of medicines was 55.6 (0.5–2731) and 87.2 (3.6–2517) respectively. Cost of hospitalization did not differ significantly but cost of investigations was 103.3 (0–1175) and 69.1 (6.1–1468) respectively. Indirect costs were 398.9 (54.3–2564) and 234.3 (5.1–1777) respectively. Among these, transportation for outstation patients and work loss for young accounted for major expenditure. **CONCLUSIONS:** There has been a great emphasis on affordability of anticancer medicines in India. However, medicines accounted for only 1/5th costs in our study. Medical investigations and/or indirect costs substantially add to the overall financial burden. Additional measures such as judicious use of investigations and optimizing outpatient treatment are required to ensure treatment access in the absence of widespread medical insurance.

PCN82: VARIATION TREND OF ANNUAL MEDICAL COST FOR SEVERAL KINDS OF MALIGNANT TUMORS IN CHINA: ANALYSIS BASED ON A REGIONAL PUBLIC HEALTH INSURANCE CLAIM DATABASE (2011-2015)

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**OBJECTIVES:** To demonstrate the variation trend of annual medical cost for several kinds of malignant tumors in China based on a regional public health insurance claim database from 2011 to 2015. **METHODS:** Records of all diagnosed patients for 7 kinds of malignant tumors (gastric malignant tumor, intestinal malignant tumor, pulmonary malignant tumor, nasopharyngeal malignant tumor, renal malignant tumor, breast malignant tumor, and leukemia) in claim database were got. Annual medial cost of 1-5 year after diagnosis was calculated. The cost of 1st year after diagnosis was taken as baseline for comparison. Due to small time span in this study, no discounting for cost was performed. **RESULTS:** Totally 33,667 malignant tumor patients were got in claim database. For all kinds of malignant tumors, the cost of 1st year after diagnosis was significantly higher than cost of consequent years. The variation trends were different among different kinds of malignant tumors. For intestinal malignant tumor and leukemia, the cost decreased rapidly after diagnosis and at 5th year the cost was close to 20% of cost of 1st year after diagnosis. For gastric malignant tumor, pulmonary malignant tumor, nasopharyngeal malignant tumor, and breast malignant tumor, the cost decrease relatively slowly and at 5th year the cost was close to 40-50% of 1st year after diagnosis. Finally, renal malignant tumor was different with others with cost slowly decreasing to 60% of cost of 1st year after diagnosis and at 5th year the cost bounced. **CONCLUSIONS:** The annual medical cost of malignant tumors after diagnosis would not be constant and there were different variation types for different kinds of malignant tumors.

PCN83: COST OF NIVOLUMAB IN COMBINATION WITH IPVILIMUMAB AS FIRST LINE TREATMENT IN ADVANCED MELANOMA ACROSS VARIOUS EUROPEAN MARKETS

OBJECTIVES: Advanced melanoma is an aggressive disease accounting for 90% of skin cancer-related deaths. The aim of this study was to compare costs associated with nivolumab plus ipilimumab combination regimen (N+I), N monotherapy and I monotherapy. METHODS: Individual patient-level trial data for healthcare resource utilisation (HCRU) of European patients enrolled in the CheckMate 067 trial were used to derive costs associated with treatment with N+I, N, and I. Unit costs for each country were applied to the HCRU data for the first year of the trial and aggregated to determine the cost for each patient. The model developed by authors counted cost of: core regimen dosage and administration; concomitant medication; subsequent melanoma treatments; diagnostic and procedures; laboratory tests, hospitalisations and surgeries. The average cost per patient per month was calculated using the trial population censored at each month. RESULTS: After 1-year of follow-up the total treatment costs for each regimen for the average patient enrolled in the CheckMate 067 trial for the N+I, N, and I arms were: €101,419, €109,496 and €124,901 in Portugal; €91,492, €72,807 and €91,283 in Greece; €121,949, €100,836 and €126,670 in Spain; and NOK1,187,223, NOK978,723 and NOK1,244,794 in Norway. Though N+I treatment resulted in higher drug costs, it also resulted in savings in subsequent melanoma treatment and reduced costs in surgeries. Furthermore, patients in the N arm had higher administration and lab costs. Drug costs contribute most to the total costs (N+I 68-84%; N 39-63%; I 42-62%) followed by subsequent treatment (N+I 5-8%; N 24-33%; I 26-39%), lab and hospitalisation costs (N+I 6-18%; N 4-15%; I 5-16%). Data from 28 months of follow-up in CheckMate 067 will be presented to provide additional information. CONCLUSIONS: The higher initial investment for first line treatment with N+I compared to monotherapies is partially compensated by a lower subsequent therapies cost.

PCN84: COST IMPACT OF PROTOCOL COMPLIANCE FOR CANCER TREATMENT PLANS IN THE PRIVATE HEALTHCARE ENVIRONMENT

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OBJECTIVES: The Independent Clinical Oncology Network (ICON) is a provider-driven clinical care solution in South Africa managed by ISIMO Health. ICON’s EBM protocols and formularies are driven by clinical outcomes. The aim of the study was to assess the clinical and cost impact of this solution in a third-party funder environment. METHODS: A retrospective analysis of cancer treatment plan requests to third-party funders over a period of 24 months was conducted. The data (n1=41515) was extracted from an authorisation request system, eAuth®, where submissions to network funders are governed by a requirement to adhere to treatment protocols. The control group (n2=40258) was under no protocol restriction yet seen by almost the same group of providers. Clinical factors that have an impact on cost of treatment was identified and used to account for case-mix. These factors included: diagnosis, age, treatment phase (metastatic and non-metastatic) and treatment duration. Case-mix was accounted for by extrapolating the data of both cohorts to be equal in size within the risk cells (random sampling with replacement). A risk cell was grouped by: diagnosis, age, treatment phase and duration. Quality metrics constructed by clinicians was used to measure whether care was denied to promote cost savings. RESULTS: The cost of treatment under protocolisation is significantly less (95% CI = (24%;29%), p<0.0001, Student’s t-test). The validity of the results was confirmed by performing the analysis on a previous year’s data (n1=36844, n2=37438, p<0.0001, 95% CI = (24%;28%)). A sensitivity analysis was performed using the minimum cost (95% CI = (25%;30%)) to extrapolate the data as well as using the maximum cost (95% CI = (25%;31%)). The 15 measured quality metrics showed no denial of care. CONCLUSIONS: The ICON solution results in similar or better clinical outcome but with putative reduction in cost.

PCN85: TRABECTEDIN VERSUS PAZOPANIB WITHIN THE TREATMENT OF ADVANCED, METASTATIC, LEIOMYOSARCOMAS IN SCOTLAND: RESULTS OF A COST-EFFECTIVENESS ANALYSIS FOLLOWING A MATCHING ADJUSTED INDIRECT COMPARISON

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OBJECTIVES: To perform an incremental cost-effectiveness analysis (ICER) on the treatment of advanced, metastatic leiomyosarcomas –one of the most common STS subtypes- comparing two licensed drugs in Scotland: trabectedin and pazopanib; assessed from the Scottish Medicines Consortia’s (SMC) perspective. METHODS: Clinical efficacy data were sourced from two independent randomized, phase III trials: ET743-SAR-30071 (individual patient level data) and PALETTE2 (aggregated data). Following a MAIC3; adjusted survival Hazard Ratios (HRs) were derived and plugged into a standard partitioned survival model containing three health states: stable disease, progressive disease, and death; in line with other oncology treatments submissions to the SMC. Medical resource costs –treatment administration, diagnostics, referrals, treatment related adverse effects-
PCN86: SOCIETAL COSTS OF ER+/HER2- ADVANCED OR METASTATIC BREAST CANCER IN POST-MENOPAUSAL WOMEN IN THE UNITED KINGDOM

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OBJECTIVES: To estimate indirect and societal costs for post-menopausal women with HR+/HER2- metastatic breast cancer (mBC) in the United Kingdom (UK), and how disease progression impacts these costs. METHODS: We systematically identified studies that assessed the impact of mBC on activities of daily living and lost productivity (ADL/LP). Key ADL/LP categories identified were early mortality, productivity loss, replacement housework, childcare, informal care, lost leisure time, and transportation. UK-specific data were preferred, with data sought from other countries where not available. Costs were estimated in GBP, per woman, per month, for two ‘health states’: stable and progressed disease. RESULTS: Of 35 identified studies, three were conducted in the UK and one pan-European. Due to the paucity of UK data, ADL/LP data from other OECD countries were also used. Indirect costs for women with stable HR+/HER2- mBC were calculated at £2,179 per month. Indirect costs in the progressed HR+/HER2- mBC state were calculated as £2,597 (Scenario A) or £2,990 (Scenario B) per month. These scenarios assumed either: (A) ADL/LP was the same in the progressed state and the stable state, if state-specific ADL/LP was not reported; or (B) women in the progressed state suffered a higher ADL/LP impact than in stable disease (by a factor derived from literature and expert opinion). Total indirect costs from metastatic diagnosis to death were £59,819 (Scenario A) or £66,352 (Scenario B) per woman. CONCLUSIONS: We estimated that stable disease incurs £418 to £811 less indirect cost per woman per month than progressed disease. To our knowledge, no previous study estimates the progression-related indirect and societal costs of HR+/HER2- mBC in the UK. There is a lack of data regarding the impact of mBC on ADL/LP; more sophisticated data collection is needed to better characterise the financial burden of HR+/HER2- mBC for policy makers, patients and carers.

PCN87: COST BURDEN ASSOCIATED WITH ADVANCED NON-SMALL CELL LUNG CANCER (A-NSCLC): IMPACT OF DISEASE STAGE

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OBJECTIVES: To quantify the financial burden of A-NSCLC from a patient and caregiver perspective and to evaluate the impact of disease stage on costs. METHODS: Financial data were collected between May 2015 and June 2016 as part of a multinational (France, Germany and Italy), cross-sectional study of adult patients with A-NSCLC (Stage IIIb/IV) and their informal caregivers. Data were obtained via medical chart reviews and patient and caregiver self-completion forms and included, but were not limited to: wage/productivity losses, formal/informal care requirements, government financial support and out-of-pocket expenses. Statistical significance was assessed using Mann–Whitney U tests. RESULTS: In total, 1030 patients and 427 accompanying informal caregivers were recruited. The majority of patients were receiving first-line therapy (70.5%); patients were largely receiving chemotherapy, regardless of line of therapy. Mean annual wage losses, productivity losses, unadjusted out-of-pocket costs and out-of-pocket costs adjusted for government financial support were £2076.86, £8743.73, £3774.33 and £822.66 (patients); and £436.47, £7041.79, £1755.59 and £1019.31 (caregivers). Mean annual societal costs for A-NSCLC were £12,588.64 (patients) and £7786.39 (caregivers). Mean annual wage losses, productivity losses, unadjusted out-of-pocket costs and out-of-pocket costs adjusted for government financial support were higher for Stage IV versus Stage IIIB disease for patients (£2281.84 vs £499.44; P=0.0135; £8791.00 vs £8436.62; P=NS; £4019.95 vs £1545.51; P=0.0306; £848.71 vs £583.73; P=NS) with a similar but non-significant trend for caregivers (£473.28 vs £60.00; £7180.15 vs £4482.07; £1895.81 vs £493.71; £1055.42 vs £414.40). Mean annual societal costs for A-NSCLC were higher for Stage IV
disease for patients (€12,654.32 vs €11,918.75) and caregivers (€6015.91 vs €5261.57). **CONCLUSIONS:** A-NSCLC is associated with a substantial financial burden for patients, caregivers and society. In this analysis, mean annual societal costs for a patient with A-NSCLC and their accompanying caregiver support exceeded €20,000. Furthermore, the findings indicate that costs related to NSCLC increase as the disease progresses.

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**PCN88: BURDEN OF HEALTHCARE COSTS FOR MERKEL CELL CARCINOMA MANAGEMENT IN SPAIN**

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**OBJECTIVES:** Scarce published evidence is available about cost related to Merkel Cell Carcinoma (MCC) case management. This study aimed to assess the direct healthcare cost related to management of MCC patients, in Spain. **METHODS:** A cost-estimation analysis from the National Health System perspective was developed by identification of the detailed healthcare-resource consumption required for clinical management of MCC patients at 3 different disease stages (local, locoregional and metastatic disease) through a literature review and a Delphi panel. Diagnosis costs at each stage were calculated as one-off cost. Management at local and locoregional stages were split in 3 time periods (1st-2nd year, 3rd-4th year and 5th year onwards) and expressed as average annual cost. Metastatic MCC case-management was estimated assuming an average survival of 10 months. The cost estimation (€, 2017) included health-professional visits, laboratory test or diagnostic procedures, interventions or surgeries, hospitalisations, radiotherapy and current chemotherapy pattern (85%: platinum-based schemes, 8%: weekly paclitaxel, 4%: capecitabine-temozolomide; 4%: cyclophosphamide-doxorubicina-vincristine). Resource-use data were provided by local dermatologists and oncologists, members of an expert panel. Unitary costs for healthcare resources were obtained from local databases. **RESULTS:** Cost of disease diagnosis accounted for €8988.38, €1,760.86 and €707.19 for local, locoregional and metastatic disease respectively. The annual cost per patient varied from €5,409.05 in 1st-2nd year, €822.72 during 3rd-4th year and €219.56 for 5th year onwards, related to local MCC management. Locoregional cases resulted €9,360.23, €1,888.14 and €293.56, per patient and year respectively. Average cost for a metastatic MCC patient accounted €8,035.68 directly related to disease, plus the cost associated to first-line chemotherapy (€2,094.07 per average patient). **CONCLUSIONS:** Metastatic MCC resulted the most costly disease stage. Estimation of MCC management costs at different disease-stages could help medical decision-makers for better allocation of the available resources in Spain.

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**PCN89: ESTIMATION OF THE COST OF METASTATIC MELANOMA IN FRANCE USING MELBASE DATA**

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**OBJECTIVES:** The management of metastatic melanoma (MM) patients has known huge advances since 6 years, with seven innovative and expensive drugs being now available. In France, the economic burden of MM was estimated at 1653 € per patient in 2004 (Chevalier and al), with treatment representing 17% of the total cost. The therapeutic revolution points out how important reassessing the cost of management is. The objective of the present study is to estimate the cost of management of MM in France. **METHODS:** Costs were estimated through MelBase cohort, which is a prospective French multicentric clinical and biological cohort dedicated to the follow-up of adults with MM. Costs were assessed from the French national health insurance perspective. Resources use were prospectively collected since the inclusion of the patient until their last follow-up in MelBase, including cost of treatments, hospitalizations, specialists visits, imaging procedures, biological exams and radiotherapy. Valuation was done using national tariffs. **RESULTS:** Costs estimations were based on 483 patients included between March 2013 and December 2016. The median follow-up is 11 months with 250 (52%) patients dead. Mean age was 65 years old. In first line, 213 (44%) patients were treated by immunotherapy (nivolumab or pembrolizumab), 203 (42%) by BRAF inhibitors (vemurafenib, dabrafenib, trametinib, cobimetinib), 48 (10%) by chemotherapy and 19 (4%) were included in a clinical trial. The mean total cost per patient treated for MM was evaluated at 107,846€ [CI95%: 8,889;323,771] with 91,613€ [CI95%: 813,309,086] for the treatments, 12,676€ [CI95%: 586,40,034] for the hospitalizations, 1,599€
visceral melanoma is associated with significantly higher costs. The largest driver of this difference was outpatient costs ($2,631 vs. $1,005€) for the radiotherapy, $48.64/day, at the 50th quantile $5.69/day and at the 75th quantile $7.23/day. For diabetic NSCLC patients, the predicted mean value at the 25th quantile was $2.36/day.

**CONCLUSIONS:** Since 2004, the management cost of patient with MM was multiplied by 65, mainly driven by the evolution of the treatment costs.

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**PCN90: ASSESSING THE HEALTHCARE COST OF DIABETIC NON-SMALL CELL LUNG CANCER PATIENTS COMPARED TO NON-SMALL CELL LUNG CANCER PATIENTS**

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**OBJECTIVES:** Cancer is the second leading cause of death worldwide. Mechanisms involved in the relationship between type 2 Diabetes (T2D) and cancer is not completely understood, and even less is known about its association with Non-Small Cell Lung Cancer (NSCLC). While these systemic responses are reasonably well understood, an adequate explanation how health care utilization is impacted for patients with both T2D and NSCLC is lacking. Our objective was to investigate the cost of care for T2D patients with NSCLC. **METHODS:** We conducted a cohort study design utilizing Medicare claims from the SEER-Medicare linked database (2007 - 2014). Quantile regression was used to estimate the predicted mean at the 25th, 50th and 75th percentile for total healthcare costs after incident NSCLC diagnosis. The quantile regression was adjusted for cancer stage, geographical region, gender, age, race and comorbidities. Total healthcare costs were then divided by the number of days within the 25th, 50th and 75th quantiles to adjust for varying follow up. Cost data represented the actual paid (reimbursed by Medicare) amounts for health services. x

**RESULTS:** Of 17,176 NSCLC patients, 5,096 patients had T2D in the pre-period. For NSCLC patients, the predicted mean value at the 25th quantile was $2.36/day, at the 50th quantile $5.69/day and at the 75th quantile $7.23/day. For diabetic NSCLC patients, the predicted mean value at the 25th quantile was $4.13/day, at the 50th quantile $9.16/day and at the 75th quantile $48.64/day.

**CONCLUSIONS:** This study demonstrates the challenges in analyzing cost data due to variations in factors impacting healthcare costs. Care should be taken when developing interventions directing resources at those most likely to benefit as traditional regression analysis may be less useful than methods such as quantile regression, which provide robust insights into healthcare cost of specific patient sub-groups.

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**PCN91: COSTS ASSOCIATED WITH DISEASE PROGRESSION IN ADVANCED MELANOMA - A CLAIMS ANALYSIS USING A NOVEL STAGING ALGORITHM**

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**OBJECTIVES:** To estimate the real-world costs associated with disease progression among patients with advanced melanoma. **METHODS:** Patients with advanced melanoma that progressed from non-visceral (stage IIIA/B/C and IVM1a) to visceral (stage IVM1b and IVM1c) disease were identified using a novel clinical algorithm based on secondary neoplasm diagnoses, melanoma treatments, and elevated lactic dehydrogenase level in three US claims databases (2009-2015). Each progressed patient was matched with a patient whose disease remained non-visceral (non-progressed) based on age and gender. Each non-progressed patient's observed period was divided into quasi pre- and post-"progression" periods, such that the pre-"progression" duration matched that of the corresponding progressed patient. Differences between pre- and post-progression per-patient-per-month all-cause direct healthcare costs were reported in 2015 US dollars and compared using Wilcoxon signed-rank test and generalized estimating equations, adjusting for first observed non-visceral stage, comorbidities, and region of residence. **RESULTS:** The analyses included 2,126 patients (1,063 per cohort). Mean age was 58 years and 65% were male. On average, patients had 9 months of observed pre-progression period. Compared to non-progressed patients, a larger proportion of progressed patients were initially diagnosed with stage IVM1a instead of stage III (35% vs. 13%; p<0.001). Progressed patients also had more comorbidities, with significantly higher rates of mild liver disease (11% vs. 4%; p<0.001), cerebrovascular disease (6% vs. 3%; p=0.01), and myocardial infarction (2% vs. 1%; p=0.041) during the 6 months before progression. From the pre- to the post-progression period, progressed patients saw an average increase in costs ($5,467) compared to a decrease for non-progressed patients (-$3,260), with a difference in difference of $8,727 (p<0.001), which decreased to $8,627 (p<0.001) after adjusting for patient characteristics. The largest driver of this difference was outpatient costs ($2,631 vs. $2,233; p<0.001).

**CONCLUSIONS:** Progression to visceral melanoma is associated with significantly higher costs.
PCN92: REAL LIFE COST OF TREATMENT AND FOLLOW-UP IN PANCREATIC ADENOCARCINOMA PATIENTS TREATED AT THE ANTWERP UNIVERSITY HOSPITAL (UZA), BELGIUM

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OBJECTIVES: To assess the costs associated with the management of patients with pancreatic adenocarcinoma from diagnosis until death. METHODS: Charts of all patients with histologically confirmed pancreatic adenocarcinoma diagnosis between 2007 and 2016 at UZA were retrospectively reviewed. Eligible for this analysis were patients who deceased prior to March 2017 and for whom complete information on resource use is available at UZA. Resource use (hospitalization, tests, treatment, drugs) was collected per patient from pancreatic adenocarcinoma diagnosis till death. Costs were calculated using 2017 unit costs defined by the National Institute for Health and Disability Insurance (NIHDI). Average (95% bootstrap confidence interval [CI]) costs per patient were calculated from both a public payer’s and patient’s perspective. RESULTS: 75 patients (43 male, 32 female) fulfilled all eligibility criteria. Median age was years 69 (range 38-87). Stage at diagnosis: IA: 1 (1%); IIA: 3 (4%); IIB: 16 (21%); III: 9 (12%); IV: 41 (55%); unknown: 5 (7%). Median overall survival is 6.8 months (95% CI 4.7-8.9). The average survival time is 10 months (95% CI 7.1-12.9). All patients have been hospitalized at least once. The average number of hospitalizations was 3.6 times and the average length of stay was 14 days (SD: 18). The average overall cost of treatment and follow-up per patient is €57,054 (95% CI 48,228-66,406), of which €55,054 (95% CI 46,477-64,109 ) was covered by NIHDI. Costs are driven by hospitalization costs (66% of total costs). Patients diagnosed with stage IV disease had an average overall cost of € 49,636 (95% CI: 38,402-62,405). CONCLUSIONS: The management of pancreatic adenocarcinoma is associated with considerable costs for both NIHDI and patient.

PCN93: BURDEN OF HOSPITALIZATIONS RELATED TO SPINAL TUMORS IN FRANCE: EVOLUTION BETWEEN 2012 AND 2014

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OBJECTIVES: Burden of hospitalizations related to spinal tumors was estimated in 2012-2013 through data from the PMSI. The objective was to reassess this burden through the PMSI 2014-2015. METHODS: All hospital stays with spinal tumors were extracted from the PMSI-MCO 2012 and 2014 database (French Medical Information System Program- Medicine, Surgery, Obstetric), using ICD-10 codes as principal/related or significantly associated diagnosis (PD/RD/SAD) for primary and secondary spine tumors. Patients were followed during one year from their first stay (e.g. March 2012/March 2013; October 2014/October 2015). An algorithm and a medical review excluded non spinal tumor related stays. Associated costs during the period were added up: a total annual cost ("burden") as well as a mean annual cost per patient were estimated. Valuation was performed considering French official tariffs for 2012 to 2015 and expressed in 2017 Euro. RESULTS: In 2014, 10,029 stays were extracted and considered as directly related to spinal tumors corresponding to 3,445 patients (9,415 stays and 3,284 patients in 2012). Mean age slightly increased between 2012 and 2014 (65.7±19.1 vs 66.4±19.5 years old), as well as the proportion of men (45% vs 47%). Around 95% of stays occurred in public hospitals and 56% were ambulatory. Median LOS associated with full hospitalizations was 7 days (Q1 3-Q3 15). Chemotherapy and radiotherapy accounted for 23%, 34% of stays, respectively. Overall, the economic annual burden of hospitalizations for the treatment of spinal tumors reached €28.5 million in 2014-2015 (10% increase over 2012-2013); expensive drugs and implants funded in addition to hospital stays accounted for almost 6%. Similarly, the median annual cost corresponded to €6,566 (Q1 €3,522 – Q3 €9,681) per patient (+14% vs 2012-2013). CONCLUSIONS: The population of patients hospitalized for spinal tumors slightly increased (+5% of patients and +7% of stays), as did hospital-related costs. New spinal tumors treatment modalities could reverse this trend.

PCN94: THE ECONOMIC BURDEN OF BREAST CANCER IN RUSSIA

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OBJECTIVES: To estimate the annual costs of breast cancer (BC) in Russia. METHODS: We estimated annual direct medical costs (for diagnostics, treatment, follow-up and palliative care), direct non-medical costs (sick leave payments and disability pensions) and productivity losses attributable to BC from the perspective of Russian government in 2014. Calculations were done for the total population of patients, including both newly diagnosed patients stratified by cancer stage and patients diagnosed in previous years, still alive in the study year. The data for calculations were derived from national statistics, regional cancer and prescription registries, experts’ survey and published research. The cost of medical services was assessed using public health insurance rates. Value of
increasing awareness, early diagnosis, access to treatment. Cancer is an important economic burden for our country. National policy is needed for prevention of disease, increasing awareness, early diagnosis, access to treatment.

**PCN96: ECONOMIC BURDEN OF GASTRIC CANCER IN TURKEY**

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**OBJECTIVES:** The aim of this study is to investigate the economic burden of gastric cancer in Turkey by evaluating it in terms of direct and indirect costs. **METHODS:** Cost of illness methodology was used. After the annual direct and indirect costs per patient were determined, the total cost based on prevalence was found. For the direct costs, the patient's consultation to the hospital during the year, laboratory and imaging tests conducted during consultation, hospitalization and medical interventions, drugs, and side effects were evaluated. Indirect costs were calculated on three parameters as premature death, labor loss, early retirement, and transportation costs to the hospital. In addition, labor costs, transportation and food expenses were taken into account as companion costs. **RESULTS:** The calculations were made according to the information obtained from the expert panel, medical expenditures were calculated in accordance with the repayment perspective. It has been detected that the annual average outpatient cost of gastric cancer patients is $ 429.86 per patient, and the cost of medical and laboratory costs is $ 775.59, hospitalization and medical interventions costs are $ 1,837.18, medication and application costs are $ 4,751.98, and the cost of side effects and complications is $ 5,106.88. The cost of an average gastric cancer patient from the health care payer perspective was $ 12,901.49 annually. According to the expert panel, the indirect cost per patient was $ 157,907.3, while the companion cost was $ 3,217.7. There are a total of 8,865 patients in Turkey, according to Globocan data and Ministry of Health. Total direct costs are $ 114,377,573 and indirect costs are $ 95% of this cost. **CONCLUSIONS:** Gastric cancer is an important economic burden for our country. National policy is needed for prevention of disease, increasing awareness, early diagnosis, access to treatment.
PCN97: TREATMENT COST OF HEPATOCELLULAR CARCINOMA FROM THE HEALTH INSURANCE’S PERSPECTIVE IN VIET NAM

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OBJECTIVES: Hepatocellular carcinoma (HCC) is a leading cause of cancer-related death, causing high disease and economic burden in upcoming years. In spite of its popularity and importance of treatment, the number of research focusing on HCC-related treatment costs in Viet Nam is still limited, so this study aims to evaluate the treatment costs of HCC from the health insurance’s perspective of Viet Nam. METHODS: The decision-tree model was built based on the HCC treatment guideline of American Association for the Study of Liver Diseases – AASLD and Ministry of public health Viet Nam 2013 to estimate the direct treatment cost per patient per year. The data was collected in Bach Mai hospital - a large hospital specializing in HCC treatment in Viet Nam - from a cohort of all HCC patients in 2015. Costs included the unit costs of test, procedures, imaging, hospitalizations, medications, and all subsequent care of the HCC patients until either death or the end of follow-up. RESULTS: Study sample included 216 patients with average age at 56.88 ± 0.74, 88% of men and 12% of women, 16.72 ± 0.99 days of the length hospital stay. Initial primary treatment modalities were sorafenib therapy 0.9%, RFA 5.6%, TACE 31.9%, symptomatic treatment 55.6% and liver surgery 6.0%. The decision-tree model was built with 11 steps to estimate the direct treatment cost of HCC. Overall costs included a median of VND 48,130,694 per patient per year; in which, 83% was covered by healthcare insurance and 17% by patients. The medical service cost was 4.8 times higher than the medication cost (VND 39.76 mil vs 8.37 mil). CONCLUSIONS: The results show a considerable economic burden of HCC in Vietnam. With an upward trend of HCC in Vietnam and the high-cost burden of treatment, healthcare policies and national medical programs should be considered.

PCN98: COST OF ILLNESS ANALYSIS: A COMPARISON OF THE COSTS OF DRUG THERAPY FOR PATIENTS WITH PROSTATE CANCER, BREAST CANCER, COLON CANCER, MELANOMA AND RENAL CELL CARCINOMA IN MOSCOW

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OBJECTIVES: According to experts from the Moscow City Health Department, prostate cancer (PC), breast cancer (BC), colon cancer (CC), melanoma (MEL) and renal cell carcinoma (RCC) are the most high-cost oncological diseases. The aim of our study was to calculate the costs for each of these nosologies from the point of view of Moscow’s budget and compare them with each other. METHODS: To assess the annual costs of drug therapy in Moscow in patients with PC, BC, CC, MEL and RCC we have developed an analytical model, taking into account the data of Cancer Register for 2015 and 2016, as well as literature sources. RESULTS: We have estimated that if the costs of drug therapy for all five of assessed types of cancer are taken as 100%, then the most costly is BC (41% of costs), then MEL (20%), RCC (15%), CC (13%) and PC (12%). We have also calculated, that if the number of patients with all five types of assessed cancer undergoing drug therapy, we would consider as 100%, the highest percentage of them is in BC (50% of all patients), then - PC (36%), CC (9%), MEL (3%) and RCC (1%). CONCLUSIONS: The structure of drug therapy costs in patients with PC, BC, MEL, CC and RCC in Moscow shows that the most expensive is the treatment of patients with melanoma (for 3% of patients Moscow City Health Department spends 20% of costs) and RCC (1% of patients cost 15% of costs).

PCN99: LABOUR PRODUCTIVITY LOSSES ASSOCIATED WITH BREAST CANCER: AN ANALYSIS ALONG A DECADE IN SPAIN

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OBJECTIVES: In Spain, breast cancer is the most frequently diagnosed tumor in women, with an estimated prevalence of 104,210 cases, being the leading cause of death in tumors in women with more than 6,000 annual deaths. A relevant aspect of this disease is, given the average age of the women affected, its negative impact on the work environment. The main aim is to estimate the labour losses associated with breast cancer in women in Spain along a decade: 2005-2014. METHODS: Data was collected from several official sources (Registration of Deaths, Labor Force Survey and Wage Structure Survey). All of them were conducted by National Statistics Institute from the 2005 to 2014. It was performed simulation models based on the human capital approach to estimate labour productivity losses flows due to premature deaths, adjusted by employment and wage rates for each age group. It was calculated years of potential productive life lost (YPLL). RESULTS: A total of 61,445 women died due breast
cancer in the period considered (22,716 of death in working age). The total YPLL is estimated in 292,848. The estimated productivity losses amounted to 2,137.32 million throughout the period (base year 2014). This figure range between 1,672.59 to 2,907.34 in the sensibility analysis. Breast cancer caused the 3.3% of total women deaths, the 11.7% of total women deceases in working age and the 10.0% of total YPLL and the 10.45% of women labour productivity losses estimated in the period considered. CONCLUSIONS: In spite of therapeutic advances produced in the last decade, breast cancer caused a strong impact in terms of premature deaths, years of potential productive life lost and labour productivity losses in women. The results obtained might be useful to improve knowledge about the economic impact of such disease and to incorporate this information into economic assessments into social perspective.

**PCN100: RESOURCE USE AND HEALTH-CARE COSTS OF CHRONIC LYMPHOCYTIC LEUKEMIA IN SLOVAKIA**

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OBJECTIVES: The objective of this study was to measure the resource utilisation and the direct costs associated with health-care management of chronic lymphocytic leukemia (CLL) in Slovakia and to provide a basis for cost-effectiveness evaluations. METHODS: The extended cross-sectional survey was performed according to internationally accepted recommendations. The survey, conducted through the Key Opinion Leaders, was performed to obtain the information on the management of patients with CLL and to estimate the direct costs of the disease management. The working group included experts from all the onco-hematology centers in Slovakia. The primary population studied was the cohort of adult patients with CLL, with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy. The cost-data were analysed according to the first-line treatment and were assessed for the year 2017. All types of health care used were evaluated. Costs of adverse events (AEs) were set for treatment of one single event. RESULTS: The most frequent treatment regimens used in the 1st treatment line of CLL patients not suitable for fludarabine regimen was rituximab+bendamustine (43.30%), followed by ofatumumab+bendamustine (28.26%), obinutuzumab+chlorambucil (23.93%) and rituximab+chlorambucil (4.51%). The most frequent 2nd line treatment after rituximab+bendamustine in early versus late progression was methylprednisone versus rituximab+bendamustine (30% versus 86.32%). Weekly cost of CLL management in stable disease were highest in rituximab+bendamustine treatment (€36.27/patient), followed by ofatumumab+bendamustine (35.80 €/patient), obinutuzumab+chlorambucil (€35.62/patient), rituximab+chlorambucil (€35.23/patient). Cost for treating AEs were evaluated for grade 3/4. The most costly AEs were febrile neutropenia (€1 703.22), thrombocytopenia (€1 265.71) and anaemia (€817.55). CONCLUSIONS: In order to prove the cost-effectiveness, the local resource use data need to be collected, which are key drivers for health-economic modelling and can guide resource allocation decisions in CLL in Slovakia. This survey provides information to support these decisions.

**PCN101: ANNUAL COSTS OF BEST SUPPORTIVE CARE FOR PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG CANCER (NSCLC) IN GERMANY**

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OBJECTIVES: Patients with advanced NSCLC for whom antineoplastics are not suitable are usually treated individually with best supportive care (BSC). This research aims to estimate annual costs of BSC for these patients from the perspective of the Statutory Health Insurance (SHI) in Germany. METHODS: Recommended measures for BSC were identified from the German development stage 3 (S3) guideline for lung cancer. The costs of these measures were estimated based on public German cost data. RESULTS: The annual costs of the recommended measure are as follows: for drugs (analgesics, opioids, corticosteroids, bronchodilators, benzodiazepines, antidepressants, laxatives, bisphosphonates, denosumab, levodropropizine, metoclopramide, anticonvulsants) from 116.80 € to 2023.88 €, for radiotherapy 2390.00 € and 5888.51 €, respectively (depending on regime), for palliative surgery 5447.63 €, for rehabilitation 3660.20 € and for three further measures (psychotherapy, physical therapy, therapy with oxygen) from 756.60 € to 2194.25 €. Summing up the costs of these measures, the upper limit of annual costs is 27,838.81 €. These costs do not include costs for inpatient palliative care or treatment in the terminal phase (approx. 400 € per day). CONCLUSIONS: As BSC is provided individually to patients, the annual costs of BSC in Germany for patients with advanced NSCLC lay within a wide range from 0 € (less likely) to 27,838.81 €. In order to estimate the costs of BSC more precisely, further research regarding the frequency of each recommended measure for BSC in Germany is needed.

**PCN102: PRICE-DOSE RELATIONSHIP: THE CASE OF ORAL ONCOLOGY DRUGS IN EU5**

OBJECTIVES: Most oral oncology drugs are linearly or flatly priced but country differences exist within pharmaceutical pricing strategies. This study aims to explore and compare the pricing strategies for oral oncology products in the EU5 countries. METHODS: All 14 oral oncology drugs that have received marketing authorization by the European Medicine Agency since 2000 were included in the analysis. The ex-manufacturer prices were sourced from national pricing databases in May 2017. Unit prices were calculated as a price per milligram and price per tablet for each individual product in scope countries. The price-dose relationship was characterised as flat, linear or mixed pricing for each product based on each country unit price per dose. A cross-country comparison was then performed to identify dominant strategies and explore local specificities, if any. RESULTS: The pricing strategy of oral oncology products appears to be similar in EU5 as 71% (10/14 products; 5 linear pricing, 4 flat pricing, 1 mixed pricing strategy) of the products had the same pricing strategy in all countries. Pricing strategy differed for 29% (4/14) of products between scope countries. In Germany, flat pricing was a frequent strategy (3/4 products) whilst different pricing strategies were applied for the same product in other countries. Linear pricing was dominant (3/4 products) in the UK, however no dominant pricing strategy was observed in Spain, Italy and France, as either flat or linear pricing was used when pricing strategy differed for the same product. CONCLUSIONS: Our findings suggest that most often companies apply the same pricing strategies for oral oncology products in EU5 counties. However, in some cases we identified different pricing strategies within EU5 for a given product.

PCN103: DOES CCG SPENDING ON CANCER AFFECT OUTCOMES IN BREAST AND LUNG CANCER?

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OBJECTIVES: Clinical commissioning groups (CCGs) are given autonomy through which they can allocate their budget to fund treatments. Current funding pressures mean that there is a greater need to find efficiencies within the National Health Service (NHS). The objective of this study was to investigate the relationship between CCG expenditure on lung and breast cancer outcomes in England. METHODS: CCG data for breast and lung cancer for one-year survival, early stage diagnosis (stage 1 or 2), total spend, and age standardised under 75 mortality were extracted using the Cancer and Tumours Focus Pack online tool. Budget spend per event of lung and breast cancer was calculated. Pearson rank correlation coefficients were calculated to determine the relationship of budget spend per event versus outcomes. All calculations were performed using Microsoft Excel 2013®. RESULTS: There were 209 CCGs with data available. In 2013, average spend per 100,000 incidence of breast and lung cancer was £3,704 (£1,364-£8,692) and £2,122 (£1,082-£11,820), respectively. Our analysis revealed a non-significant positive correlation between spend per event and one-year survival rate for breast cancer and lung cancer (R=0.04 [p=0.543], R=0.01 [p=0.817], respectively). In addition, there was a statistically significant positive correlation between age standardised under 75 mortality and spend per event of breast cancer (R=0.15 [p=0.021]), though no correlation was identified for lung cancer (R=0.06 [p=0.31]). Similarly, there was a statistically significant positive correlation for spend per event and early stage diagnosis (R=0.16 [P=0.021] and R=0.08 [p=0.232] for breast and lung cancer, respectively). CONCLUSIONS: Whilst CCGs face pressures on funding, these data suggest that large variations in cancer expenditure does not necessarily lead to better outcomes in breast or lung cancer. CCGs need to understand why this is the case to reduce inefficiencies during times of higher budget constraints and to improve cancer outcomes.

PCN104: A SYSTEMATIC REVIEW OF THE HEALTH-RELATED QUALITY OF LIFE AND COSTS IN DIFFUSE LARGE B-CELL LYMPHOMA

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OBJECTIVES: As survival outcomes improve for patients with diffuse large B-cell lymphoma (DLBCL), it is increasingly important to understand costs and humanistic burden to evaluate the need for new treatments. We conducted systematic reviews to understand the health-related quality of life (HRQoL) of patients with DLBCL and costs associated with treatment. METHODS: MEDLINE, EMBASE, EconLit, UK National Health Service Economic Evaluation Database, and Tufts University Cost-Effectiveness Analysis Registry were searched for studies published between 2000-2016. Trial registries and health technology assessment websites were searched for appraisals with relevant economic and HRQoL data; abstracts were identified from ASCO, ESMO, ASH, EHA, and ISPOR. RESULTS: After screening, 25 of 2184 references were included for HRQoL; 20 of 1481 references were included for costs. Ten studies used the EORTC QLQ-C30. The EQ-5D and FACT-Lym are used in trials with unpublished data. Patients who achieve complete response after first-line treatment have significantly greater improvements on HRQoL compared to non-complete responders (p=0.05). Symptoms that compromise HRQoL persist for up to 5 years for patients that do not respond to first-line treatment. Economic studies focused on cost of
treatment and hospitalization, with few studies reporting societal costs. Cost-effectiveness analyses in the UK, France, US and Canada concluded that R-CHOP is a cost-effective first-line treatment compared to CHOP; R-CHOP was not found to be cost effective in a Chinese study. Second-line treatment results in additional costs, with autologous stem cell transplantation and hospitalization being most costly. Stratification of treatment according to DLBCL subtype (GCB vs ABC) has been shown to be cost-effective. CONCLUSIONS: Novel, targeted DLBCL first-line treatments have the potential to provide a more cost-effective, manageable budgeted treatment paradigm, reduce disease progression, and improve HRQoL. Although DLBCL subgroups are recognized in clinical guidelines, further studies are needed to understand their specific HRQoL and economic burden.

**PCN105: REAL-WORLD DATA ANALYSIS OF CANCER TREATMENT COST DRIVERS BY TYPE AND PLACE OF SERVICE**

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**OBJECTIVES:** As the US healthcare system transitions from one of volume based delivery to one focused on quality and value there is a continued focus on understanding the drivers of cost, especially in oncology. Cancer drug costs have been a focus of much debate and this study analyzes real world data from two large volume cancer centers in the US to quantify drivers of cancer treatment costs. **METHODS:** Integra Connect utilized Medicare claims data from two large cancer treatment centers in the US with over 60,000 cancer patients treated in the last 12 months. Overall treatment costs were categorized into 9 cost buckets (including Part B drug costs, Part D drug costs, Inpatient, E&M, Lab testing, Imaging, Emergency visits, etc.). Treatment costs were based on amounts paid by CMS from July 2016 through August 2016. Secondary research included a review of previously published studies on cost drivers of cancer care for comparison to current results. **RESULTS:** Our research found that prescription drug costs from both Part B and Part D paid Medicare claims accounted for 47% (site 1) and 51% (site 2) of total cancer treatment costs. Second to cancer treatment costs, inpatient hospitalization related costs accounted for 20% (site 1) and 17% (site 2) of overall costs. **CONCLUSIONS:** These results contrast previously published research that found cancer drug costs to be a smaller proportion of overall treatment costs (18% of overall costs attributed to chemotherapy and other cancer drugs). This real-world data analysis highlights the variability in cancer treatment costs and the continued need for cancer treatments to demonstrate value and savings among other areas that drive overall cost. 1"Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014”, Milliman

**PCN106: ESTIMATING THE DRUG TREATMENT COST OF BREAST CANCER**

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**OBJECTIVES:** Overall treatment costs in oncology are increasing rapidly due to the increasing availability of expensive drugs. Comparing the costs of currently used drugs and assessing the cost-effectiveness of new drugs requires a transparent overview of actual breast cancer treatment prices. As such an overview is lacking, this study aims to synthesize evidence on the reimbursement and costs to estimate the total treatment cost of expensive breast cancer drugs for the Netherlands. **METHODS:** Evidence on the approval, reimbursement and list prices of expensive breast cancer drugs was identified from the Dutch Administrative Health Authority (ZINL). Data on the average length of treatment and dosing schedules was obtained from European Parliament Assessment Reports (EPARs) or ZINL reports. All evidence was aggregated in the estimation of actual treatment cost. **RESULTS:** In the Netherlands, 31 breast cancer drugs are approved (available in 41 different forms). Based on drug list prices Pertuzumab, Trastuzumab Emtansine and Trastuzumab are the most expensive drugs. For 17/41 (41.5%), no evidence on the average treatment length was available in EPARs or ZINL reports. Comparing list prices to the estimated treatment cost per patient resulted in substantial differences in the ranking of expensiveness of the drugs. Overall, estimated treatment costs were highest for Bevacizumab, Pertuzumab and Trastuzumab Emtansine. **CONCLUSIONS:** Estimating treatment costs is far from trivial, given the wide range of evidence sources that need to be synthesized. This complicates rapid and transparent assessment of actual cancer drug treatment cost, which is necessary to focus strategies aiming to limit the increasing healthcare costs. Differences exist in list prices within countries and between countries, thereby influencing the corresponding estimated treatment costs and resulting in list prices having limited value in this context. Therefore, extending standardization in presenting information on costs per cancer drug and implementing real world price estimates in such calculations is highly recommended.

**PCN107: LANDSCAPE OF MALIGNANT MELANOMA: THE IMPACT OF UPCOMING THERAPIES**

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OBJECTIVES: Malignant melanoma (MM) is both the most aggressive and fatal form of skin cancer, with an increasing incidence over the past years. Treatment options have evolved significantly, with the emergence of targeted therapies and immunotherapy, and recently with the adoption of combination therapies. This study aims to analyze and estimate the financial impact for the Portuguese NHS of the MM market dynamics until 2020. METHODS: MM patients estimation was calculated through a linear prediction of historical data (considering disease incidence, staging, net survival, mutation split, progression rates between treatment lines and regimen share per line) impacted by the probability of influential upcoming events. Treated patients were converted to expenditure considering a cost per patient that comprised both products’ list price and expected time on therapy. RESULTS: MM incidence is expected to increase at an annual rate of 3.4% until 2020. Targeted therapy combinations for BRAF+ and immunotherapy for BRAF wt patients, besides being more expensive, brought an increase in Progression-Free Survival figures, leading to an annual increment of MM drug related expenditures of 20.8%. Thus, it is estimated that in 2020 MM drug expenditure will account for 62.9 M€, more than doubling 2015 figures. CONCLUSIONS: Innovative therapies are highly anticipated and perceived as beneficial for all cancer patients, and MM is no exception. However, oncology drugs are fully-funded by the Portuguese State and Hospitals have therefore a limited budget to ensure treatment for all the population, making it increasingly important to have visibility on the different diseases burden. As in previous years, the Portuguese MoH intends to curb drug expenditure, hence estimating the drug-related expenditure for the most prevalent diseases enables a more efficient decision-making process for Hospital management and a more informed discussion on access to innovation by the entire Society.

PCN108: CLINICAL AND ECONOMIC HISTORY OF THE ONCOLOGICAL PATIENT AT THE END OF LIFE

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OBJECTIVES: The objective of this work is to calculate the individualized cost of healthcare to cancer patients at the end of life by aggregating all the hospital activity performed to each patient. METHODS: Descriptive study based on administrative records of activity and costs. The study population are cancer patients died in the province of Granada (Spain) during the years 2009-2012. No sampling is performed. The data sources are the Registry of Cancer of Granada, records of health care activity of public hospitals in the province and the Analytical Accounting System of the Public Health care System of Andalusia. Combining the information collected in the above mentioned systems, a database of the Economic History of the Patient is generated, which includes the last 24 months of life. The minimum unit of information is each patient’s contact with the health care system, with details of the date, medical specialty, reason for attendance and reason for discharge. RESULTS: A total of 2978 patients from the Granada Register of Cancer with health care activity have been identified. To date, information has been gathered from external consultations, hospitalization, surgery, diagnostic laboratory tests and radiodiagnosis and ambulatory hospital sessions. The consolidated information provides a chronology of the assistance received that allows to reconstruct, for each patient, the actual development of their care process in the last months of life and the cost associated with that process. CONCLUSIONS: The reconstruction of the process of health care activity at patient level through administrative records is a practice still not very widespread in the public health care sector. The knowledge of the unit hospital cost of the treatment of a cancer patient at the end of life and its composition will facilitate an improvement in clinical-economic efficiency in cancer patients and the identification of more efficient treatment patterns according to clinical situation.

PCN109: REAL-WORLD HEALTH CARE RESOURCE UTILIZATION AND RELATED COSTS AMONG PATIENTS WHO RECEIVED AT LEAST TWO LINES OF TREATMENT FOR ADVANCED NSCLC IN ENGLAND, THE NETHERLANDS, AND SWEDEN

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OBJECTIVES: Advanced (stage IIIb/IV) non-small cell lung cancer (aNSCLC) presents a high burden to society. This study aimed to quantify real-world health care resource utilization (HRCU) and related costs of patients with squamous (SQ) and non-SQ (NSQ) aNSCLC who received ≥2 lines of treatment (2L+) in England, the Netherlands, and Sweden. METHODS: Within wave 2 of the 7-country Leading the Evaluation of NSQ and SQ NSCLC (LENS) retrospective chart review study, patients diagnosed with aNSCLC between 07/2010-09/2012 who initiated 2L were sampled from oncology/pulmonology practices and followed from diagnosis through most recent visit/death. HRCU
Healthcare Costs of Ipilimumab in Patients with Advanced Cutaneous Melanoma in Dutch Clinical Practice


OBJECTIVES: There is limited evidence on costs associated with ipilimumab. We investigated healthcare costs of ipilimumab treatment in Dutch patients with advanced cutaneous melanoma and compared costs across subgroups.

METHODS: Data were retrieved from the nation-wide Dutch Melanoma Treatment Registry for patients diagnosed between July 2012 and July 2015. Ipilimumab episode duration was computed from start of ipilimumab until start of a next systemic treatment, death, or last date of follow-up. Costs were determined by applying unit costs to individual patient resource use. Patient subgroups were stratified by experiencing an immune related adverse event (irAE): no irAE, colitis, and irAE other than colitis.

RESULTS: A total of 807 patients received ipilimumab in Dutch clinical practice. Baseline characteristics were comparable across subgroups. Mean [median] episode duration was 6.27 [4.61] months. Average total healthcare costs amounted to €160,002. Ipilimumab was the most important cost driver (€73,739, 90.5%). Most patients (65%) received 4 cycles of ipilimumab (average dosage: 240mg [SD:45.6mg]). Other healthcare costs (€7,745) were related to hospital admissions (€3,323), hospital visits (€1,791), diagnostics and imaging (€1,505), radiotherapy (€828), and surgery (€297). Although patients with colitis (n=106) had higher costs for resource use other than ipilimumab (€11,426) compared to patients with other types of irAEs (n=90; €9,850) and patients with no irAE (n=611; €6,796), they had lower total costs (€76,075 versus €87,882 and €81,484, respectively) due to less cycles of ipilimumab. Patients with an irAE other than colitis had a longer (mean [median]) episode duration (7.96 [5.92] months) compared to patients with colitis (6.91 [4.92] months) and patients with no irAE (5.92 [4.28] months).

CONCLUSIONS: Healthcare costs associated with ipilimumab treatment are considerable in Dutch patients with advanced cutaneous melanoma. Although costs were mainly related to drug costs of ipilimumab, total costs and the distribution of the costs varied significantly across subgroups.

Healthcare Costs of Lung Cancer Care: Results from a Retrospective Chart Review of Pretreated Advanced NSCLC Patients in Europe

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(aNSCLC-related hospital/ER visits, surgeries, radiotherapy, ancillary care [hospice, nursing home, in-home], biomarker tests) and systemic treatment use was extracted from medical charts. Country-specific unit costs, inflated to 2016€, were multiplied by HCRU to derive aNSCLC-related costs. RESULTS: Of 138 patients (n=52 England, 57 Netherlands, 29 Sweden; n=42 SQ, 96 NSQ), 95.7% were followed through death (median observation time: 16.5 months [4.0-68.6]). From diagnosis through most recent visit/death, 44.2% of patients were hospitalized (median duration: 0.8 days/patient-month). 25.4% had ≥1 ER visit; 44.9% radiotherapy; 3.4% surgery; 23.2% received ancillary care. Median total per-patient costs were €6,431 per SQ (€6,442 England; €10,577 Netherlands; €11,857 Sweden) and €15,989 per NSQ patient (€6,442 England, €26,647 Netherlands, €27,909 Sweden). Drug costs accounted for 48.5%/52.1%/48.4% of total median overall/SQ/NSQ costs, and were highest/lowest in Netherlands/England. During the last month of life, median costs were €939/2,032 per SQ/NSQ patient, with hospice presenting the largest cost portion. CONCLUSIONS: Prior to availability of immunotherapy, HCRU and costs were substantial in aNSCLC patients, with systemic treatment accounting for 48.5% of total median costs. NSQ patients incurred higher total costs than SQ patients in Sweden and the Netherlands, and similar costs in England. Ongoing real-word data are needed to capture changes in HCRU patterns due to the evolving NSCLC treatment landscape.
OBJECTIVES: Advanced (stage IIIb/IV) non-small cell lung cancer (aNSCLC) has a significant economic impact on society. This 7-country European study describes predictors of real-world per-patient costs [systemic treatment and health care resource utilization (HRCU)] of patients with aNSCLC who received at least 2 lines of systemic treatment (2L+). METHODS: The LENS (Leading the Evaluation of non-squamous and squamous NSCLC) retrospective chart review was a 7-country study conducted in 2 waves: W1 included France, Germany, Italy, Spain, and W2 included England, the Netherlands, Sweden. Within LENS, patients with aNSCLC diagnosis who initiated 2L were sampled from oncology/pulmonology practices, and followed from diagnosis (W1: 07/2009-08/2011; W2: 07/2010-09/2012) through most recent visit/death. Weighted average of country-specific unit costs (2016 Euro) was applied to systemic anticancer therapy usage and HCRU (hospital/ER visits, surgeries, radiotherapy, ancillary care, biomarker testing) to determine total cost from aNSCLC diagnosis to death. Generalized linear models (gamma distribution, log link) were used to assess clinical and demographic predictors associated with higher total costs. RESULTS: Of 973 2L+ patients with median overall survival (OS) of 19.8 months from advanced diagnosis (range 3.1-68.7 months; median OS squamous: 18.8, non-squamous: 21.4), 79.0% were followed through death. Weighted median total per-patient costs were €10,991 [ranges: €7,197 (Germany) to €27,381 (Sweden); €7,183 (squamous) to €18,340 (non-squamous)]. Drug costs were 67.5% of total costs. Statistically significant (p<0.05) predictors for higher total lifetime HCRU costs were non-squamous histology and private insurance status. Positive EGFR mutation status predicted significantly lower costs. CONCLUSIONS: Drug costs were the primary cost driver in this pre-immunotherapy era real-world study, although this may partially be due to the 2L+ study population. Within this cohort, histology, EGFR mutation and insurance status were significant predictors for total treatment and HRCU costs, whereas characteristics such as age, gender, smoking history, ECOG PS, and IASLC disease stage were not significant.

PCN112: COST ANALYSIS OF LUNG CANCER IN CHINA

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OBJECTIVES: Lung cancer is a disease with high incidence(733.3 thousand, 2015) and mortality(610.2 thousand, 2015) while bring tremendous economic burden to patients in China. In current study, lack of research on medical resources distribution and annual medical cost in disease development process based on panel data. Cost of managing patients with lung cancer and the trend of medical cost are worth to explore. To demonstrate the trend of annual medical cost and cost allocation of lung cancer from first diagnosis to the end of database basing on Qingdao medical institutions panel data from 2012 to 2015. METHODS: Totally 150 lung cancer patients who alive four years and all medical records were got in database. Annual medical cost and cost allocation of 1-4 year after diagnosis were calculated. RESULTS: Total medical cost for four years are RMB 78914, RMB 52612, RMB 70383 and RMB 47280 which the cost of 1st year after diagnosis was higher than consequent years. Total cost decrease significantly in second year after diagnosis, at 3th year the cost bounces and dropped at 4th year . The top three of total medical cost are drugs, test and treatment, which account for average 69%, 13% and 8%, respectively. Drug cost has similar trend with total medical cost. Test cost decrease relatively slow in second year after diagnosis, at 3th year the cost dropped to the maximum and dropped at 4th year . Treatment cost keep stable in first two years and increased 68% at 3th year and decreased markedly at 4th year. CONCLUSIONS: The economic burden of lung cancer is extremely high compare with per capita disposable income of RMB 35680 in Qingdao. The biggest portion of medical cost is related to drug used during the overall treatment period.

PCN113: COST-EFFECTIVENESS OF PEMBROLIZUMAB FOR THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL CELL LUNG CARCINOMA IN PORTUGAL

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OBJECTIVES: To assess the cost-effectiveness of pembrolizumab compared to platinum-based chemotherapy in previously untreated patients with metastatic non-small cell lung carcinoma (NSCLC) with strong positive programmed death 1 protein ligands (PD-L1 ≥ 50%) expression in Portugal. METHODS: A partitioned-survival model was parameterized using clinical data from a head-to-head phase III randomized clinical trial, KEYNOTE-024. A two-stage approach was used to adjust for crossover in the comparator arm. Utility was derived from KEYNOTE-024 using time-to-death weights. Portuguese-specific disease management resource use was estimated by a panel of clinical experts; resources were valued using national unit costs. The analysis was conducted from a societal perspective, assuming a life-time horizon and a 5% discount rate. Deterministic and probabilistic sensitivity analyses
assessed the robustness of results. **RESULTS:** Pembrolizumab increases average life expectancy by 3.8 undiscounted life-years (LY) and 2.1 discounted LY. This allows an increase of 1.7 quality adjusted life-year (QALY). Economic analysis shows that higher costs of pembrolizumab arm are mainly due to longer treatment duration and patient survival. The estimated incremental cost-effectiveness ratios (ICER) are 51,944€/LY and 64,205€/QALY. Deterministic sensitivity analysis shows that results are robust to most scenarios, but sensitive to treatment duration and parametric extrapolation options. Probabilistic sensitivity analysis resulted in a median ICER of 64,249€/QALY. **CONCLUSIONS:** Considering usually accepted thresholds in oncology and the unmet need in metastatic NSCLC, the cost-effectiveness of pembrolizumab compared to chemotherapy regimen might be acceptable.

**PCN114: COST-EFFECTIVENESS OF NIVOLUMAB IN COMBINATION WITH IPILIMUB IN FIRST-LINE TREATMENT OF ADVANCED MELANOMA IN THREE EUROPEAN COUNTRIES USING 28-MONTH OVERALL SURVIVAL FROM CHECKMATE 067**

**OBJECTIVES:** The objective of this study was to assess the cost-effectiveness of nivolumab in combination with ipilimumab (Nivo+Ipi) as first line advanced melanoma treatment across 3 European countries. **METHODS:** A cost-effectiveness model, using a three-state partitioned survival structure was developed. The model utilised the intent-to-treat 28-month progression-free survival data and overall survival data from the CheckMate 067 trial and a network meta-analysis which considers time-varying hazard ratios. The model utilised inputs for Greece, Spain and Portugal. The model considered a 30 year time horizon. Drug acquisition, administration, follow-up, subsequent therapy and adverse event costs were obtained via published unit prices and expert input on resource utilization. Adverse event frequencies were derived from the CheckMate 067 trial and published literature. Utility weights were also estimated from the trial, based on UK tariffs. The key comparators included in the analysis are nivolumab and ipilimumab monotherapy, however an additional comparison with pembrolizumab was considered in sensitivity analysis. **RESULTS:** The incremental cost per quality adjusted life years (QALY) ratios (ICUR) were consistent across the three countries. Nivo+Ipi had an ICUR ranging from €2,488 (Greece – incremental cost €8,110, incremental QALY 3.260) to €7,311 (Spain – incremental cost €23,857, incremental QALY 3.263) compared to ipilimumab and ranging from €21,812 (Portugal – incremental cost €16,090, incremental QALY 0.738) to €28,399 (Spain – incremental cost €27,768, incremental QALY 0.978) compared to nivolumab. The differences in results were shown to be driven by subsequent treatment costs and follow-up costs. When comparing to pembrolizumab, Nivo+Ipi had the greatest QALY and life years and had an ICUR ranging from €12,323 (Greece – incremental cost €31,942, incremental QALY 2.592) and €17,962 (Spain – incremental cost €46,614, incremental QALY 2.595). **CONCLUSIONS:** Nivo+Ipi represents a cost-effective option for the first-line treatment of advanced melanoma in these 3 European markets.

**PCN115: A POPULATION-BASED STUDY ON CLINICAL OUTCOMES AND MEDICAL COSTS OF LAPAROSCOPIC VERSUS OPEN SURGERY FOR COLON CANCER PATIENTS IN TAIWAN**

**OBJECTIVES:** Due to the increasing incidence rate of colorectal cancer worldwide, and its subsequent high medical care utilization, colorectal cancer has become one of the important health issues. In addition to traditional open surgery, laparoscopic surgery has gradually gain its popularity in treating colorectal patients in recent years. However, the impact of laparoscopic on clinical outcomes and medical care has rarely been studied. Thus, the aims of this population-based study were to compare the clinical outcomes and medical costs between laparoscopic and open surgery for colon cancer patients from the perspective of National Health Insurance (NHI) in Taiwan. **METHODS:** This study used the 2010 Longitudinal Health Insurance Database which contains one million randomly chosen enrollees of the NHI. Incident patient received either laparoscopic or open surgery from 2007 to 2012 were first identified and included. Patients younger than 20 years old, had intestinal disease before receiving surgery were excluded. Propensity score matching (PSM) was conducted to reduce the heterogeneous imbalance between laparoscopic and open surgery group. The generalized estimating equation (GEE) and cox proportional hazards regression were performed to examine the differences in clinical outcomes and medical costs. **RESULTS:** There were 125 patients in each of the laparoscopic surgery and open surgery group after PSM. Colon cancer patients received laparoscopic surgery had significantly shorter length of stay (3.6 days; p <0.01). The overall 3-year survival (p =0.227) and recurrence-free 3-year survival (p =0.689) were similar between these two
groups. For medical costs, laparoscopic surgery saved US$109 (p =0.63) for hospitalization due to surgery, US$177 (p <0.01) for ward costs, US$44 (p <0.01) for diagnosis costs, and US$386 (p =0.58) for total medical costs within 1 year. CONCLUSIONS: For colon cancer patients, laparoscopic surgery had better clinical outcomes and lower medical costs compared to open surgery.

**PCN116: EVALUATING ADVERSE EVENTS COSTS IN CANCER PATIENTS IN LEBANON FROM TWO PAYERS PERSPECTIVE**

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**OBJECTIVES:** The objective of the study was to evaluate the cost of adverse events in cancer patients in Lebanon from private and public sector payer perspectives. **METHODS:** Claims data was retrieved from a third-party payer that represents 50% of the private insurance companies in Lebanon of whom 38% of adherent have complementary NSSF insurance, The NSSF (National Social Security Funds) sector, in turn, represent 28.6% from the total healthcare sector in Lebanon. Two sets of 2016 data were retrieved, one for multiple myeloma patients and the second for all cancer patients admitted specifically for any of three types of adverse events: anemia, thrombocytopenia, and neutropenia. For the multiple myeloma data set, 26 patients had 280 claims. For the all cancer data set, 18 claims of patients with private public insurance (co-NSSF) were retrieved for patients admitted for adverse events. For the set of multiple myeloma patients the mean average costs was calculated across all claims; for the all cancer patients the median was calculated. **RESULTS:** From the all cancer patients set, we found the adverse event treatment total costs was respectively as follows: neutropenia (3,587,875LBP) and the NSSF represented 39.2% from the total cost which was (1,406,655LBP), anemia (3,767,000LBP) and the NSSF represented 23.8% from the total cost (898,500LBP) and thrombocytopenia (5,025,570LBP) where the NSSF represented respectively, 39.3% and it was (1,975,500LBP). The multiple myeloma claims provided two adverse events from the NSSF perspective: diarrhea (5,871,000LBP) and febrile neutropenia (8,962,000LBP) and one adverse event from the private perspective that is severe pneumonia (46,419,000LBP). **CONCLUSIONS:** Although these results were limited, this is the first time that the cost of treating adverse events for multiple myeloma and cancer patients have been analyzed in the Lebanese market. These analysis may help with the setting of guidelines for cancer-related adverse events management.

**PCN117: COST-EFFECTIVENESS ANALYSIS OF ALECTINIB COMPARED TO CHEMOTHERAPY FOR THE TREATMENT OF TREATMENT-NAÏVE PATIENTS WITH ALK POSITIVE LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) IN GREECE**

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**OBJECTIVES:** Lung cancer remains the commonest cause of death from cancer worldwide, posing a high disease and economic burden on healthcare systems globally. Alectinib is a highly selective, CNS-active anaplastic lymphoma kinase (ALK) inhibitor. 5% of non-small cell lung cancer (NSCLC) patients carry mutations associated with ALK (ALK positive). The objective of this analysis was to perform a cost-effectiveness analysis of Alectinib compared to chemotherapy for the treatment of treatment-naïve patients with ALK positive locally advanced or metastatic NSCLC in Greece. **METHODS:** A health economic model was developed using an "area under the curve" partitioned survival (three mutually exclusive health states) semi-Markov type analysis. The model was populated with clinical effectiveness data from the literature and Greek-specific data on health resource use and costs collected from an expert panel of 10 oncologists. This analysis did not account for discounts/rebates. The analysis followed a third-party payer perspective (Greek Social Insurance). **RESULTS:** Alectinib compared to chemotherapy was accompanied by gains of 2.1 total life years (LY) (5.01 vs 2.91) and a gain in Quality Adjusted Life Expectancy of 1.76 QALYs (1.76 vs 0.01 QALY’s gained). Alectinib is associated with an additional cost of €151.550 (€201.554 vs €50.004) compared to chemotherapy per patient, resulting in an incremental cost effectiveness ratio (ICER) of 72.348 per LY gained and 1,76 QALY’s gained). Alectinib is associated with an additional cost of €151.550 (€201.554 vs €50.004) compared to chemotherapy per QALY gained. The results are sensitive to the price of the intervention. **CONCLUSIONS:** The population of ALK positive NSCLC patients in Greece is estimated to be approximately 120 patients per year in Greece. Alectinib contributes towards significant health gains in LY and QALYs compared to chemotherapy at a reasonable cost.

**PCN118: THE CLINICAL AND COST EFFECTIVENESS OF DASATINIB VERSUS NILOTINIB FOR THE FIRST AND SECOND LINE TREATMENT OF PEOPLE WITH CHRONIC MYELOID LEUKAEMIA**

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**OBJECTIVES:** Chronic myeloid leukaemia (CML) is associated with reduced survival and quality of life; however,
BCR-ABL tyrosine kinase inhibitors (TKIs) have dramatically improved outcomes in patients. Although generic imatinib is provided in the UK, outcomes are superior for second-generation TKIs (dasatinib and nilotinib) and their availability enables clinicians to optimise treatment in clinical practice. The objective of this study was to determine the cost-effectiveness of dasatinib versus nilotinib for the treatment of CML in the UK. **METHODS:** A lifetime Markov disease progression and cost-effectiveness model was developed. Complete and partial cytogenetic response rates were derived from systematic literature review and network meta-analysis of studies in treatment-naïve (first-line) patients, and naïve comparison between non-comparative studies in treatment-experienced (second-line) patients. Response-specific survival was derived from patient-level data of dasatinib studies and applied to both treatment arms. Remaining model inputs were derived from previously published literature and UK health technology assessments. A UK payer perspective was adopted; costs and benefits were discounted at 3.5% annually. **RESULTS:** Dasatinib and nilotinib response rates were comparable in the first-line and second-line settings; minor differences resulted in marginally improved mean survival (an additional 0.186 and 0.187 years, respectively) and longer time in the pre-progression state for the dasatinib arm. Due to improved mean survival outcomes and lower acquisition costs (dasatinib: £30,498/annum; nilotinib: £31,736/annum), dasatinib was associated with lifetime cost-savings, and therefore dominance, compared to nilotinib in the first-line and second-line settings (savings of £29,308 and £28,706, respectively). Results were relatively insensitive to alternative assumptions and inputs. **CONCLUSIONS:** Dasatinib and nilotinib provide comparable clinical benefits; however, it was estimated that dasatinib would result in a reduction in total lifetime costs. Availability of both therapies enables clinicians to tailor the CML therapy to an individual patient, potentially improving outcomes in clinical practice, with no additional cost to the NHS.

**PCN119:** **COST-EFFECTIVENESS OF RIBOCICLIB PLUS LETROZOLE VERSUS PALBOCICLIB PLUS LETROZOLE FOR POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE (HR+), HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE (HER2–) ADVANCED/METASTATIC BREAST CANCER FROM A UK NATIONAL HEALTH SERVICE PERSPECTIVE**

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**OBJECTIVES:** Assess the cost-effectiveness of ribociclib plus letrozole versus palbociclib plus letrozole as first-line treatments for postmenopausal women with HR+/HER2– advanced/metastatic breast cancer from a UK National Health Service perspective. **METHODS:** Incremental cost-effectiveness of ribociclib versus palbociclib was simulated using a cohort-based, three-state (progression-free [PF], progressed disease [PD], and death) partition survival model with a 1-month cycle length. Clinical data were derived from the MONALEESA-2 January 2017 data cut for ribociclib and from aggregate palbociclib data from PALOMA-1 and -2. Treatment effect was modelled using hazard ratios of PF survival and overall survival for ribociclib versus letrozole and palbociclib versus letrozole. Cost inputs included drug acquisition, administration and monitoring, routine follow-up, Grade ≥3 adverse events, and subsequent therapy costs. Drug costs for both palbociclib and ribociclib were adjusted for discontinuation and dose reductions. Health benefits were valued in quality-adjusted life years (QALYs), with utility weights derived from EQ-5D-5L data collected in MONALEESA-2 for PF and using literature for PD. Costs and effects were discounted at 3.5% per year for a lifetime horizon of 40 years. Uncertainty was assessed using deterministic and probabilistic sensitivity analyses. **RESULTS:** At lifetime, total discounted cost of ribociclib was £107,128 (drug cost = £58,939; health state cost = £48,189) versus £115,012 (69,949 and 45,063, respectively) for palbociclib. Discounted QALYs for ribociclib were 3.08 (PF = 2.33; PD = 0.75) versus 2.85 (PF = 2.15; PD = 0.70) for palbociclib. Ribociclib was less costly (–£7,884) and resulted in more QALYs (+0.230) than palbociclib, and was the dominant strategy. The probability of ribociclib being cost-effective versus palbociclib at £30,000 per QALY was 77.25%. Drug acquisition cost differences were key drivers of results. **CONCLUSIONS:** Ribociclib is likely to be dominant over palbociclib in cost-effectiveness terms as a first-line treatment for postmenopausal women with HR+/HER2– advanced/metastatic breast cancer.

**PCN120:** **THE COST-EFFECTIVENESS OF NIVOLUMAB FOR THE TREATMENT OF PEOPLE WITH RELAPSED OR REFRACTORY CLASSICAL HODGKIN LYMPHOMA FOLLOWING AUTOLOGOUS STEM CELL TRANSPLANT AND BRENTUXIMAB VEDOTIN**

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**OBJECTIVES:** Treatment of classical Hodgkin Lymphoma (cHL) is highly effective in early lines of treatment; however, for patients who relapse or become refractory after receiving both autologous haematopoietic cell transplantation (auto-HCT) and brentuximab vedotin (BV), treatment options are extremely limited. Nivolumab is a PD-1 inhibitor that may potentially offer significant improvements in disease control and quality-of-life over standards.
of care (SoC) in this setting. Additionally, nivolumab may enable allogeneic HCT (allo-HCT), a potentially curative procedure. The objective of this study was to estimate the clinical- and cost-effectiveness of nivolumab compared to SoC. METHODS: A three-state Markov disease progression and cost-effectiveness model of CHL was developed. Relative efficacy was established by naive and adjusted comparisons of patient-level clinical trial data (nivolumab; CA209-039 and CheckMate 205 B and C) with a retrospective study (SoC; Cheah 2016). Costs were derived from published UK estimates; remaining model inputs were consistent with previous UK health technology assessments. A lifetime horizon was applied; costs and benefits were discounted at 3.5% annually (GBP 2014-15). An additional scenario was modelled in which a proportion of patients received allo-HCT after 6 months of treatment, dependent on response. RESULTS: Nivolumab resulted in an estimated additional 2.80 quality-adjusted life years (QALYs) and 2.90 life years versus SoC, with 1.67 years spent in the pre-progression state and 3.34 years in the post-progression state (versus 0.41 and 1.70 years for SoC, respectively). Estimated incremental costs were £82,897 with a resultant incremental cost-effectiveness ratio (ICER) of £29,631/QALY. Assuming a proportion of patients receive allo-HCT resulted in an ICER of £16,457/QALY. CONCLUSIONS: Nivolumab is estimated to offer significant benefit in terms of improved survival and quality-of-life whilst offering a cost-effective alternative to SoC, addressing a significant unmet need in people with relapsed or refractory cHL who have received both auto-HCT and BV.

PCN122: A HEALTH TECHNOLOGY ASSESSMENT OF HYPERthermic intraperitoneal chemotherapy ADDED TO INTERVAL CYToreductive SURGERY IN STAGE III OVARIAN CANCER

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OBJECTIVES: Hyperthermic intraperitoneal chemotherapy (HIPEC) is a new addition to standard treatment of stage III ovarian cancer with neoadjuvant chemotherapy plus interval cytoreductive surgery (CRS). To support information for policy decision making upon reimbursement, the purpose of this study was to perform a cost-effectiveness analysis and assess organizational implications of introducing HIPEC for ovarian cancer (OVHIPEC). METHODS: A Markov model was build to compare OVHIPEC (in combination with CRS) to standard interval CRS. The analysis was performed from a societal perspective of the Netherlands. Clinical outcomes were derived from a recently presented Dutch randomized controlled trial (OVHIPEC1 study, NCT004262577). Cost data were based on the OVHIPEC1 study, from treatment protocols and standard prices. Costs included neo-adjuvant chemotherapy, surgery +/- HIPEC, admission days, complications, outpatient visits, end-of-life-care and societal costs. Utilities were derived from literature. Interviews with medical oncologists and gynecological surgeons were conducted to determine organizational implications and possible barriers for the uptake of OVHIPEC. RESULTS: Total healthcare costs were €45,829 (95%-Credible Interval (CrI) 43,199-48,627) for interval CRS compared to €56,921 (95%-CrI 53,312-61,100) for OVHIPEC. OVHIPEC resulted in 1.93 (95%CrI 1.58-2.25) Quality Adjusted Life Years (QALY) and interval CRS only resulted in 1.58 (95%-CrI 1.31-1.85) QALYs. The incremental cost effectiveness ratio was €31,759/QALY. Given a willingness to pay (WTP) threshold of €80,000/QALY in the Netherlands, OVHIPEC had a probability of being cost effective of 83.3%. In case of a €30,000/QALY threshold (more common in Europe), the results will mainly depend on country-specific OVHIPEC- and CRS-intervention costs. Hospital capacity of performing OVHIPEC procedures in the Netherlands was identified as a possible implementation barrier. CONCLUSIONS: Although more costly than interval CRS only, the combination with OVHIPEC resulted in QALY gain. Given the current Dutch WTP threshold, OVHIPEC has a higher probability of being cost effective compared to interval CRS in stage III ovarian cancer.

PCN121: COST EFFECTIVENESS ANALYSIS (CEA) OF NIVOLUMAB IN 2ND LINE NON-SMALL CELL LUNG CANCER (NSCLC) WITH NON-SQUAMOUS HISTOLOGY (NSQ) USING A MIXED COMPARATOR OF DOCETAXEL AND PEMETREXED IN AN AUSTRALIAN SETTING

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OBJECTIVES: Lung cancer is the leading cause of cancer-related deaths in Australia with NSCLC NSQ accounting for the majority of cases. Current 2nd line treatment for NSCLC NSQ in Australia is limited to either docetaxel or pemetrexed which largely are ineffective and have a low response rate. Nivolumab, an immunotherapy which blocks programmed cell death-1 inhibition of the immune system, has recently demonstrated superior overall survival in 2nd line treatment of NSCLC NSQ patients vs docetaxel in a clinical trial setting. The aim of this study was to evaluate the cost-effectiveness of nivolumab versus a basket of comparators containing docetaxel and pemetrexed which could be considered standard of care in an Australian setting. METHODS: A partitioned survival model with three health states (progression free, progressive disease and death) was developed for this CEA. The model was run for both docetaxel and pemetrexed and an average ICER was calculated. Clinical trial data was utilised for the docetaxel comparison whereas an indirect comparison was performed in order to inform the pemetrexed component of the evaluation. Australian specific cost in terms of drugs and health resources were applied. Both one/two way and probabilistic sensitivity analyses were performed. RESULTS: The results of the CEA showed that patients treated
with nivolumab saved 1.02 life years (LY) (nivolumab=2.22 vs mixed comparator=1.20). Similarly for quality adjusted life years (QALYs), nivolumab saved 0.80 QALYs when compared to the mixed comparator. This came at an additional cost of US$49.0k which equates ICERs of US$48k/LY and US$60.9k/QALY. The model was most sensitive to comparator price, extrapolation method and discount rate. **CONCLUSIONS:** This study indicates that nivolumab is a cost-effective alternative to docetaxel and metepretex in Australia with the potential of significantly decreasing both mortality and morbidity for patients treated for 2nd line NSCLC NSQ.

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**PCN123: COST-EFFECTIVENESS ANALYSIS OF CRIZOTINIB FOR UNTREATED ANAPLASTIC LYMPHOMA KINASE-POSITIVE ADVANCED NON-SMALL-CELL LUNG CANCER IN PORTUGAL**

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**OBJECTIVES:** To evaluate the cost-effectiveness of crizotinib in the treatment of ALK-positive non-small cell lung cancer (ALK+NSCLC) in the Portuguese NHS. **METHODS:** A previously developed and validated state transition Markov cohort model was used. The economic model was adapted to consider treatment strategies relevant to Portuguese setting and clinical practice. The economic model was adapted to consider treatment strategies relevant to the Portuguese clinical practice and populated with relevant epidemiological, quality of life and economic/resource use data; the latter mainly driven by evidence elicited from a panel of six Portuguese clinical experts with extensive clinical experience. First-line treatment with pemetrexed and platinum followed by switch to crizotinib (second-line) and best-supportive-care (third-line) in case of disease progression was compared with first-line treatment with crizotinib followed by switch to docetaxel (second-line) and best-supportive-care (third-line). Unit costs (medicines, procedures and hospitalizations) were extracted from Portuguese official sources. A societal perspective was adopted. Both costs and effects were discounted at 5%, and a lifetime horizon was considered. Univariate sensitivity analyses were performed over key model parameters. **RESULTS:** A treatment strategy considering crizotinib as first-line option was found to be more costly per patient, but also more effective than one considering first-line pemetrexed and platinum for patients with ALK+NSCLC. This resulted in an incremental cost-effectiveness ratio (ICER) of 29326 € per LY gained (48691 € per QALY gained). Sensitivity analyses over key model parameters indicated that the base case results were generally robust. **CONCLUSIONS:** Compared with standard first-line chemotherapy, first-line treatment with crizotinib in patients with ALK+NSCLC can be considered a cost-effective option for the Portuguese NHS by commonly used criteria in oncology.

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**PCN124: COST EFFECTIVENESS ANALYSIS OF EXEMESTANE VERSUS CAPECITABINE MONOTHERAPY FOR PATIENTS WITH HORMONE RECEPTOR-POSITIVE AND HER2-NEGATIVE, METASTATIC BREAST CANCER FROM NATIONAL CANCER INSTITUTE PRESPECTIVE IN EGYPT**

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**OBJECTIVES:** Both hormonal therapy (HT) and maintenance Capecitabine mono therapy (MCT) have been shown to extend time to progression (TTP) in patients with metastatic breast cancer (MBC) after failure of taxanes and anthracycline-containing regimens. The main objective of this study is to evaluate over a 4- year period from National Cancer Institute the costs and outcomes associated with the use of Exemestane 25mg versus Capecitabine 400mg in patients with metastatic breast cancer. **METHODS:** A Markov model with three mutually exclusive health states (metastasis, progression and death) was developed. Transition probabilities used in the model were calculated based on time to progression and overall survival data which derived from previously published clinical trial. Utility data was derived from previously published sources. Direct medical costs were collected from The National Cancer Institute. Costs and effects were discounted at 3.5% annually. Deterministic sensitivity analysis was performed. **RESULTS:** The total QALYs of the Exemestane group were estimated to be 167.3 compared with 129.5 for the Capecitabine group, with a net difference of 37.7 QALYs. The total costs for the Exemestane group and Capecitabine group were 1,699,087 EGP and 2,389,345 EGP respectively, with a net difference of 690258 EGP. These results showed that Exemestane provide better QALYS at lower costs compared to Capecitabine. **CONCLUSIONS:** Exemestane 25 mg is cost saving compared to capecitabine 400 mg in patients with metastatic breast cancer and should be recommended in National Cancer Institute tender list.

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**PCN125: ECONOMIC EVALUATION OF TRIFLURIDINE AND TIPIRACIL HYDROCHLORIDE IN THE TREATMENT OF METASTATIC COLORECTAL CANCER IN GREECE**

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OBJECTIVES: To evaluate the cost-effectiveness of triftirudine and tipiracil hydrochloride (FTD/TPI) compared with best supportive care (BSC) or regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with or are not considered candidates for available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents and anti-epidermal growth factor receptor agents in Greece. METHODS: A partitioned survival model was locally adapted from a third-party payer perspective over a 10-year time horizon. Efficacy, safety data and utility values were extracted from relevant clinical trials and published studies. Resource consumption data were obtained from local experts, using a questionnaire developed for the purpose of the study and was combined with unit costs obtained from official sources. All costs reflect the year 2017 in euros. Primary outcomes were patients’ life years (LYs), quality-adjusted life years (QALYs), total costs and incremental cost-effectiveness ratios (ICERs) per QALY and LYs gained. Both cost and outcomes were discounted at 3.5% per year. A threshold of €51,000 per QALY gained was used (3 times the GDP per capita of Greece based on WHO Guidelines). A probabilistic sensitivity analysis (PSA) was conducted. RESULTS: Total life time cost per patient for FTD/TPI, BSC and Regorafenib was estimated to be €10,443, €1,879 and €11,094 respectively. In terms of health outcomes, FTD/TPI was associated with 0.25 and 0.11 incremen in LYs compared with BSC and Regorafenib respectively. Furthermore, FTD/TPI was associated with 0.17, and 0.07 increment in QALYs compared with BSC and Regorafenib, resulting in ICERs of €34,137 per LY gained and €49,732 per QALY gained versus BSC. Moreover, FTD/TPI was a dominant alternative over Regorafenib. PSA confirmed the deterministic results. CONCLUSIONS: The results indicate that FTD/TPI may represent a cost-effective treatment option compared to other alternative therapies as a third-line treatment of mCRC in Greece.

PCN126: THE COST AND OUTCOMES OF BREAST CANCER SCREENING FOR WOMEN 40-49 YEARS OLD IN RUSSIA

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INTRODUCTION: In Russia screening for breast cancer (BC) is recommended for women 39-75 years old, though WHO recommends starting BC screening at the age of 50 in the limited resource settings. OBJECTIVES: To assess the cost and outcomes of BC screening in women 40-49 years old in Russia. METHODS: Using published data on BC screening in Russia, we estimated the number of women, who underwent screening in 2014 in age groups 40-49 and 50-69 and respective number of BC cases detected. Also for every age group we calculated expected numbers of false positive results based on published data on sensitivity and specificity of mammography. Costs of screening were estimated using the average public health insurance tariffs for mammography in the frames of screening and biopsy. RESULTS: In 2014 1.72 million women underwent screening in the age group 40-49, with the total cost of screening €6.01 million and 1,287 BC cases detected. In the age group 50-69 3.74 million women were screened, total cost of screening was €12.8 million and 5,568 BC cases were diagnosed. Thus, the average cost of BC case detected was €4,671 in age group 40-49 and €2,298 in age group 50-69. The number of false positive results of mammography per BC case detected was also twice higher in age group 40-49 than in 50-69 years old – 45 vs 21. CONCLUSIONS: BC screening in the age group 40-49 results not only in higher cost per BC case detected, but also in higher numbers of false positive results, thus questioning the expected benefits of existing screening program for the society.

PCN127: COST-EFFECTIVENESS OF AFATINIB VERSUS ERLOTINIB FOR THE TREATMENT OF SQUAMOUS NON-SMALL CELL LUNG CANCER IN FRANCE AFTER A FIRST-LINE PLATINUM BASED THERAPY


OBJECTIVES: To assess the cost-effectiveness of afatinib compared to erlotinib for the treatment of squamous NSCLC after first-line platinum based therapy from the French healthcare funders perspective. METHODS: A partitioned survival model was developed containing three health states: pre-progression, post-progression and death. Results from the LUX-Lung 8 trial which compared afatinib with erlotinib in patients with squamous NSCLC were used. Life expectancy, quality-adjusted life expectancy and direct costs were evaluated over a 10-year time horizon. Future costs and clinical benefits were discounted at 4% annually. Deterministic and probabilistic sensitivity analyses were performed. RESULTS: From the French healthcare funders perspective, patients receiving afatinib for squamous NSCLC after first-line platinum benefitted from longer life expectancy than those treated with erlotinib,
(0.94 years versus 0.78 years respectively) translating in an increase of 0.16 years. Quality adjusted life expectancy was also projected to be greater in patients treated with afatinib with an increase of 0.094 QALYs (0.567 QALYs versus 0.473 QALYs) for afatinib and erlotinib respectively. The total cost of treatment over a 10-year time horizon was higher for afatinib than erlotinib, EUR 12,364 versus EUR 9,510, leading to an incremental cost-effectiveness ratio of EUR 30,277 per QALY gained for afatinib versus erlotinib. Sensitivity analyses showed the robustness of the cost-effectiveness analysis. The base case findings remained stable under variation in a range of model inputs. CONCLUSIONS: Based on data from the LUX-Lung 8 trial, afatinib was projected to improve clinical outcomes versus erlotinib, with an 89% probability of being cost-effective assuming a willingness to pay of EUR 50,000 per QALY gained, following a first-line platinum based therapy for patients with squamous NSCLC in France.

**PCN128: TREATMENT IN TRANSPLANT ELIGIBLE MULTIPLE MYELOMA PATIENTS IN MACEDONIA: DEVELOPMENT OF COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES**: We developed a decision-analytic model to study the impact of the three induction regimens: Vincristine-Adriamycin-Dexamethasone (VAD), Thalidomide-Dexamethasone (TD), and Bortezomib-Dexamethasone (BorD) followed by autologous stem cell transplantation (ASCT) for treating multiple myeloma (MM) patients in Macedonia. Additionally, we performed a cost-effectiveness analysis (CEA) of treatment sequences to predict health effects and costs of different treatment sequences. METHODS: Model strategies were based on a previously published study for treating patients with MM in Macedonia. The data on disease progression and treatment effectiveness were obtained from the published reports of the randomized clinical trials (GIMEMA M-B2005, IFM 2005-01). Utility parameters were derived from the literature. To compare treatment combinations, we developed a decision tree model. Additionally, a cost-analysis for one time per-protocol costs was performed from a Macedonian national health-care perspective. We determined the incremental cost-effectiveness ratios (ICERs)/QALYs gained for 1-, 10-, and 20-year time horizons (TH). Costs and health outcomes were discounted for 3% to evaluate the effects of time in the model. RESULTS: The one-time per-protocol costs of BorD (€5,608) were higher than those for VAD (€299) and TD (€326), increasing the overall costs for BorD. Thus, the BorD combination was dominated in the baseline results and the ICER for VAD vs. TD was €9,607/QALY (10-year TH). However, in the discounted 20–year TH, BorD had a benefit of 7.5 QALYs (0.43–1.63 QALYs higher than TD and VAD) with ICER: €158,822/QALYs and €49,076/QALYs, respectively. CONCLUSIONS: Our analysis suggest that for the 1-year TH, VAD may be cost-effective compared to TD and BorD. However, our analysis show a gain in QALYs with BorD if we consider discounting future costs and outcomes. These results should be considered as a supportive evidence by decision makers and providers when deciding for an induction treatment strategy prior to ASCT in MM patients.

**PCN129: COST-EFFECTIVENESS OF PONATINIB IN THE TREATMENT OF PATIENTS WITH CHRONIC PHASE-CHRONIC MYELOID LEUKEMIA IN GREECE**

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**OBJECTIVES**: To evaluate the cost-effectiveness of ponatinib compared to bosutinib, allogeneic stem cell transplantation(allo-SCT) and hydroxyurea as treatment of adult patients with Chronic Phase-Chronic Myeloid Leukemia (CP-CML) who failed prior therapy with dasatinib or nilotinib for reasons of resistance/intolerance to, and for whom subsequent treatment with imatinib is not clinically appropriate, or who have the T315I mutation in the Greek healthcare setting. METHODS: A markov model with three-month cycle was locally adapted from a third-party payer perspective to reflect the natural progression of patients with CP-CML through different health states over a life-time horizon (50-years). The clinical inputs as well as utility values were extracted from relevant clinical trials and published studies. Resource consumption data of CP-CML patients were obtained from local experts and the relevant unit costs from local resources (in €2017). Primary outcomes were patient quality-adjusted life years (QALYs), total costs and incremental cost-effectiveness ratios (ICERs) per QALY gained. Both costs and outcomes were discounted at 3.5% per annum. A probabilistic sensitivity analysis (PSA) was conducted to account for uncertainty in the model. RESULTS: The analysis showed that ponatinib was associated with 4.21, 4.09 and 5.99 incremental cost-effectiveness ratios (ICERs) per QALY gained versus bosutinib, allo-SCT, and hydroxyurea, respectively. The corresponding ICERs were €38,161, €18,226 and €30,050 per QALY gained versus bosutinib, allo-SCT, and hydroxyurea, respectively. At the predefined willingness to pay threshold of €51,000
per QALY gained (3 times of Greek GDP, based on WHO), PSA estimated that treatment with ponatinib had a probability of 80% to be a cost-effective option compared to bosutinib and 94% compared to allo-SCT and hydroxyurea. CONCLUSIONS: The results indicate that ponatinib provides substantial clinical benefit as compared with current treatment alternatives at a reasonable cost. Hence, ponatinib may represent a cost–effective treatment option for patients with CP-CML in Greece.

**PCN130: TREATMENT FOR CERVIX UTERI CANCER: COST-EFFECTIVENESS ANALYSIS IN A DEVELOPING COUNTRY CONTEXT**

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**INTRODUCTION:** The cervical uteri cancer (CUCa) continues being an economic, social burden. Represents the second most common women’s cancer death. In developing countries CUCa presents in loco-regional advanced stages (IB2–IIB), and it is treated with the NCCN guidelines that recommend concurrent Radiotherapy/Chemotherapy (pRT/CT) as primary treatment. These is reduced to 66% in IIB stages. The role for surgery in IB2–IIB is controversial. Asian and some European groups use surgery as primary treatment in those stages, and could be an effective alternative in developing countries. **OBJECTIVES:** Cost-effectiveness model to compare the performance of the pRT/CT, the Total Mesometrial Resection (TMMR) and the current treatment used in a Public-Health Institution. **METHODS:** 167 cases of CACu patients with clinical stages IB2–IIB in a five-year period were studied. Clinical data, costs of attention, treatment and relapses were obtained from medical charts and micro-costing. Effectiveness was calculated from survival free relapse percentage to five years (0.81, 0.76, 0.68, 0.52, 0.56). The costs for pRT/CT and TMMR alternatives were simulated based on costs obtained from de Diario Oficial de la Federación and from the Instituto Mexicano del Seguro Social web sites. For the pRT/CT and the TMMR treatments effectiveness rates were obtained from published data (0.7 and 0.9 respectively). The standard of treatment was the pRT/CT against which we compared the TMMR and the current treatment (CuT) used at our institution. All the costs were expressed in USD **RESULTS:** From 2009-2013 we identified 167 CACu cases distributed as follows: 36, 42, 22, 28 and 39, respectively. The ICER expressed for CuT vs TMMR were as follows: 2009: $27,874.71/$17,230.29; 2011: $141,496.51/$13,493.81; 2012: $13,012.09/$7,983.11 and 2013: $8,578.07/$4,297.45, respectively. **CONCLUSIONS:** For the quinquennial, the TMMR was the dominating treatment option over CuT according to the ICER results

**PCN131: COST EFFECTIVENESS OF FULVESTRANT 500 MG IN ENDOCRINE THERAPY-NAÏVE WOMEN WITH HORMONE RECEPTOR-POSITIVE ADVANCED BREAST CANCER IN THE UK**


**OBJECTIVES:** Fulvestrant is approved for the treatment of hormone receptor (HR)-positive advanced breast cancer (ABC) after progression on anti-estrogen therapy, and in combination with palbociclib, for HR-positive, human epidermal growth factor receptor 2 (HER2)-negative ABC after disease progression on endocrine therapy. This cost-effectiveness analysis evaluated fulvestrant 500 mg versus comparators (anastrozole, letrozole, tamoxifen, exemestane, palbociclib+letrozole) in endocrine therapy-naïve patients with HR-positive, HER2-negative ABC. **METHODS:** A three-health-state partitioned survival model from the National Health Service and personal social services perspective was developed. Survival, response and adverse event (AE) data for fulvestrant and anastrozole were derived from the Phase 3 FALCON study (NCT01602380) and the Phase 2 FIRST study (NCT00274469); relative comparator data were derived from systematic literature reviews and network meta-analyses. Costs included drug acquisition, administration, disease management (progression-free, progressed disease, end-of-life), management of grade ≥3 AEs, and subsequent second- and third-line treatments (£UK,2016). Base-case health-state utility values were derived from FALCON (mixed model repeated measures analysis); scenario analysis utility values were based on FALCON and published literature. The model also considered utility decrements for AEs from published sources. **RESULTS:** Across a 30-year time horizon, incremental costs for fulvestrant versus anastrozole, letrozole, exemestane, tamoxifen or palbociclib+letrozole were £19,039, £23,317, £21,232, £17,205 and £120,658, respectively. Incremental quality-adjusted life-years (QALYs) were 0.56, 0.77, 0.87, 0.76 and 0.09, respectively. This led to incremental cost-effectiveness ratios of £54,194, £30,139, £24,472 and
£22,495 per QALY versus anastrozole, letrozole, exemestane and tamoxifen, respectively, while fulvestrant dominated palbociclib+letrozole. Fulvestrant was associated with longer time to disease progression and time alive versus all comparators except palbociclib+letrozole, which had greater time to disease progression. **CONCLUSIONS:** Results suggest fulvestrant 500 mg is cost effective versus other endocrine monotherapies, and dominant versus palbociclib+letrozole, in patients with endocrine therapy-naïve, HR-positive, HER2-negative ABC, with clinically significant overall survival gains and maintained quality of life.

**PCN132: AN EMPIRICAL ANALYSIS OF THE ROLE OF LEARNING BY DOING IN DYNAMIC COST-EFFECTIVENESS**

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**OBJECTIVES:** Recent literature suggests the cost-effectiveness of a therapy may vary during its lifetime. Studies have examined the rate at which benefits accrue due to new indications or higher utilization in later years when prices may decrease. This study examined the impact on cost-effectiveness due to effectiveness changes over time attributed to learning by doing within an indication, thus providing greater consistency in assessing an incremental cost-effectiveness ratio (ICER) against a common standard. **METHODS:** The clinical effectiveness of three cancer regimens was estimated at product launch using data from pivotal randomized controlled clinical trials: FOLFOX (leucovorin, 5-fluorouracil, oxaliplatin) vs LVFU (leucovorin, 5-fluorouracil) for first- and second-line colorectal cancer, and gemicitabine vs 5-fluorouracil for first-line pancreatic cancer. Trends in clinical effectiveness over time were estimated using 1998–2011 data from the Surveillance, Epidemiology and End Results-Medicare linked database. Incremental costs were based on 1981–2017 time-series price data from AnalySource. **RESULTS:** The hazard ratio relative to that of the comparator drug fell over time for all three regimens, suggesting improving relative effectiveness. All three regimens showed the same price patterns with moderate initial rises followed by precipitous declines after loss of exclusivity. The relative effectiveness and price trends caused the cost-effectiveness ratios of each regimen to improve over their lifecycles. For example, the first-line FOLFOX ICER began at $70,000 when launched in 2000, but decreased to $20,000 per life-year gained by 2011. **CONCLUSIONS:** This study suggests that ICERs estimated at launch based on clinical trial effectiveness data may be unrepresentative of actual cost-effectiveness across the lifecycle of therapies, and may underestimate the societal value of therapeutic innovation in cancer. Additionally, it suggests that learning by doing effects can drive changes in incremental effectiveness that outweigh the effects seen in studies looking only at price, indication, and utilization patterns over time.

**PCN133: COST EFFECTIVENESS OF RIBOCICLIB PLUS LETROZOLE VERSUS PALBOCICLIB PLUS LETROZOLE FOR THE TREATMENT OF POST-MENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE (HR+), HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE (HER2-) ADVANCED OR METASTATIC BREAST CANCER FROM A US PRIVATE THIRD-PARTY PAYER PERSPECTIVE**

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**OBJECTIVES:** To assess the cost effectiveness of ribociclib+letrozole (Rib) versus palbociclib+letrozole (Pal) for the first-line treatment of post-menopausal women with HR+/HER2- advanced or metastatic breast cancer using a US third-party payer perspective (commercial). **METHODS:** The lifetime costs and effectiveness of treatment were simulated using a cohort-based, three-state (progression-free [PF], progressed disease [PD], and death) partition survival model with a one-month cycle length. Clinical data were derived from the MONALEESA-2 trial of Rib and a meta-analysis of Pal studies. Cost inputs included costs for wholesale drug acquisition excluding co-payment (28-day treatment cycle price: $10,950, $8,760, and $4,380 for ribociclib 600mg, 400mg and 200mg, respectively, versus $10,963 for palbociclib [all strengths]), administration (Medicare physician fee schedule), disease monitoring, adverse events (treatment-related Grade 3+), and subsequent therapies. The impact of discontinuation and dose reduction on drug costs were considered for both therapies. Effectiveness was valued in quality-adjusted life years (QALYs), with utility weights derived from EQ-5D-5L data collected in MONALEESA-2 for PF and from the literature for PD. Costs and effects were discounted at 3.0% per year. Uncertainty was assessed via deterministic and probabilistic sensitivity analyses. **RESULTS:** At lifetime, the total cost of Rib was $432,095 (drug cost=$228,801; health state cost=$203,294) versus $475,132 ($256,509 and $218,623, respectively) for Pal. The QALYs for Rib were 3.07 (PFS=2.17; PD=0.90) versus 2.99 (PFS=1.99; PD=1.00) for Pal. Rib was less costly (-$43,037) and more effective (+0.086 QALY) than Pal, and was hence the dominant strategy. The probability that Rib was cost-effective versus Pal at $50,000 per QALY was 72.5%. Differences in drug acquisition costs were the key driver of results. **CONCLUSIONS:** In the US, Rib is a cost-effective alternative to Pal for first-line treatment of post-menopausal women with HR+/HER2- advanced or metastatic breast cancer.
PCN135: COST-EFFECTIVENESS OF NIVOLUMAB (NIVO) COMBINED WITH IPILUMIMAB (IPI) COMPARED WITH NIVO AND IPI MONOTHERAPIES IN THE FIRST-LINE TREATMENT OF ADVANCED MELANOMA IN THE UNITED STATES: ANALYSIS USING 28-MONTH OVERALL SURVIVAL (OS) DATA FROM CHECKMATE 067

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OBJECTIVES: The objective of this study was to evaluate the cost-effectiveness of NIVO+IPI versus NIVO and IPI monotherapies in the first-line treatment of patients with advanced melanoma from a US payer perspective, using recently reported 28-month OS data from the CheckMate 067 trial. METHODS: This three-state partitioned survival model was developed from projections of OS and progression-free survival (PFS) to estimate accrued quality-adjusted life-years (QALYs), drug acquisition, follow-up, and toxicity costs over a life span time horizon (30 years). While previous models were informed by network meta-analysis methods, our analysis used survival extrapolations based on within-trial parametric modeling to test model sensitivity. Parametric fits were selected based on statistical and visual goodness of fit and the clinical plausibility and consistency of the OS and PFS combinations (NIVO+IPI: Gompertz for OS and PFS; both NIVO and IPI: log normal for OS and generalized gamma for PFS). General population mortality was also applied. Adverse-event frequencies and utility weights were obtained from CheckMate 067, and all costs from expert input and publicly available sources/literature. Incremental cost-utility ratios (ICURs) for NIVO+IPI were estimated. A 3.5% discount rate was applied to costs ($US 2016) and utilities. Deterministic and probabilistic sensitivity analyses were conducted. RESULTS: Using the best fitting curves, NIVO+IPI was estimated to have 2.46 and 4.23 incremental QALYs and $88,344 and $149,903 incremental costs over NIVO and IPI monotherapies, respectively. The ICURs for NIVO+IPI were $35,893 versus NIVO and $35,431 versus IPI. These findings were found to be consistent in the deterministic and probabilistic sensitivity analyses. CONCLUSIONS: This analysis highlights that NIVO+IPI combination has a longer survival than either monotherapy and, when combined with the incremental costs associated with NIVO+IPI, the ICURs indicate that it is likely to be a cost-effective option compared with monotherapy.

PCN136: COST-EFFECTIVENESS OF PONATINIB IN THE TREATMENT OF PATIENTS WITH ACCELERATED OR BLAST PHASE - CHRONIC MYELOID LEUKEMIA IN GREECE

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OBJECTIVES: To evaluate the cost-effectiveness of ponatinib compared to bosutinib, allogeneic stem cell transplantation (allo-SCT) and hydroxyurea in the treatment of adult patients with accelerated or blast phase - Chronic Myeloid Leukemia (AP/BP-CML) whose disease is resistant/ intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate, or who have the T315I mutation in the Greek healthcare setting. METHODS: A markov model was locally adapted from a third-party payer perspective over a 50-year time horizon. Efficacy, safety and utility data were extracted from relevant clinical trials and the literature. Resource consumption data were obtained from local experts and were combined with unit costs (in €2017) obtained from official sources. Primary outcomes were patient quality-adjusted life years (QALYs), total costs and incremental cost-effectiveness ratios (ICERs) per QALY gained. All the future outcomes were discounted at 3.5% per annum. A probabilistic sensitivity analysis (PSA) was conducted. RESULTS: Total life time cost per patient in BP-CML was estimated at €29,895, €16,038, €42,893, and €60,609 for ponatinib, bosutinib, allo-SCT and hydroxyurea, respectively. In terms of health outcomes, ponatinib was associated with 0.96, 0.48 and 1.05 increment in QALYs compared with bosutinib, allo-SCT and hydroxyurea respectively, resulting in ICERs of €14,481 and €20,288 per QALY gained versus bosutinib and hydroxyurea. Similar results were found in AP-CML with ICERs reaching at €679 and €13,878 per QALY gained, respectively. Moreover, ponatinib was a dominant alternative over allo-SCT in both AP/BP-CML. PSA revealed that the probability of ponatinib being a cost-effective option at the predetermined threshold of €51,000 per QALY gained was higher than 95% versus all available comparators in both AP/BP-CML. CONCLUSIONS: The results indicate that, ponatinib seems to be a cost-effective option compared to other alternative therapies in the treatment of AP/BP-CML patients in Greece.

PCN137: PHARMACOECONOMIC ANALYSIS OF ENZALUTAMIDE AND ABIRATERONE FOR TREATMENT OF CHEMOTHERAPY-NAIVE PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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OBJECTIVES: Enzalutamide and abiraterone acetate plus prednisone (hereafter referred to as abiraterone) are approved for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in Russia, both for chemotherapy-naïve and post-chemotherapy patients. Currently, abiraterone is included in the Vital and Essential Drug List (VEDL) in Russia, while enzalutamide is not. This pharmacoeconomic evaluation compared enzalutamide and abiraterone used prior to chemotherapy in patients with mCRPC from the Russian healthcare system perspective. METHODS: Based on PREVAIL (enzalutamide), COU-AA-302 (abiraterone), TAX327 (docetaxel) and TROPIC (cabazitaxel) data, we proposed an mCRPC Markov chain stochastic process model and calculated medical costs (medications, adverse events treatments, treatments of bone metastases, pre-medications, pain relief and oncologist visits) associated with two options considered as best practise by Russian experts: consecutive use of enzalutamide or abiraterone, followed by docetaxel and then cabazitaxel after progression on docetaxel. We used the 8-year time horizon because >97% of patients in the model die by the end of this period. Budget impact, cost-effectiveness and cost-utility analyses were conducted for enzalutamide and abiraterone. Each of them was compared with consecutive use of docetaxel and cabazitaxel without the preceding therapy with any of the studied drugs. RESULTS: Enzalutamide was found to be a cost-saving option compared to abiraterone. Monthly medication costs for enzalutamide were $3760 per patient, 11.7% less than for abiraterone. The 8-year discounted total medical costs for enzalutamide and abiraterone were $114,307 and $121,272 per patient, respectively, indicating that the 8-year health budget could be cut by $696,500 per 100 mCRPC patients through treatment with enzalutamide. Enzalutamide was also found to be cost-effective compared to abiraterone when both were compared against chemotherapy alone. CONCLUSIONS: Enzalutamide is a cost-saving and cost-effective option compared to abiraterone and should be recommended for inclusion into the VEDL in Russia.

PCN138: THE IMPACT OF TREATMENT-FREE REMISSION OF TASIGNA® FOR CML PATIENTS IN CHINA – A COST EFFECTIVENESS ANALYSIS

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OBJECTIVES: Tasigna (TAS) has been approved by CFDA and been recommended as the first-line treatment of CML in China in 2016, since TAS was designed to be a more potent and selective inhibitor of BCR-ABL than Glivec (GLV), and TAS achieves deeper responses earlier. This study aims to conduct a cost effectiveness analysis (CEA) of following two initiatives in managing CML patients in China: 1) first line treatment using TAS for newly diagnosed CML-CP patients versus GLV; 2) impact of treatment-free remission (TFR) from TAS. METHODS: Local clinical and cost data were collected in a top-level hospital in China. A decision-analytic model based on a previously published structure and real world evidence were applied to simulate and evaluate the long term clinical and economic outcomes associated with different CML treatments (TAS or GLV). Treatment discontinuation were followed by ELN 2013 guidelines and safety. The condition for TFR was that the patients have had at least 36 months of TKI and maintained MR4.5 for the last 12 months. TFR data were extracted from ENESTfreedom trial, and more cost for monitoring of molecular responses considered during TFR. The association were identified between 3-month BCR-ABL level and the long term MR4.5 accumulated rate among CML-CP patients with TKI treatment from ENESTnd trial data. RESULTS: TAS was a cost effective alternative of GLV when considering TFR. Different assumptions of treatment benefits and costs were taken to address uncertainties and were tested with sensitivity analyses, but didn’t change the outcome. CONCLUSIONS: The RWE and CEA proved the physicians and payers’ belief of replacing GLV by TAS, as the consequent TFR from TAS is a key contributor to better patient outcomes and less cost, hence dramatically increasing life expectancy and quality-of-life (QoL) saving for CML-CP patients.

PCN139: COST-EFFECTIVENESS ANALYSIS OF HAPLOIDENTICAL VS MATCHED UNRELATED ALLOGENEIC HEMATOPOIETIC STEM CELLS TRANSPLANTATION IN PATIENTS OLDER THAN 55 YEARS

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Due to limited donor availability, high comorbidities and cost issues, allogeneic hematopoietic stem cell transplant is not universally accessible. Haploidentical related donors can be found for almost every patient but no economic evaluation has been previously conducted to compare this alternative strategy to match sibling
transplant. **OBJECTIVES:** The aim of our study was to conduct a cost-effectiveness analysis of haploidentical vs matched unrelated donor (MUD) transplant. **METHODS:** 55 patients with hematological malignancies older than 55 years who underwent haploidentical or MUD between 2011 and 2013 in Marseille (Institut Paoli-Calmettes). The ICER has been calculated using OS as effectiveness. Costs were calculated using a micro-costing strategy from the societal perspective restricted to direct medical costs with a time horizon at two years. Mean and median OS and PFS were assessed using Kaplan-Meier estimator. The confidence regions of the ICERs were calculated with the Fieller’s method. Probabilistic and sensitivity analyses were performed on the incremental cost-effectiveness ratio. **RESULTS:** 29 patients underwent haploidentical transplant and 63 matched unrelated transplant. Clinical results were already published (Blaise D et al, Biol Blood Marrow Transplant. 2015). The mean OS was respectively 19.4 (1.8) months and 15.1 (1.2) months (p=0.06) and the mean cost was respectively 98,304 (40,872) € and 151,373 (65,742) € (p<0.01). In our study, HRD-SCT dominated UD-SCT with a better effectiveness at a lower cost. Sensitivity analysis showed that our results were robust to changes in expensive drug's unit costs and hospitalisation unit costs. The incremental cost-effectiveness ratio was assessed to -148,485 [-1,265,550; -64,368] € per life year gained. **CONCLUSIONS:** Our study was associated with a “real world” practice observation, with data offering good external validity characteristics. Among older patients suffering from hematological malignancies, haploidentical transplant is a promising alternative to matched unrelated transplant and first economic arguments supports its diffusion.

**PCN140:** THE COST-EFFECTIVENESS OF BRENTUXIMAB VEDOTIN AS CONSOLIDATION TREATMENT AFTER AUTOLOGOUS STEM-CELL TRANSPLANTATION IN PATIENTS WITH HODGKIN LYMPHOMA AND INCREASED RISK OF RELAPSE

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**OBJECTIVES:** To assess the cost-effectiveness of brentuximab vedotin (BV) as consolidation treatment for patients diagnosed with Hodgkin Lymphoma (HL) who have an increased risk of relapse following autologous stem cell transplant (ASCT), in a Swedish healthcare setting. **METHODS:** A Markov model with area under the curve (AUC) components, with a lifetime horizon, was constructed to compare BV to best supportive care (BSC) as consolidation treatment following an ASCT. Costs and outcomes of subsequent treatments for patients experiencing relapse were also incorporated in to the model. Clinical effectiveness for BV and BSC as consolidation treatment was based on the double blind randomized controlled phase III study AETHERA. Data on the effectiveness of subsequent treatments were collected from published data from the literature and from pivotal clinical trial results for BV in relapsed and refractory HL. Costs and epidemiological parameters were relevant to Sweden. Outcomes were measured in quality adjusted life years (QALYs). Both costs and effects were discounted at 3% as according to Swedish guidelines. To assess uncertainty, univariate deterministic and multivariate probabilistic sensitivity analyses (PSA) were performed. **RESULTS:** The estimated incremental cost-effectiveness ratio (ICER) of BV compared to BSC was SEK 409 000 (€ 42 000). One-way sensitivity analyses showed that the results were stable when central variables were varied. The PSA also showed that the model was robust and indicated that BV, as consolidation treatment following ASCT, had a high probability of being cost-effective at the willingness-to-pay thresholds accepted in Sweden. **CONCLUSIONS:** The estimated ICER was robust and below the accepted willingness-to-pay for a QALY in Sweden considering the severity of the disease. Our model indicates that consolidation treatment with BV following an ASCT is cost-effective for patients diagnosed with Hodgkin Lymphoma who have an increased risk of relapse following an ASCT, when compared to BSC in the Swedish healthcare setting.

**PCN141:** COST-EFFECTIVENESS OF TRIFLURIDINE/TIPIRACIL FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER IN PORTUGAL


**OBJECTIVES:** Colorectal cancer is the second cause of cancer related deaths in Europe. Approximately 75% of patients with colorectal cancer will present metastasis. After two treatment lines, the prognosis is poor and the average survival is about 4–6 months with best supportive care (BSC). Nonetheless, one third of metastatic colorectal cancer (mCRC) patients are still in a good condition and willing to receive further therapy. This study aimed to assess the cost-effectiveness of trifluridine/tipiracil (TAS-102) for third/fourth-line treatment of mCRC in Portugal. **METHODS:** A partitioned survival model was developed to represent the natural history of mCRC, considering a lifetime horizon. BSC was set as comparator. Efficacy and safety derived from a pooled analysis of phase II (J003) and III (RE COURSE), multicentre, randomized trials. Parametric survival analyses were performed and the best fitting survival function was selected using Akaike’s Information Criterion. Costs were retrieved from public sources. A 5% annual discount rate was adopted for costs and effects. Results were expressed in incremental
costs per life year (LY). RESULTS: On average, trifluridine/tipiracil is expected to increase mCRC patients’ undiscounted life expectancy by 0.27 LYs relative to BSC (11.1 versus 7.8 months). Trifluridine/tipiracil is expected to augment overall treatment costs by 9,899€/patient (discounted) mainly related to higher drug costs and higher patients’ survival, corresponding to an incremental cost-effectiveness ratio (ICER) of 39,487€/LY. The sensitivity analysis performed for costs and effectiveness parameters revealed low variation, with LYs gained and ICERs ranging between 0.24-0.26 and 37,489-41,508€/LY. The probabilistic sensitivity analysis confirmed that trifluridine/tipiracil is estimated to present an 80% probability of being cost-effective at a threshold of 50,000€/LY. CONCLUSIONS: In this later line setting with limited treatment options, trifluridine/tipiracil is expected to provide a clinically meaningful life expectancy increase at an incremental cost per life year gained within an acceptable range.

PCN142: TECHNICAL CHALLENGES IN COST-EFFECTIVENESS ANALYSIS FOR ONCOLOGY TREATMENTS: IDENTIFYING FREQUENT ISSUES IN MODELLING FROM NICE PERSPECTIVE


OBJECTIVES: As of today the value for money through economic models remains a significant challenge in the field of oncology. The aim of this study is to identify hurdles and causes of uncertainty in the cost-effectiveness models submitted to the National Institute for Clinical Excellence (NICE) for oncology treatments. METHODS: Since 2000, 25 oncology products (in 40 indications) received marketing authorisation by EMA. Out of the 40 indications, NICE only performed an HTA for 31 of them. A retrospective analysis of NICE technical committee’s published recommendations and comments was conducted to identify frequent technical issues in modelling. RESULTS: Overall, 45% partition-survival models (PSM), 39% Markov models, 13% semi-Markov models, were submitted and only 3% of the submissions comprised of discrete event simulations (DES). Out of the 14 submitted PSM, 43% failed to present an acceptable incremental cost-effectiveness ratio (ICER) due to biased curve-fitting/extrapolation, incorrect time horizon, inaccurate utility or survival estimates. The use of Markov models led to an underestimation of ICERS as 33% of the submissions were not recommended. Moreover, NICE pointed out the insufficient quality of data inputs. Despite the positive recommendations for the remaining submissions, DES was perceived too complex and not in line with the statistical framework expected by the technical committee. Furthermore, overall survival was not modelled accurately when semi Markov models were used. CONCLUSIONS: Our findings suggest that NICE found that the most commonly used methods (e.g. PSM, Markov model, semi-Markov model) often lack precision. In particular most complex methods (e.g. DES) lacked transparency which ultimately undermines the ability to demonstrate cost-effectiveness.

PCN143: A LITERATURE REVIEW OF HEALTH ECONOMIC ASSESSMENTS, HEALTH CARE RESOURCE UTILIZATION (HCRU), AND HEALTH RELATED QUALITY-OF-LIFE (HRQOL) IN PATIENTS WITH GASTRIC CANCER (GC)

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OBJECTIVES: To review the published evidence on health economic assessments/modelling, cost of illness/HCRU, and HRQOL/utility studies of pharmacological treatments in unresectable, advanced or recurrent GC. METHODS: Three targeted literature reviews (TLRs) were completed with searches performed in PubMed and Embase (restricted to the last 10 years), key international health technology assessment websites and databases, and recent relevant conference websites. Searches were not restricted by treatment line RESULTS: In total, 65 studies were found (economic modelling [21], HCRU and costs [25] and HRQOL [19, of which 8 reported utility data]). Twenty economic modelling studies were evaluations of first-line (1L) or second-line (2L) treatments. Where third-line (3L) modelling was performed, data was mostly taken from earlier lines. Thirteen studies were cost-effectiveness studies, mostly reporting three-state Markov models; 8 were cost-minimisation studies. HCRU and costs were mostly reported for 1L/2L settings and were not uniform across regions. Where information was reported, increase in treatment line appeared to increase length of inpatient stays and to reduce treatment duration. Utility studies reported mainly baseline utilities (0.70 - 0.75). Few studies reported post-progression utilities (0.60-0.69). One study at 2L reported utility decrements for disease progression (0.07), hospitalisation (0.08) and time-to-death (0.37, s3 months to death; 0.23, 3 to 9 months to death). Literature indicates HRQOL to be mainly driven by emotional functioning (EF), along with global quality of life (during or after treatment). EF appears to improve with treatment indicating that EF can be considered important in patients with GC. CONCLUSIONS: TLRs show that some literature exists on cost-effectiveness, HCRU, and HRQOL for advanced GC in 1L and 2L. However, further evidence generation is still warranted, mainly in the 3L setting.
PCN144: PHARMACOECONOMIC MODELLING IN THE EARLY HEALTH TECHNOLOGY ASSESSMENT OF GENERIC PEGYLATED LIPOSOMAL DOXORUBICIN

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OBJECTIVES: to carry out pharmacoeconomic modeling for an early health technology assessment (HTA) of the generic pegylated liposomal doxorubicin (PLD) drug in patients with metastatic breast cancer (MBC) at a high risk of cardiac events with prior adjuvant anthracycline therapy. METHODS: a Markov model and Decision tree model were developed to simulate and to compare the costs and effects of new generic PLD versus doxorubicin. Treatment efficacy data were derived from the clinical trials: overall survival, fatal and non-fatal cardiac events. Time horizon of the analysis was 6 years, costs and benefits were discounted by 3.5%. Using the willingness to pay threshold (WTP) criteria for economic value, we determine value-based pricing for new generic PLD. WTP for Russian health care system was estimated at €26,383 (1648924 RUB), exchange rate mean in 2017 - €1 = 62.5 RUB. RESULTS: in case of cardiac mortality events PLD provides additional 1.30 incremental life years gained (LYG) versus doxorubicin. At price 620 RUB/mg and lower (equivalent €10) new generic PLD will be more cost-effective (CER for 1 LYG) than doxorubicin. At price 620-4748 RUB/mg (€10-76) PLD will be more effective, but more expensive, showing ICER less then WTP threshold (€26,383). At price more than 4748 RUB (€76) PLD has ICER higher than WTP for Russian health care system. At price less than 1869 RUB/1 mg (€30) new generic drug will have advantages over original PLD from position of treatment cost. CONCLUSIONS: pharmacoeconomic modeling can be used for an early HTA of new medicines to determine value-based pricing for new pharmaceuticals and its financial impact on Russian health care system.

PCN145: PHARMACOECONOMIC ANALYSIS OF TRASTUZUMAB EMTANZINE IN PATIENTS WITH METASTATIC BREAST CANCER AND CENTRAL NERVOUS SYSTEM METASTASES

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OBJECTIVES: Breast cancer (BC) morbidity in Russia is the highest among all tumors. The central nervous system (CNS) is a common site of BC metastasis. CNS metastasis are associated with poor survival and disability in young age. Therapeutic options are limited to trastuzumab emtansine (T-DM1) and lapatinib plus capecitabine (LAP+CAP). The aim is to perform health-economic evaluation of trastuzumab emtansine in patients with metastatic BC and CNS metastases. METHODS: Cost-effectiveness analysis and sensitivity analysis were performed. Progression-free survival and overall survival were included into the model as the effectiveness criteria. Decision tree model with Markov cycles was used. All direct costs were calculated from the healthcare system perspective. Indirect costs (GDP loss) were calculated from social insurance funds. Costs were discounted at 3.5%. RESULTS: AEs correction was comparable in both groups. Indirect cost were 984 909 RUR/patient and 1 113 552 RUR/patient in T-DM1 group (2.23 and 1.08 years for T-DM1 and LAP+CAP, consequently). Costs of AEs were 522 380 RUR/patient/year and 686 222 RUR/patient/year, consequently when accounting for direct costs only and by 28% lower comparing to LAP+CAP (2 127 227 RUR/patient/year and 2 740 348 RUR/patient/year, consequently) when accounting for total costs. T-DM1 ICER (OS) was 1 669 273 RUR/LYG which is slightly less than cost-effectiveness threshold in Russia in 2016. Sensitivity analysis confirmed results of the baseline scenario. CONCLUSIONS: The study showed T-DM1 is a cost-effective strategy in patient with metastatic BC and CNS metastases.

PCN146: HEALTH-ECONOMICS EVALUATIONS IN FRANCE, ENGLAND, CANADA AND AUSTRALIA: COMPARISON OF METHODOLOGIES AND IMPACT ON DRUGS’ ACCESS TO PATIENTS

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OBJECTIVES: To compare health-economics methodologies between four Health Technology Assessment (HTA) bodies (CEESP, NICE, CADTH and PBAC) and evaluate their impact on drugs’ access. METHODS: Each agency’s methodologies were compared based on their official guidance. An assessment grid with common key criteria was created for the analysis. Then, using HTA-Accelerator™, drugs were selected if they had a public assessment report available in each of the four agencies. Patient access was assessed by volumes reported in MIDAS™ database. The final opinions were analyzed and balanced with the effective drugs’ access to patients. RESULTS: The four agencies’ guidelines assessed similar criteria, but their expectations differed mostly in terms of perspective, numerical values,
comparators and Incremental Cost-Effectiveness Ratio thresholds with different impacts on the decision-making process. This was mainly due to different objectives in the results’ interpretation between countries: access versus price negotiation. A total of nine drugs were selected, including three hepatitis C products, three oncology drugs and three immunology therapies. Some discrepancies could be pointed out across the four agencies’ final opinions. In France, the nine drugs was commercialized and publicly funded, whatever the methodology limitations pointed out by CEESP. In England, Canada, and Australia, a third of these evaluations led to a negative or a deferred recommendation. Despite of these unfavorable evaluations, some drugs were covered by public or private funds. Patient access has sometimes been restricted to sub-populations, especially for hepatitis. CONCLUSIONS: Health-economic evaluations are more and more used by HTA authorities in their decision-making process. Despite similarities in their methodologies, the outcomes drove to heterogeneous drugs’ access. In some cases, a negative recommendation could have led to some restrictions rather than a total access deny. Despite it reflects each countries’ cultural context, there are some opportunities to create a global evaluation framework.

**PCN147: A SYSTEMATIC REVIEW OF PHARMACOECONOMIC EVALUATION OF ERLOTINIB IN THE FIRST-LINE TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER**

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**OBJECTIVES:** Targeted therapy, erlotinib, nowadays plays an important role in the first-line treatment of advanced non-small cell lung cancer (NSCLC) thanks to its effectiveness. However, its cost-effectiveness is still controversial. The aim of the study is to review the available evidence on cost-effectiveness of erlotinib in the first-line treatment of advanced NSCLC. METHODS: A systematic review was conducted to identify full-text publications in 3 electronic databases (Sciencedirect, Pubmed, Cochrane) from 2000 with key words through MeSH tool. The researches met inclusion criteria (an original economic evaluation of erlotinib in the first-line treatment of advanced NSCLC and written in English) were extracted data and summarized results into pre-specified information table. To compare the results of studies, all currency values were transferred into $USD in 2016 based on Consumer Price Index. The report’s quality of the studies was assessed via the Quality of Health Economic Studies (QHES) instrument by 3 blinded reviewers. RESULTS: From a total 94 detected papers, 9 studies were included in the review. 4 studies compared erlotinib with the best supportive care, 2 studies dealt with reverse strategy, the others compared with cisplatin plus pemetrexed, gefitinib and carboplatin plus gemcitabine. Cost-effectiveness analysis, modeling and sensitivity analysis were mostly used methods in these studies. All researches evaluated direct costs and used QALY as outcome with 3% discount rate. The ICR/QALY of studies ranged from dominant to $275,428/QALY. Based on WTP threshold, 7/9 studies concluded that erlotinib was cost-effectiveness, 2 studies comparing erlotinib with reverse strategy did not find the difference in cost-effectiveness. Using QHES tool, it has been shown the high quality of these studies with the mean score of 82.17 (6.85) on a scale of 100. CONCLUSIONS: Most studies suggested that erlotinib was cost-effectiveness in the first-line treatment of advanced NSCLC and the report’s quality of studies was high.

**PCN148: PHARMACOECONOMIC ANALYSIS OF OBITINUTUMAB PLUS CHLORAMBUCIL IN PATIENTS WITH PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA AND COEXISTING CONDITIONS**

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**OBJECTIVES:** Chronic lymphocytic leukemia (CLL) is the most frequent leukemia in adults. The majority of patients are older than 70 years, and many present with coexisting conditions. Patients with CLL and coexisting conditions have less favorable outcome. The main objective of the study was to perform health-economic evaluation of obinutuzumab plus chlorambucil in patients with CLL and coexisting conditions in comparison to ibrutinib. METHODS: Research was conducted from a position of the state healthcare system by means of decision tree modeling with Markov cycles. Direct costs were considered. Cost-effectiveness analysis and sensitivity analysis were performed. Progression-free survival (PFS) by the end of the first modeling year, overall survival (OS), and overall response (OR) by the end of modeling period were used as the effectiveness criteria. RESULTS: The use of obinutuzumab plus chlorambucil was characterized by smaller direct total cost (3 682 192 RUB/patient) in comparison with ibrutinib (12 453 527 RUB/patient): the difference in total costs for one patient reached 338% or 8 771 335 RUB at the modeling horizon of 27 months. The two drug strategy had comparable effectiveness: the difference in effectiveness criteria values did not exceed 10%. CER PFS, CER OS, and CER OR for obinutuzumab plus chlorambucil were considerably lower compared to ibrutinib (3 780 005 RUB vs 6 148 776 RUB; 4 046 364 RUB vs 14 480 845 RUB, respectively). The results of budget impact analysis showed that in comparison to ibrutinib strategy, obinutuzumab strategy is more preferable, as it allows to save up to 877 133 516 RUB and to additionally treat up to 238 people. Sensitivity analysis confirmed the results of the baseline
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OBJECTIVES: As treatment is determined predominantly by the early stage of NSCLC, the objective of this study is to assess if staging only with PET/CT and Brain MRI without CT is accurate, reliable and cost-effective. CT staging may suggest curative resection with its subsequent costs and outcomes, but with PET/CT staging surgical procedures may be proved unnecessary, reducing costs and help patients avoid futile therapeutic procedures. METHODS: The study is based on 30 NSCLC patients from a prospective clinical study who underwent diagnostic Thorax CT and integrated PET/CT combined with Brain MRI. Imaging was performed between December 2014 and November 2016 and positive Brain MRI was used to exclude patients and only patients staged from I A to I I A by the CT imaging were included. To calculate treatment costs, we differentiated among costs for diagnosis, and cost for non-surgical treatment according to the clinical tumor stage. RESULTS: Divergence among staging with CT alone or PET/CT alone occurred in 50% of the cases. 16 patients underwent a surgery after PET/CT scanning, 7 directly and 9 after receiving cytostatic treatment, while 14 avoided an unnecessary thoracotomy as even after chemotherapy were medically inoperable. CT imaging suggested 9 surgeries without further scanning or/and a chemotherapeutic scheme, from which only 3 patients could really undergo curative resective surgery. Average cost for direct thoracentesis was 6.06€, for those who needed priorly chemotherapy was 9.06€ and for inoperable patients with palliative therapy 5.109€, while the average cost for both PET/CT and Brain MRI was 1.337€. CONCLUSIONS: Accurate staging of patients with NSCLC plays a significant role in determining the adequate treatment strategy and optimizing the patient prognosis. The combination of PET/CT-Brain MRI can provide a reliable method for tumor and nodal staging plus distant metastasis detecting, reducing needless thoracotomies and its associated morbidity and costs.

PCN152: COST EFFECTIVENESS ANALYSIS OF SORAFENIB VERSUS BEST SUPPORTIVE CARE IN PATIENTS WITH ADVANCED HEPATOCELLULAR CARCINOMA FROM HEALTH CARE SYSTEM PERSPECTIVE IN EGYPT.

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OBJECTIVES: Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is a major health problem accounting for more than 626 000 new cases per year worldwide. It is the third most common cause of cancer death with mortality to incidence ratio of 0.93. The objective of this study was to compare costs and outcomes associated with the use of Sorafenib 200 mg versus best supportive care in patients with advanced HCC over a time horizon of 4 years from the Egyptian health care system perspective. METHODS: A Markov model was developed to estimate the project- economic implications of this therapy. Transition probabilities were estimated from the SHARP randomized controlled trial. Health effects were expressed in terms of life-years gained (LYGs). Direct medical costs were collected from the local hospitals. All costs and effects were discounted at 3.5% annually, as recommended by Egyptian guidelines. Deterministic sensitivity analysis was performed. RESULTS: Sorafenib 200mg is revealed to cost an additional cost of EGP 9,906,257 with an expected gain in life years by 0.87 LYG or an incremental cost effectiveness ratio (ICER) of EGP 11,391,257.74 /LYG compared with best supportive care. Deterministic sensitivity analysis showed that Sorafenib median time to radiological progression had the greatest impact on the results. CONCLUSIONS: Compared with commonly accepted willingness-to-pay threshold Sorafenib is not cost effective, and yields an ICER value higher than societal willingness- to- pay threshold limits.

PCN153: COST-EFFECTIVENESS ANALYSIS OF AFATINIB VERSUS GEFITINIB IN EGFR-MUTATED POPULATION WITH ADVANCED NON-SMALL-CELL LUNG CANCER IN FRANCE


OBJECTIVES: The irreversible ErbB-family–blocker afatinib and the reversible EGFR tyrosine-kinase–inhibitor gefitinib were compared in the multicenter, international, randomized, head-to-head phase-2b LUX-Lung 7 trial for first-line treatment of advanced EGFR-mutation–positive non–small-cell lung cancers (EGFRm+ NSCLCs). Afatinib and gefitinib costs and patients’ outcomes in France were assessed. METHODS: A partitioned survival model was designed to assess the cost-effectiveness of afatinib vs. gefitinib for EGFRm+ NSCLCs. Outcomes and safety were taken primarily from the LUX-Lung 7 trial. Resource use and utilities were derived from the trial, an expert-panel questionnaire and published literature, limiting expenditures to direct costs. Incremental cost-effectiveness ratios (ICERs) were calculated over a 10 year-time horizon for the entire population, and EGFR exon-19 deletion (del19) or...
exon-21 L858R-mutation (L858R) subgroups. Deterministic and probabilistic sensitivity analyses were conducted. **RESULTS:** For all EGFR-m+ NSCLCs, the afatinib-vs.-gefitinib ICER of was €45,211 per quality-adjusted life year (QALY) (0.170 QALY gain for an incremental cost of €7,697). ICERs for del19 and L858R populations were €38,970 and €52,518, respectively. Afatinib had 100% probability to be cost-effective at a willingness-to-pay threshold of €70,000 per QALY for patients with common EGFR mutations. **CONCLUSIONS:** First-line afatinib appears cost-effective compared to gefitinib for patients with EGFR-m+ NSCLCs.

PCN154: THE CHOICE OF EFFECTIVENESS CRITERIA AFFECTS CONCLUSIONS OF ECONOMIC EVALUATION OF HEALTH CARE INNOVATIONS: EXAMPLE BASED ON A RANDOMISED MULTICENTER TRIAL COMPARING TWO REDUCED INTENSITY CONDITIONING REGIMEN (FLU-BU-ATG) VS. (FLU-TBI) FOR MATCHED RELATED ALLOGENEIC STEM CELLS TRANSPLANTATION.

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**OBJECTIVES:** Our study compared cost-effectiveness analyses using three different effectiveness criteria: the PFS, the OS and the QALY on the basis of a multicenter randomized trial comparing two Reduced Intensity conditioning regimen for matched related allo-SCT published in 2013 (Blaise et al, Cancer, 119(3):602-11, 2013). **METHODS:** 139 patients were treated (FBA:N=69; FTBI:N=70). Groups were comparable. Direct medical transplant costs were estimated by micro-costing on the basis of patients’ CRF until 18 months after transplant from the hospital point of view. Costs of treatment of progression were estimated within 5 years after transplant. We performed 3 separated cost-effectiveness analysis, using respectively PFS, OS and QALY as endpoint. When using PFS as effectiveness, relapse costs were not included. **RESULTS:** At five years, OS and PFS did not statistically differ between groups. The mean total cost per patient was not statistically different between groups (111725€ for FBA vs 98316€ for FTBI, NS). Using PFS as endpoint, the ICER of FBA compared to FTBI is 35034 € per year of PFS gained, and the probability of FBA being a cost-effective choice of treatment was ~70% at the willingness-to-pay level of euros 50 000/year of PFS gained. Using OS, the ICER became non-statistically significant. Using QALY the ICER is non-statistically significant again, even considering 3 weighted health states (DFS, progression and death) and 4 weighted health states (DFS without GVHD, DFS with GVHD, progression and death) for the QALY calculation. **CONCLUSIONS:** The choice of effectiveness criteria is crucial since it affects conclusions of economic evaluation. Using Intermediary endpoints allows economic evaluation to be available earlier in the life cycle of an innovation. However, it implies strong hypotheses about the predictive value of the PFS over the OS, and it does not include quality of life considerations. Longer period evaluation and QALY may reverse preliminary results.

PCN155: COST EFFECTIVENESS OF NIVOLUMAB FOR PATIENTS WITH ADVANCED, PREVIOUSLY TREATED RENAL CELL CARCINOMA IN SCOTLAND

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**OBJECTIVES:** In advanced, previously-treated renal cell carcinoma (RCC), nivolumab monotherapy was the first treatment to demonstrate a significant overall survival (OS) benefit in a Phase III trial setting (CheckMate 025). The superior OS benefit observed versus everolimus [hazard ratio: 0.73 (98.5% confidence interval: 0.57, 0.93); p=0.0018] is expected to translate into long-term OS benefits for a substantial proportion of patients treated with nivolumab. This expectation is based on the immunogenic nature of RCC, the immunomodulatory action of nivolumab and supportive Phase I/II data with up to 5 years follow-up. This study aimed to assess the cost effectiveness of nivolumab versus everolimus or axitinib as monotherapies for the treatment of advanced, previously-treated RCC from a Scottish National Health Service (NHS) perspective. **METHODS:** A previously reviewed de novo state-transition model was adapted to the NHS Scotland perspective. The model is based on the key clinical outcomes of disease progression and death, and is informed by CheckMate 025 data and published literature, with modelling assumptions clinically and economically validated for the NHS Scotland setting. The base case assumes efficacy and utility equivalence between everolimus (mTORi class) and axitinib (VEGFR-TKI class), and considers nivolumab’s expected immunomodulatory effect on OS. **RESULTS:** Nivolumab was associated with incremental cost-effectiveness ratios (ICERs) of €36,685 and €46,140 versus axitinib and everolimus, respectively (all list prices, Dec 2016). Robust sensitivity analyses suggest that nivolumab is a cost-effective alternative to the primary comparator of axitinib; ICERs were below £50,000 for all scenarios tested. **CONCLUSIONS:** The results show nivolumab to be a highly effective and cost-effective end-of-life treatment option for patients with advanced, previously-treated RCC in Scotland. As the first immunotherapy in RCC, nivolumab represents a notable advancement in current treatment options and is considered a step-change in the management of this life-limiting condition.
PCN156: THE IMPACT OF INCREASE IN THE PROPORTION OF EARLY BREAST CANCER CASES ON COSTS AND OUTCOMES

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INTRODUCTION: There is a widespread belief among medical specialists in Russia, that increase in the proportion of breast cancer (BC) cases detected on early stages would lead to the substantial decrease in BC costs in the following years, thus all screening interventions are considered as cost-saving. OBJECTIVES: To estimate the impact of the increase of the proportion of early BC cases on costs and outcomes for the cohort of women 50-54 years old. METHODS: We developed a model to assess lifelong costs and outcomes for the cohort of patients diagnosed with BC in 2014 at age of 50-54 (7,450 cases, 69.1% with stage I-II). Only direct medical costs (treatment and follow-up) of the BC covered by health care system were estimated, based on federal statistics, cancer registry data and experts’ survey. During the first year, costs and survival for the initial treatment were assessed. Then patients entered Markov model with 3 states: “progression-free”, “progression”, “death” with cycle length of 1 year. Transition probabilities were defined using published data, risk of death in “progression-free” state was assumed to be the same as in general population. At the next step, we estimated costs and outcomes if the proportion of early BC cases would increase by 1% (75 cases diagnosed at stage I-II, instead of IV). Costs and outcomes were discounted at 3.5% rate. RESULTS: In the base case analysis lifelong costs per cohort were €44.04 million and outcome–60,655 life years. Increase in the proportion of early BC cases by 1% resulted in €120,414 decrease in costs during the first year, but at the lifelong horizon costs increased by €110,072, and 513 life years were gained per cohort. CONCLUSIONS: The improvement in the survival of BC patients due to earlier diagnosis results in higher lifelong costs, which are not compensated by the lower cost of initial cancer treatment.

PCN157: ECONOMIC EVALUATION OF EXEMESTANE VERSUS TAMOXIFEN IN POST-MENOPAUSAL WOMEN WITH EARLY BREAST CANCER FROM THE EGYPTIAN HEALTH CARE SYSTEM PERSPECTIVE

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OBJECTIVES: Breast cancer is the most common cause of cancer death in women worldwide. It imposes a substantial economic burden on the healthcare resources in Egypt each year. It is therefore becoming increasingly important to evaluate the cost-effectiveness of Exemestane 25mg versus Tamoxifen 20mg in post-menopausal women with early breast cancer from the Health Care system perspective in Egypt. METHODS: A Markov process model over 15-year time horizon with five health states (no recurrence, local or distant recurrence, contralateral breast cancer and death) based on the Egyptian clinical practice was developed. Transition probabilities were estimated based on the results from The Intergroup Exemestane Study (IES). Health effects were expressed in terms of quality adjusted life years (QALYS). Direct medical costs were obtained from the governmental hospitals in Egypt. All costs and effects were discounted at 3.5% annually according to the Egyptian pharmaco-economic guidelines. Deterministic sensitivity analyses were conducted. RESULTS: The study revealed that Exemestane yielded an additional gain of 0.23 QALYs at lower cost estimated by EGP 24,976 than Tamoxifen over 15-years, Exemestane is the dominant therapy. Deterministic sensitivity analyses indicated that the transition probability between health states of no recurrence to distant metastasis for Exemestane arm had the greatest impact on the results. CONCLUSIONS: Exemestane 25mg is a cost saving strategy compared to Tamoxifen 20mg in post-menopausal women with early breast cancer.

PCN158: PHARMACOECONOMIC ANALYSIS OF IXABEPILON MONOTHERAPY IN PATIENTS WITH ADVANCED OR METASTATIC BREAST CANCER RESISTANT TO ANTHRACYCLINES, TAXANES AND CAPECITABINE

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OBJECTIVES: Breast cancer (BC) morbidity in Russia is the highest among all tumors. The increasing use of anthracyclines and taxanes causes growing number of patients that has developed resistance. Therapeutic options in such patients are limited to ixabepilone, eribulin or chemotherapy combination regimens. The aim is to perform health-economic evaluation of ixabepilone in patients with metastatic BC. METHODS: Cost-effectiveness analysis and sensitivity analysis were performed. Progression-free survival and overall survival were included into the model as the effectiveness criteria. Decision tree model with Markov cycles was used. All costs were calculated from the healthcare system perspective. RESULTS: An analysis showed that direct medical total costs of ixabepilone...
The primary outcome was the incremental cost per patient while providing them with 2.80 life years (LY) and 2.21 quality adjusted life years (QALY) compared to everolimus, and an ICER of 78,716 GBP/LY and 97,224 GBP/QALY compared to axitinib. The study showed ixabepilone is a cost-effective strategy in patient with advanced or metastatic BC resistant to anthracyclines, taxanes and capetitabine.

**OBJECTIVES:** To compare the cost-effectiveness in Scotland of cabozantinib with axitinib and everolimus in adult patients with aRCC following prior vascular endothelial growth factor receptors (VEGFR) targeted therapy.  

**METHODS:** An economic model was developed to assess the cost-effectiveness using a lifetime time horizon, which equated to 30 years. Efficacy (time to discontinuation, progression free survival (PFS), overall survival) data came from the phase III trial METEOR (NCT01865747) comparing cabozantinib to everolimus. Equal efficacy for axitinib and everolimus was assumed due to the absence of head-to-head studies and differences in the design of pivotal trials, which precluded an indirect comparison. Tolerability (grade 3 and 4 adverse events) data came from two phase III trials: METEOR and AXIS (NCT00678392). Treatment duration for cabozantinib and everolimus was modelled through estimating time to treatment discontinuation (TTD), while treatment duration for axitinib was assumed to reflect PFS. For all efficacy endpoints, parametric curves were independently fitted to Kaplan-Meier curves of the three treatments to estimate outcomes during and beyond the trial period. Utilities were taken from the phase III trial METEOR (NCT01865747) comparing cabozantinib to everolimus. Equal efficacy for axitinib and everolimus was assumed due to the absence of head-to-head studies and differences in the design of pivotal trials, which precluded an indirect comparison. Tolerability (grade 3 and 4 adverse events) data came from two phase III trials: METEOR and AXIS (NCT00678392). Treatment duration for cabozantinib and everolimus was modelled through estimating time to treatment discontinuation (TTD), while treatment duration for axitinib was assumed to reflect PFS. For all efficacy endpoints, parametric curves were independently fitted to Kaplan-Meier curves of the three treatments to estimate outcomes during and beyond the trial period. Utilities were taken from the phase III trial METEOR. Costs data were specific to Scotland and list prices from the British National Formulary were used for drugs for this analysis.  

**RESULTS:** In the base case, treatment with cabozantinib was estimated to cost an average of 86,378 GBP per patient while providing them with 2.80 life-years (LY) and 2.21 quality-adjusted life-years (QALY). It resulted in an incremental cost effectiveness ratio (ICER) of 93,221 GBP/LY and 115,473 GBP/QALY compared to everolimus, and an ICER of 78,716 GBP/LY and 97,224 GBP/QALY compared to axitinib. 

**CONCLUSIONS:** Treatment with cabozantinib was more costly but also more effective in terms of LYs and QALYs gained than treatment with everolimus or axitinib. These conclusions held true across a range of scenarios and sensitivity analyses, including one-way and probabilistic analyses.

**OBJECTIVES:** Tyrosine kinase inhibitors of the epidermal growth factor receptor (EGFR) are the standard treatments for Chinese patients with advanced non-small cell lung cancer (NSCLC) harboring an EGFR mutation, but their economic impact is unclear in China. 

**METHODS:** A decision-analytic model was developed to simulate 1-month patient transitions in a 10-year time horizon from Chinese healthcare system’s perspective. The health and economic outcomes of four first-line strategies (pemetrexed plus cisplatin [PC], gefitinib, erlotinib, and afatinib) among NSCLC patients harboring EGFR mutations were estimated. The clinical parameters including survival and safety data were derived from afatinib LUX-Lung trials or indirect comparison. Utilities from LUX-Lung and LUCEOR studies were used in the model. The costs were estimated through local hospital data and literature review. The patient assistance program (PAP) in China was considered. The PAP schemes of afatinib, gefitinib, and erlotinib were “buy 7, 8, and 4 months and get the rest for free,” respectively. A 5% annual discount rate was applied to both costs and outcomes. 

**RESULTS:** In the base case, treatment with cabozantinib was estimated to cost an average of 86,378 GBP per patient while providing them with 2.80 life-years (LY) and 2.21 quality-adjusted life-years (QALY). It resulted in an incremental cost effectiveness ratio (ICER) of 93,221 GBP/LY and 115,473 GBP/QALY compared to everolimus, and an ICER of 78,716 GBP/LY and 97,224 GBP/QALY compared to axitinib. 

**CONCLUSIONS:** Treatment with cabozantinib was more costly but also more effective in terms of LYs and QALYs gained than treatment with everolimus or axitinib. These conclusions held true across a range of scenarios and sensitivity analyses, including one-way and probabilistic analyses.
PERFORMED. RESULTS: Afatinib achieved additional 0.38, 0.22, and 0.17 quality-adjusted life-years (QALYs) with marginal costs of ¥20,545, ¥31,760, and ¥−10,917 with the PAP, which resulted in ICERs of ¥53,834, ¥147,059 and ¥−62,812 (afatinib dominates) per QALY gained, compared to PC, gefitinib, and erlotinib, respectively. These results indicated that afatinib is cost-effective at a willingness-to-pay threshold ¥161,940/QALY in China. The price of pemetrexed, the EGFR mutation prevalence, and the utility of progression-free survival were those factors that had considerable impacts on the model outcomes. CONCLUSIONS: These results indicated that EGFR TKI, afatinib, might be a cost-effective treatment option than traditional chemotherapy and other EGFR-TKIs in China.

PCN161: THE COST-EFFECTIVENESS OF LIVER TRANSPLANTATION COMPARED TO CHEMOTHERAPY FOR NON-RESECTABLE LIVER-ONLY METASTASES AFTER COLORECTAL CANCER (MCRC).

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OBJECTIVES: Patients with non-resectable liver-only metastases after colorectal cancer (mCRC) are currently treated with palliative chemotherapy. mCRC has for a long time been considered a contraindication for liver transplantation (LTx). LTx was revisited as a treatment option for mCRC through the SECA-I trial (n=23). LTx increased the 5-year survival from 10% to 60%. Our objective was to estimate the cost-effectiveness of LTx compared to chemotherapy for patients with non-resectable liver-only mCRC. METHODS: We developed a Markov Model with a lifetime perspective, and estimated the life years (LY) and quality-adjusted life years (QALYs) gained, health care costs and cost-effectiveness of LTx compared to chemotherapy for patients aged 55 years with non-resectable liver-only mCRC. Model inputs were estimated using patient-level data from the SECA-I trial, reconstructed data on patients who received chemotherapy (NORDIV VII-trial) that have previously been matched to the SECA-I trial, a previously developed decision-model on the cost of chemotherapy, treatment protocols, literature and experts opinions. We ran probabilistic analyses and estimated the cost-effectiveness acceptability (CEAC) and the expected value of perfect information (EVPI). We explored how more strict treatment criteria, based on tumor diameter, time from primary diagnosis, CEA levels and chemotherapy response, affected the results. RESULTS: LTx increased the life expectancy and QALYs by 2.81 years and 2.00 QALYs, to a cost of $269,289 and $57,642 for LTx and chemotherapy, respectively. Given a willingness to pay (WTP) of $98,000, LTx had an 88% (LY) / 50% (QALYs) probability of being cost-effective, with an individual EVPI of $4,000 (LY). More strict treatment criteria increased the probability for LTx to be cost-effective. CONCLUSIONS: LTx was cost-effective with an 88% (LY)/50% (QALYs) probability. More strict treatment criteria increases the probability of LTx to be cost-effective. Our results support continued exploration of liver transplantation for patients with mCRC.

PCN162: COST-EFFECTIVENESS IN ENGLAND OF CABOZANTINIB FOR PATIENTS WITH ADVANCED RENAL CELL CARCINOMA (ARCC) AFTER FAILURE OF PRIOR THERAPY

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OBJECTIVES: The aim of this study was to compare the cost-effectiveness of cabozantinib with an appropriate comparator in adult patients with ARCC following prior vascular endothelial growth factor receptor (VEGFR) targeted therapy from an English National Health Service (NHS) perspective METHODS: A 3-stage, partitioned-survival model was developed to assess the cost-effectiveness of cabozantinib and its comparators. Efficacy (time to discontinuation, progression free survival [PFS], overall survival [OS]) and tolerability (grade 3 and 4 adverse events) data came from the METEOR (NCT01865747, cabozantinib vs everolimus), CheckMate025 (NCT01668784, nivolumab vs everolimus) and AXIS (NCT00678392, axitinib vs sorafenib) trials. An indirect treatment comparison was performed. RESULTS: Afatinib achieved additional 0.38, 0.22, and 0.17 quality-adjusted life-years (QALYs) with marginal costs of ¥20,545, ¥31,760, and ¥−10,917 with the PAP, which resulted in ICERs of ¥53,834, ¥147,059 and ¥−62,812 (afatinib dominates) per QALY gained, compared to PC, gefitinib, and erlotinib, respectively. These results indicated that afatinib is cost-effective at a willingness-to-pay threshold ¥161,940/QALY in China. The price of pemetrexed, the EGFR mutation prevalence, and the utility of progression-free survival were those factors that had considerable impacts on the model outcomes. CONCLUSIONS: These results indicated that EGFR TKI, afatinib, might be a cost-effective treatment option than traditional chemotherapy and other EGFR-TKIs in China.

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OBJECTIVES: Patients with non-resectable liver-only metastases after colorectal cancer (mCRC) are currently treated with palliative chemotherapy. mCRC has for a long time been considered a contraindication for liver transplantation (LTx). LTx was revisited as a treatment option for mCRC through the SECA-I trial (n=23). LTx increased the 5-year survival from 10% to 60%. Our objective was to estimate the cost-effectiveness of LTx compared to chemotherapy for patients with non-resectable liver-only mCRC. METHODS: We developed a Markov Model with a lifetime perspective, and estimated the life years (LY) and quality-adjusted life years (QALYs) gained, health care costs and cost-effectiveness of LTx compared to chemotherapy for patients aged 55 years with non-resectable liver-only mCRC. Model inputs were estimated using patient-level data from the SECA-I trial, reconstructed data on patients who received chemotherapy (NORDIV VII-trial) that have previously been matched to the SECA-I trial, a previously developed decision-model on the cost of chemotherapy, treatment protocols, literature and experts opinions. We ran probabilistic analyses and estimated the cost-effectiveness acceptability (CEAC) and the expected value of perfect information (EVPI). We explored how more strict treatment criteria, based on tumor diameter, time from primary diagnosis, CEA levels and chemotherapy response, affected the results. RESULTS: LTx increased the life expectancy and QALYs by 2.81 years and 2.00 QALYs, to a cost of $269,289 and $57,642 for LTx and chemotherapy, respectively. Given a willingness to pay (WTP) of $98,000, LTx had an 88% (LY) / 50% (QALYs) probability of being cost-effective, with an individual EVPI of $4,000 (LY). More strict treatment criteria increased the probability for LTx to be cost-effective. CONCLUSIONS: LTx was cost-effective with an 88% (LY)/50% (QALYs) probability. More strict treatment criteria increases the probability of LTx to be cost-effective. Our results support continued exploration of liver transplantation for patients with mCRC.

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everolimus. These conclusions held true across a range of scenarios and sensitivity analyses, including one-way and probabilistic analyses.

PCN163: COST-EFFECTIVENESS OF IBRUTINIB IN PATIENTS WITH RELAPSED OR REFRACTORY (RR) CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL) IN ENGLAND

**Objectives:** To assess the cost-effectiveness of ibrutinib in the treatment of patients with RR CLL, an incurable disease with limited treatment options, from the perspective of the English National Health Service (NHS). This analysis formed a key component of the appraisal by the National Institute for Health and Care Excellence (NICE). **Methods:** A three-state partitioned-survival model was used to extrapolate progression-free survival (PFS) and overall survival (OS) over a 20-year time horizon. Cost-effectiveness was estimated in RR CLL patients receiving ibrutinib vs ofatumumab (RESONATE) and vs bendamustine-rituximab (BR), idelalisib-rituximab (IR), and physician’s choice (PC) (relative efficacy based on indirect treatment comparisons). The PC comparator reflects that there was no standard of care in England and was comprised of the comparators listed within the final NICE scope. Utility values were either derived from RESONATE EQ-5D data or based on published sources and were age-adjusted. Costs of drug acquisition and administration, adverse event management, and clinical management were taken from the British National Formulary and NHS Reference costs. Costs and benefits were discounted at 3.5% p.a. Uncertainty was tested through deterministic, probabilistic, and scenario analyses. **Results:** The lifetime incremental health gains measured in quality-adjusted life years (QALYs) for ibrutinib were 2.48 vs ofatumumab, 3.07 vs PC, 1.82 vs IR, and 3.36 vs BR. The incremental cost-effectiveness ratios (ICERs) were £53,245, £52,787, £53,644, and £49,023 respectively; a confidential patient access scheme ensured the true ICERs were lower. Sensitivity analyses suggested that choice of extrapolation as well as duration of ibrutinib treatment benefit were the most influential parameters. **Conclusions:** The unprecedent survival benefit of ibrutinib resulted in considerable QALY gains vs all comparators even when the conservative assumptions of the NICE Committee were considered. Ibrutinib is a cost-effective treatment for RR CLL patients at an end-of-life threshold in England.

PCN164: COST-EFFECTIVENESS OF Nilotinib VERSUS Dasatinib FOR THE SECOND-LINE TREATMENT OF PATIENTS WITH PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE (CML-CP), RESISTANT OR INTOLERANT TO Imatinib, IN FRAME OF RUSSIAN HEALTHCARE SYSTEM

**Objectives:** The 2013 European LeukemiaNet (ELN) guidelines recommend switching to 2nd-line tyrosine kinase inhibitor (TKI) therapy as early as 6 months for patients who fail to achieve adequate molecular response (MR) (BCR-ABL1 ≤10%). They also recognize the possibility of treatment-free remission (TFR) for patients with deep MR. These emerging shifts in practice will dramatically change CML treatment patterns. This study examined the impact of these guidelines on the cost-effectiveness of nilotinib compared with dasatinib in the 2nd-line setting in Russia. **Methods:** A partitioned survival model was developed based on a published chart review. Model states included 2nd-line TKI treatment, 2nd-line TFR, post–2nd-line TKI treatment, and accelerated phase (AP) and blast crisis (BC). Molecular responses (BCR-ABL1 ≤10% and ≤0.01%) over time were not reported and were estimated based on published clinical trials. Patients sustaining BCR-ABL1 ≤0.01% became eligible for TFR, with approximately 50% of patients maintaining TFR beyond 12 months. All resource use estimates and costs were specific to Russia. Discounting at 5% of costs and effects was used. **Results:** Greater MR, progression-free survival (PFS), and overall survival (OS) for nilotinib translated into more total life years (1.64 more), greater year spent in 2nd-line TKI treatment (0.63) and TFR (0.31), and fewer years in AP/BC (-0.16). Total costs were greater in the nilotinib-treated group (2,046,144 RUB), despite a lower acquisition cost, due to more years of treatment. The incremental cost per QALY was 1,598,727 RUB. The model was most sensitive to assumptions regarding OS and PFS. Removing the option to enter TFR had minimal impact (1,688,256 RUB per QALY). **Conclusions:** Nilotinib is cost-effective compared with dasatinib for the 2nd-line treatment of CML-CP patients in a Russian public health care setting. Inclusion of TFR, which is currently recommended only within clinical studies, provides the opportunity for additional cost savings.
PCN166: MODELLING THE EFFECTIVENESS OF IBRUTINIB VERSUS PHYSICIAN’S CHOICE (PC) IN RELAPSED OR REFRACTORY (RR) WALDENSTRÖM’S MACROGLOBULINEMIA (WM) WITHIN ENGLAND

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OBJECTIVES: WM is a rare B-cell lymphoma that is relapsing and remitting and remains incurable. Treatment options are limited and data informing their effectiveness in the RR setting is sparse. We present a cost-utility model from the English National Health Service (NHS) perspective using an indirect treatment comparison to assess health outcomes of ibrutinib, the only licensed treatment for RR WM, versus PC, an assortment of commonly-used treatments. METHODS: A chart review (CR) of 454 symptomatic WM patients from more than 10 European countries was used to estimate efficacy of PC. A mixed-line cohort with median lines of prior lines of treatments matched to the PCYC1118e ibrutinib trial population was created by randomly sampling from the CR population (n = 175). A five-state cost-utility model with a 30-year time horizon was developed; progression-free survival (PFS) for ibrutinib was extrapolated from PCYC118e Kaplan-Meier data and a hazard ratio derived from a multivariate Cox proportional hazard model was applied to estimate the PFS of PC. Probability of death was informed by the CR for PC and assumed to be the general population mortality rate for ibrutinib based on PCYC1118e observation. Due to lack of WM utility data, a proxy was used from the ibrutinib RR CLL trial and a utility decrement from published literature was applied per expert opinion. RESULTS: Ibrutinib was associated with higher quality-adjusted PFS of 2.65 years per patient compared to 1.10 years associated with PC. The life-time health gain for ibrutinib was 4.94 quality-adjusted life years (QALYs) versus 2.76 QALYs for PC, an incremental 2.18 QALY survival benefit. CONCLUSIONS: The model demonstrates a substantial clinical benefit of ibrutinib over PC. The high unmet clinical need and limited data demonstrate the difficulties in assessing effectiveness in rare indications and suggests the need for real world evidence generation in WM.

PCN167: COST-EFFECTIVENESS OF AFATINIB AND ERLOTINIB AS SECOND-LINE TREATMENTS FOR ADVANCED SQUAMOUS CELL CARCINOMA OF THE LUNG IN CHINA

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OBJECTIVES: Afatinib demonstrated a statistically significant efficacy advantage compared to erlotinib for the second-line treatment of advanced squamous cell carcinoma (SqCC) of the lung in LUX-Lung 8 trial. It was approved...
by China FDA and thereafter recommended by 2017 CSCO guideline for the treatment of SqCC of the lung. However, the economic impact of this practice is unclear yet in China. METHODS: A decision-analytic model was developed to simulate 1-month patient transitions in a 10-year time horizon from Chinese healthcare system’s perspective. The health and economic outcomes of erlotinib and afatinib among patients whose SqCC of the lung progressed after at least four cycles of platinum-based chemotherapy were estimated. The clinical parameters and utilities were from LUX-Lung 8 trial. The costs were estimated by examining local hospital data and published literatures. A 5% annual discount rate was applied to both costs and outcomes. The primary outcome was the incremental cost-effectiveness ratio (ICER). Sensitivity analyses were performed. RESULTS: The afatinib strategy gained additional 0.154 quality-adjusted life-years (QALYs) than erlotinib with incremental costs of ¥50. Relative to erlotinib, afatinib resulted in an ICER of ¥325 per QALY gained. These results indicated that afatinib is cost-effective at a willingness-to-pay threshold (¥161,940/QALY) of China. The overall survival time of afatinib was the factor that had a considerable impact on the model outcomes. CONCLUSIONS: This result indicates that afatinib is a cost-effective treatment option compared with erlotinib in patients with SqCC of the lung.

**PCN168: RISK-STRATIFIED BREAST CANCER SCREENING AND NON-ADHERENCE IN GERMANY**

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**OBJECTIVES:** Stratified breast cancer screening describes the using of individual risk information to cluster women into groups who would overall benefit from intensified screening and groups who would overall benefit from reduced screening. Recent economic evaluations applied decision analytical modeling to test new methods of stratified mammography screening for women over 50 years. One major assumption in recent models is that women adhere fully to recommended screening protocols. In Germany, screening adherence is at 54%. Accordingly, full adherence is more the exception than the rule. We evaluate stratified breast cancer screening for the general population using both, full adherence and non-adherence, assumptions. METHODS: A micro-simulation Markov model is adapted to the German context. Model validation is based on the AdViSHE tool. German register and published data are used for parameters of cancer incidence, treatment and survival. Annual, biennial and triennial routine screening are compared against five strategies using different combination of three risk factor to stratify screening frequencies. As suggested in the German HTA procedure, all strategies are evaluated using efficiency frontiers. We evaluated three outcome variables (mortality reduction, QALY and false positive results) under the assumption of full adherence and an average adherence rate of 54%. RESULTS: Under the full adherence assumption, four of five stratified strategies and all routine strategies lie on the efficiency frontiers. Only one stratified strategies is dominated. Under the non-adherence assumption, biennial routine screening and two more stratified screening are dominated in mortality reduction and QALYs. Depending on the willingness-to-pay, one of the two remaining stratified screening should be selected as efficient alternatives to biennial routine screening. CONCLUSIONS: Routine and stratified screening strategies are found to be sensitive to non-adherence. The choice which strategy to recommend is affected by non-adherence. In the context of low screening adherence, routine mammography screening is not an efficient strategy.

**PCN169: VALUE COMMUNICATION STRATEGIES FOR IMMUNOTHERAPIES IN NSCLC: A QUICK EVIDENCE ASSESSMENT FROM THE UK**

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**OBJECTIVES:** Lung cancer is the third-most commonly diagnosed cancer and accounts for 13% of all new cases in the UK. Approximately 80% of lung cancer is of the non-small-cell type (NSCLC) and 35% of NSCLC have squamous histology. Till date, 13 immunotherapies have been approved by EMA for NSCLC. Recently, immunotherapies have demonstrated durable response in patients with metastatic NSCLC. The objective of the current review is to understand the strategies and challenges with value proposition of immunotherapies (immune check-point inhibitors) in NSCLC. METHODS: HTA website (NICE) and regulatory agency (EMA) for the UK were searched for immunotherapies in NSCLC. RESULTS: Immunotherapies with check-point inhibitors have demonstrated durable clinical response and manageable toxicity in patients with advanced NSCLC. Therefore, regulatory agencies have developed programs for expedited clinical development and approval of these immunotherapies. Of 13 approved immunotherapies in NSCLC by EMA, currently approved immune-check point inhibitors include nivolumab and pembrolizumab. Clinical trials are being conducted on atezolizumab, durvalumab, avelumab, ipilimumab, and tremelimumab as monotherapy as well as in combination with chemotherapy, radiation, and targeted therapies. According to NICE TA, pembrolizumab is the only recommended immunotherapy in NSCLC; however, with patient access scheme (PAS). Pembrolizumab has been recommended for treating PD-L1-positive NSCLC in adults who have had prior chemotherapy. The TA review of atezolizumab and nivolumab are still in progress by NICE. Additionally, in 2016-17, four immunotherapies for NSCLC were either terminated or not recommended by NICE owing to their higher cost. CONCLUSIONS: Despite better clinical outcomes, immunotherapies are associated with higher cost. The pricing strategy should thus be carefully planned based on evidence that is able to communicate
value. Possible approaches include evidence planning for specific efficacy in sub-groups with intensive unmet need or specific safety value planning. Further, PAS schemes could also be designed to support reimbursement.

PCN170: COST-EFFECTIVENESS ANALYSIS OF DARATUMUMAB IN HEAVILY PRE-TREATED MULTIPLE MYELOMA PATIENTS FOR THE ITALIAN HEALTHCARE SYSTEM

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OBJECTIVES: Multiple myeloma (MM) is a disease of the bone marrow characterized by the uncontrolled proliferation of immunoglobulin-producing plasma cells. It accounts for 1.2% of all cancers diagnosed in Italy and is associated with a significant burden of illness. Daratumumab monotherapy was recently approved for the treatment of adults with relapsed and refractory MM, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent, and who have demonstrated progression on the last therapy. The aim of the study is to assess the cost-effectiveness of daratumumab in this setting compared to pomalidomide and low-dose dexamethasone (LDD) in Italy. METHODS: The study is based on a survival partition model comparing treatment costs and outcomes from the Italian NHS perspective. The model was adapted using trial data, literature and local sources. Drug list prices and national tariffs were used to estimate treatment costs over a 10 year-timeframe with a 3.5% discount rate. Treatments were compared by incremental cost-effectiveness ratio (ICER) per life year (LY) gained. As Italy does not have a formalized cost-effectiveness threshold, a literature value of 60€k/LY was adopted (Messori, 2004). RESULTS: The results demonstrate the cost-effectiveness of daratumumab’s new immunotherapeutic approach compared to pomalidomide and LDD in the target population, providing an additional 1.1 LY with incremental direct costs of 36,681€. The analysis established an ICER of 34,151€ per LY gained versus pomalidomide and LDD, falling within the acceptability threshold of 60€k/LY. The results were confirmed through deterministic and probability sensitivity analyses, as in 94% (DSA) and 95% (PSA) of cases, the ICER lies within the above threshold. CONCLUSIONS: This study proves that daratumumab is a cost-effective therapy for the treatment of MM in the Italian NHS, compared to SOC for patients who have received ≥2 prior lines of therapy, including a PI or an IMiD, or who were double refractory to both.

PCN171: COST-EFFECTIVENESS OF ADDITIONAL HUMAN PAPILLOMAVIRUS VACCINATION PROGRAMMES, IN THE NETHERLANDS

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OBJECTIVES: Here we aimed to assess the cost-effectiveness of three different vaccination scenarios (i) increased coverage of the existing programme, (ii) vaccination of girls at an older age, and (iii) vaccination of teenage boys METHODS: A dynamic model was used to assess the clinical and economic consequences of the existing programme with and without the above mentioned alternative scenarios. Costs and health effects (life years and QALYs) of the alternative scenarios were compared with the outcomes of the existing programme. In sensitivity analyses the robustness of the model-predicted outcomes were assessed RESULTS: The cost-effectiveness of the existing HPV vaccination programme was estimated at €7,500 per QALY gained. Furthermore, the cost-effectiveness of a catch-up programme was estimated at above €50,000 per QALY gained. Taking into account the vaccine-induced cross-protection, small differences in cost-effectiveness between the bivalent (i.e. €5,900/QALY), quadrivalent (i.e. €7,000/QALY) and nonavalent (i.e. €5,400/QALY) vaccine were found, reflecting likely cost effective situations. Furthermore, in addition to the existing programme, the cost-effectiveness of an increased coverage up to 100%, assuming lifelong protection, was below €20,000 per QALY gained. With the vaccination coverage of 50%, the vaccination of girls at 20 years of age was likely cost-effective (i.e. €20,000-50,000/QALY) in combination with the existing programme. With the current vaccination coverage, the addition of vaccination for boys is likely not cost effective in the Netherlands. The cost-effectiveness was most sensitive to duration of vaccine-induced protection, discounting and coverage of the existing vaccination programme CONCLUSIONS: From a health-economic perspective, alternative vaccination programmes in addition to the existing programme should be considered. Cost-effectiveness of catch-up programmes or vaccination for boys were highly sensitive to the coverage of the existing programme.

PCN172: SUBCUTANEOUS VS INTRAVENOUS ADMINISTRATION OF TRASTUZUMAB IN HER2+ BREAST CANCER PATIENTS: A MONTENEGRIN COST-MINIMIZATION ANALYSIS

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OBJECTIVES: The aim of this economic analysis is to compare the total cost of subcutaneous trastuzumab (SC-TRA) vs intravenous trastuzumab (IV-TRA) for HER2-positive breast cancer patients at the Oncology Department at Clinical Center of Montenegro. HannaH study showed that SC-TRA has a pharmacokinetic profile and efficacy non-inferior to standard IV-TRA and is a valid alternative for the treatment of eligible breast cancer patients. METHODS: A cost-minimization analysis was performed using data from market research from 2016 and an administration time analysis. Total time and cost of both types of TRA administration were quantified in a time horizon of over 18 cycles therapy course. 55 patients (mean weight 72 kg) from the Oncology clinic were included in this analysis. Patients were HER2-positive and received the drug in the adjuvant (72 patients) or metastatic (19 patients) setting. Drug cost (direct costs) included only drug treatment per mean patient weight, and non- drug (indirect) costs included chair time treatments, daily hospital fee, active healthcare professional time, consumable disposals, patients’ transport and sick leaves. The model accounted the 5% wastage of IV-TRA administration. Unit costs were obtained utilizing official (Monetengrin Dug Agency (CALIMS) and clinic pharmacy) publicly available data and they were expressed in local currency (Euro) with discount applied for SC-TRA. RESULTS: Direct drug related costs per mean patient weight were up to 8.3 % savings for SC-TRA and up to 9.9% also for SC-TRA when indirect costs included. The results of the analysis were most sensitive to patient weight, daily hospital fee and % of wastage in IV treated patients. Mean savings (preparation and administration) in time with SC-TRA were 55 min. CONCLUSIONS: SC-TRA is time and cost-saving therapy for HER2+ breast cancer patients in Montenegro.

PCN173: COST MINIMIZATION ANALYSIS OF THE SELECTIVE AROMATASE INHIBITORS; ANASTROZOLE, VERSUS LETROZOLE AND EXEMESTANE FOR THE MANAGEMENT OF BREAST CANCER FROM PATIENT PERSPECTIVE IN EGYPT

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OBJECTIVES: Breast cancer (BC) is the second most common type of cancer worldwide and the most frequent cancer among women (approx. 25%) according to WHO. Globally, 1.67 million new BC cases were diagnosed in 2012, with an increased incidence after menopause. Since most BC subtypes are hormone-related, national comprehensive cancer network (NCCN)-2017 guidelines recommended the use of third-generation anti-estrogen aromatase-inhibitor endocrine therapy in early-stage post-menopausal women having hormone receptor-positive BC. The aromatase-inhibitors; Anastrozole, Letrozole, and Exemestane lower the risk of BC recurrence and metastasis when used as initial first-line adjuvant therapy in addition to tamoxifen. Those drugs have shown similar anti-tumor efficacy and toxicity profiles in randomized studies in adjuvant and preoperative settings, rendering them equivalent choices for the management of BC. Thus, this study aimed at performing cost minimization analysis for Anastrozole, versus Letrozole and Exemestane as a 5-year initial adjuvant therapy for the management of post-menopausal BC from patient's perspective in Egypt. METHODS: Direct medical costs are reported in Egyptian pounds (EGP) (1 USD=18.14 EGP). The single daily doses for Anastrozole, Letrozole, and Exemestane tablets are 1 mg, 2.5 mg, and 25 mg, respectively. Discounting was conducted for a treatment course of 5 years. One-way sensitivity analysis was performed where costs were varied with a range of ± 25%. RESULTS: Total costs for Anastrozole, Letrozole, and Exemestane were EGP18,071, EGP19,993, and EGP36,910, respectively. Thus, Anastrozole is the least expensive drug when compared to Letrozole and Exemestane for the management of BC. Sensitivity analysis showed that the study was insensitive to change using a range of ±25% in drugs’ costs. CONCLUSIONS: Anastrozole, Letrozole, and Exemestane are equivalent choices as adjuvant therapies in post-menopausal breast cancer patients. Therefore, having the lowest cost, Anastrozole is the most preferred option when compared to Letrozole, and Exemestane for the management of breast cancer from patient's perspective.

PCN174: ECONOMIC EVALUATION OF DASATINIB COMPARED TO NILOTINIB AS SECOND LINE TREATMENT OF CHRONIC MYELOID LEUKEMIA IN GREECE

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OBJECTIVES: To conduct an economic evaluation of Dasatinib versus Nilotinib as a second line treatment (SLT) of Chronic Myeloid Leukemia (CML) in Greece. METHODS: A systematic literature review was conducted to synthesize the evidence concerning the efficacy of alternative therapies. The review revealed that the available data do not indicate any difference in terms of efficacy between Dasatinib and Nilotinib in SLT. As such, a cost-minimization analysis was performed to compare Dasatinib and Nilotinib. The analysis was conducted from a third-party payer perspective with one-year time horizon. Resource consumption data were obtained from a local expert, using a questionnaire developed for the purpose of the study and were combined with unit costs (in €2016) obtained from official sources. Because the time horizon did not exceed 1 year, no discounting was necessary for cost.
throughput. One-way sensitivity analysis (OWSA) was undertaken to test the robustness of the results. **RESULTS:** The analysis showed that in SLT, the total annual cost per patient with Dasatinib and Nilotinib was estimated at €34,086 and €34,937, respectively, resulting in a cost-saving of €850.61, for the former. The OWSA showed that the results were more sensitive to the drug acquisition cost of Dasatinib and Nilotinib. **CONCLUSIONS:** Based on available clinical and local resource utilization and unit cost data, the present study suggests that, in a one-year time horizon, Dasatinib may be a cost-saving treatment option compared to other alternative therapies in SLT of CML patients in Greece.

**PCN175: EXPANDED ACCESS TO PEMBROLIZUMAB FROM COST-SAVINGS GENERATED BY BIOSIMILAR FILGRASTIM (BIOSIM-FIL) IN THE PROPHYLAXIS OF CHEMOTHERAPY-INDUCED (FEBRILE) NEUTROPENIA (CIN/FN): SIMULATION STUDY**

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**OBJECTIVES:** CIN/FN prophylaxis with BIOSIM-FIL may offer cost-savings over reference filgrastim (FIL) and pegfilgrastim (PEGFIL). The objectives were to [1] simulate, for a 20,000 patient panel, cost-savings achieved from CIN/FN prophylaxis with BIOSIM-FIL over FIL and PEGFIL; [2] estimate the budget-neutral expanded access to pembrolizumab treatment from these cost-savings; [3] determine the number-needed-to-convert (NNC) to purchase one additional pembrolizumab treatment. **METHODS:** Simulation analysis using 3Q2016 average selling price (ASP; US$) cost for one patient for one chemotherapy cycle with 5, 7, 11, or 14 days of prophylaxis. For a 20,000-patient panel, we calculated [1] cost-savings (US $) accrued from 5/7/11/14 prophylaxis converted to BIOSIM-FIL; [2] expanded access afforded by these cost-savings to pembrolizumab (1 administration Q3W for 2 years at $153,673); [3] NNC for one additional pembrolizumab treatment. **RESULTS:** Per-cycle cost-savings from BIOSIM-FIL over FIL were $327.00 (5d), $457.80 (7d), $719.40 (11d), and $915.60 (14d). For 20,000 patients, conversion from FIL to BIOSIM-FIL yields savings of (rounded) $6,450,000 (5d), $9,156,000(7d), $14,388,000 (11d), $18,312,000 (14d). These savings provide expanded access to 2y of pembrolizumab treatment to 43 (5d BIOSIM-FIL regimen), 60 (7d), 94 (11d), and 119 (14d) patients. The NNC is 470 (5d), 336 (7d), 214 (11d), and 168 (14d). As conversion-related savings relative to PEGFIL decline as daily injections increase, for 20,000 patients, conversion from PEGFIL to BIOSIM-FIL yields savings of $55,893,600 (5d), $47,177,600 (7d), $29,745,600 (11d), $16,671,600 (14d). These savings provide expanded access to 2y of pembrolizumab treatment to 364 (5d BIOSIM-FIL regimen), 307 (7d), 194 (11d), and 108 (14d) patients. The NNC is 55 (5d), 65 (7d), 103 (11d), and 184 (14d). **CONCLUSIONS:** Conversion from reference FIL and PEGFIL to BIOSIM-FIL not only yields significant savings, especially when converting from PEGFIL, but these savings can be applied to procure therapeutic cancer care with pembrolizumab on a budget-neutral basis.

**PCN176: COST-EFFECTIVENESS OF SEQUENTIAL TREATMENT CONTAINING CRIZOTINIB FOR NON SMALL CELL LUNG CANCER (ALK+) PATIENTS**

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**OBJECTIVES:** Crizotinib is approved in first-line for non-small cell lung cancer (NSCLC) ALK positive patients. This study aimed to estimate the cost-effectiveness of two different containing Crizotinib sequential treatments, in Spain. **METHODS:** A Markov model based on potential treatment lines in NSCLC patients, was developed to estimate health benefits (life year gained-LYG and quality adjusted life year-QALY) and total costs in a hypothetical patient cohort during a lifetime period. Sequence 1:crizotinib as first-line (crizotinib->ceritinib ->pemetrexed ->Best Supportive Care [BSC]) was compared to Sequence 2:crizotinib positioned in second-line (pemetrexed->platinum->crizotinib->ceritinib->BSC). Transitions between treatment lines were based on progression free survival (PFS) data observed in clinical trials. Overall survival (OS) was used to reflect the probability of death. Parametric functions adjusted to PFS and OS Kaplan-Meier curves, were used to extrapolate data from trials along the simulation period. Frequency of grade 3/4 adverse events (AE) per individual treatment and utilities were derived from literature. Total cost estimation (€,2016) included drug with official deduction (ex-factory list price for crizotinib and 0 for ceritinib as it is free currently for the Spanish NHS), chemotherapy administration (only pemetrexed), disease and AE management costs. An oncologists’ board validated and provided health resource consumption data for BSC and disease and AE management. Annual discount rate (3%) was applied. Several sensitivity analysis (SA) were
performed. RESULTS: Sequence 1 resulted in a more effective option, yielding 0.88 LYG and 0.68 additional QALY than sequence 2. Total costs for sequence 1 resulted €194,460 compared to €149,415 for sequence 2. The incremental cost-effectiveness ratios were €51,178/LYG and €66,486/QALY gained with crizotinib first-line-sequence versus the sequence 2, crizotinib in second-line. SA results confirmed the model’s robustness. CONCLUSIONS: A treatment sequence based on crizotinib in first-line resulted in a cost-effective option for NSCLC patients (ALK+) in Spain, compared to an alternative sequence with crizotinib in second-line.

PCN177: COST UTILITY ANALYSIS (CUA) OF NIVOLUMAB COMPARED TO EVEROLIMUS FOR THE TREATMENT OF METASTATIC RENAL CELL CARCINOMA (RCC) IN AUSTRALIA

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OBJECTIVES: International five-year survival rates for metastatic kidney and renal pelvis cancer are estimated at between 12-20%, indicating significant unmet clinical need for effective therapies. Currently, everolimus is a subsidised treatment option in Australia for patients who have progressive disease following first-line treatment with a tyrosine kinase inhibitor. Nivolumab is the first immunotherapy agent explored in RCC (CheckMate-025) and this study sought to assess the cost utility of nivolumab versus everolimus. METHODS: A 3-state (clinical progression free, clinical disease progression, dead) Markov model was developed with 2-week cycles. Individual patient data from the pivotal study directly informed the health state transition probabilities until a minimum follow-up of 14 months. Thereafter, survival curves were extrapolated to 10 years, followed by convergence of the curves at 20 years. Australian specific health state utilities, drug costs and disease management costs were drawn from published sources. A range of sensitivity analyses were undertaken to test the robustness of the results of the modelled economic evaluation. RESULTS: Nivolumab added an average of 0.78 life years (LYs) and 0.65 quality adjusted life years (QALYs) per person at an additional cost of US$45,000 (discounted), resulting in ICERs of US$58,000/LY saved and US$69,000/QALY saved. The sensitivity analysis showed that the result was most sensitive to the time horizon and duration of treatment. However, the ICER was stable and generally stayed within +/-10% of the base case for most of the scenarios in tested in the sensitivity analyses. CONCLUSIONS: Nivolumab represents a cost-effective alternative to everolimus, with potential to improve quality of life and survival for RCC patients in Australia.

PCN178: COST-EFFECTIVENESS OF NIVOLUMAB IN COMBINATION WITH IPILIMUMAB IN FIRST-LINE TREATMENT OF ADVANCED MELANOMA IN SWEDEN: ANALYSIS USING 28-MONTH OVERALL SURVIVAL FROM CHECKMATE 067


OBJECTIVES: The objective of this study was to evaluate the cost-effectiveness of nivolumab in combination with ipilimumab (Nivo+Ipi) compared to current therapeutic alternatives in first-line treatment of patients with advanced melanoma regardless of biomarker status in Sweden from a payer perspective using recently reported 28-month survival data from the CheckMate 067 Phase III trial. METHODS: A three-state partitioned survival model was developed from projections of overall survival and progression free survival based on a network meta-analysis which considers time-varying hazard ratios to estimate accrued quality-adjusted survival and costs over a 15-year time horizon. The analysis considered nivolumab monotherapy as the key comparator but also included ipilimumab, pembrolizumab, dabrafenib, dabrafenib + trametinib, vemurafenib + cobimetinib, and dacarbazine. Drug acquisition, administration, follow-up, subsequent therapy and adverse event costs were obtained via published sources and expert input. Adverse event frequencies were collected from the Checkmate 067 trial and published literature. Utility weights were estimated from the Checkmate 067 trial, based on UK tariffs. A 3% discount rate was applied to costs and utilities. Results were presented as incremental cost-utility ratios (ICURs). RESULTS: Nivo+Ipi was projected to have the greatest accrued survival among the competing treatments with 5.07 LYS and 3.93 QALYs and also the highest total costs (1,941,848 kr). The comparisons vs. nivolumab, resulted in an ICUR of 319,045 kr. Pairwise ICURs for Nivo+Ipi vs. other treatments ranged from 112,002 kr per QALY (vs. pembrolizumab) to 578,393 kr per QALY (vs. dacarbazine). CONCLUSIONS: The analysis highlighted that Nivo+Ipi is associated with the highest gain in quality-adjusted survival accompanied by higher costs compared to the current therapeutic alternatives. ICUR results indicated that Nivo+Ipi is likely to be a cost-effective option in the first-line treatment of advanced melanoma in Sweden.

PCN179: A COST-UTILITY ANALYSIS COMPARING TWO SEQUENCES OF TREATMENT FOR FIRST-LINE CHEMOTHERAPY IN METASTATIC PROSTATE CANCER (MCRPC): CABAZITAXEL FOLLOWED BY
DOCETAEL VERSUS DOCETAXEL FOLLOWED BY CABAZITAXEL


**OBJECTIVES:** Docetaxel and Cabazitaxel are taxane chemotherapy approved in men with mCRPC after they demonstrated improved survival in first and second line respectively. If recent data suggested similar efficacy, these two taxanes have different safety profile and unit price, raising the question of their administration sequence. A cost-utility analysis comparing two sequences of treatment (Cabazitaxel followed by Docetaxel versus Docetaxel followed by Cabazitaxel) for first-line chemotherapy in metastatic prostate cancer was performed in the French context, using data from the CABADOC randomized trial. **METHODS:** The CABADOC study is a randomized trial with a cross-over design. Patients were randomized to receive either Docetaxel 75mg/m²/q3w x 4 followed by Cabazitaxel 25mg/m²/q3w x 4, or the reverse sequence. The economic analysis included a prospective collection of resources consumed (chemotherapy, hospitalizations, transportation, nurses and consultations) and utility data (using the EQ-5D questionnaire administered before cycle 1, cycle 5 and at the end of chemotherapy) alongside the trial. Costs were evaluated from the French collective perspective and horizon time was limited from the randomization date to the end of 2nd sequence chemotherapy. The ICER was calculated and sensitivity analyses were conducted. **RESULTS:** From June 2014 to October 2016, 195 patients (median age of 70 years) were randomized in 17 centers. Patients received 3.8 ± 0.7 and 3.2 ± 1.5 cycles of chemotherapy during the first and the second period, respectively. The sequence Docetaxel-Cabazitaxel appears to be more effective (mean QALY per patient of 0.353 ± 0.025 versus 0.328 ± 0.063) and less expensive (mean cost per patient of 17 350 € ± 2955 versus 17 862 € ± 2320) as compared to the sequence Cabazitaxel-Docetaxel. **CONCLUSIONS:** The sequence of treatment with Docetaxel followed by Cabazitaxel appears the optimal one for first line chemotherapy in metastatic prostate cancer from a cost-utility standpoint. NCT: NCT02044354

PCN181: POTENTIAL THERAPEUTIC AND ECONOMIC VALUE OF RISK-STRATIFIED TREATMENT AS INITIAL TREATMENT OF MULTIPLE MYELOMA IN EUROPE


**OBJECTIVES:** Biomarkers in multiple myeloma (MM) can distinguish patients with different prognoses. This knowledge can be utilised to offer risk-stratified treatment (RST) which may be cost-effective versus a uniform treatment (UT) approach. We evaluated the potential therapeutic and economic value of RST compared to UT in newly diagnosed transplant-eligible MM patients in the Netherlands, Germany, France, Spain and England. **METHODS:** A Markov-type decision-analytic model compared lifetime health benefits and costs for two strategies: 1) UT where all patients received the standard of care consisting of bortezomib induction/maintenance; and 2) RST where treatment was stratified according to fluorescent in situ hybridization (FISH) and international staging system (ISS) as clinical and tumour markers (RST-FISH+ISS), molecular biomarkers via the SKY92 (RST-SKY92), or any biomarker (RST-FISH+ISS+S+SKY92). Input data originated from clinical trials, literature reviews, observational studies and national tariffs. Univariate sensitivity analyses were performed. **RESULTS:** Across all country perspectives, all RST scenarios dominated UT. In order of greatest potential for improved health, RST-SKY92 produced maximum health gains (0.031-0.039 QALYs) followed by RST-FISH+ISS-SKY92 (0.024-0.033 QALYs) and RST-FISH+ISS (0.001-0.004 QALYs) compared to UT. RST produced cost-savings due to lower costs of induction treatment, maintenance treatment and grade 3/4 peripheral neuropathy. In order of greatest potential for cost-savings, RST-FISH+ISS generated the greatest cost-savings (~€16,273 to €38,580) followed by RST-SKY92 (~€11,949 to €32,064) and RST-FISH+ISS+S+SKY92 (~€11,734 to €32,960) compared to UT. The greatest benefits of RST compared to UT were demonstrated in Germany, followed by France, Spain, UK and the Netherlands. The findings remained robust in univariate sensitivity analyses. **CONCLUSIONS:** RST in MM may improve health outcomes and lower costs compared to UT, and an RST strategy based on molecular markers like SKY92 offers the greatest value. These findings should encourage stakeholders to support the adoption of RST approaches in MM.
**PCN182: PHASE I/II BASED EARLY ECONOMIC EVALUATION OF ACALABRUTINIB FOR RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA**


**OBJECTIVES:** Early assessment of cost-effectiveness of new products may support development and could also support reimbursement processes through early dialogues between stakeholders. The objective of this study is to assess the cost-effectiveness of acalabrutinib for chronic lymphocytic leukemia (CLL) based on published phase I/II data.

**METHODS:** A partitioned survival model was constructed comparing acalabrutinib to ibrutinib for treatment of CLL until death or disease progression. Progression free survival (PFS) and overall survival (OS) were extrapolated from published data of ibrutinib and a hazard ratio was applied for acalabrutinib. The analysis was conducted over a lifetime horizon with monthly cycles from the United Kingdom (UK) healthcare payer perspective. The incremental cost-effectiveness ratio (ICER) was assessed with resource utilization inputs and discounting percentages according to guidelines of the National Institute for Health and Care Excellence (NICE). One-way sensitivity analysis was performed and 576 plausible scenarios were assessed in order to determine critical variables (defined by variations around the base case ICER larger than 15% throughout all scenarios) and likely ICER ranges.

**RESULTS:** Results show that the model is most sensitive to eleven critical input parameters. The most relevant parameters were the OS for acalabrutinib and PFS and drug costs for both treatments. Utility differences between both treatments can also have a major impact (>50%) on the ICER. In 34% of scenarios, treatment with acalabrutinib would be cost-effective with a threshold of £30,000. The ICER increases with longer PFS but decreases with longer OS.

**CONCLUSIONS:** Results are most sensitive to treatment costs and survival estimates, but are also greatly influenced by on-treatment utility differences between both treatments. Decision makers would benefit from more research into OS and on-treatment utility. This research shows that it is possible to establish a model and determine critical variables for cost-effectiveness in an early phase of development.

**PCN183: ADD-ON THERAPY IN BREAST CANCER - PROBABILITY OF COST-EFFECTIVENESS IN ECONOMIC ANALYSES**

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**OBJECTIVES:** Innovative oncological drugs added to standard therapies (called add-on therapies, AOT) have a problem in obtaining positive reimbursement decision. One of the main reasons is high incremental cost-utility ratio (ICUR) in economic analyses, which exceeds the rigid thresholds set by the country for cost-effectiveness. The goal was to estimate the probability of cost-effectiveness for add-on therapy (e.g. bevacizumab, palbocyclib) used in breast cancer (BC) patients.

**METHODS:** Systematic search (MEDLINE by PubMed) of economic analyses for oncological AOT in BC was performed. For data extraction and statistical analysis of predefined indicators MS Excel spreadsheet was prepared.

**RESULTS:** Based on the presented sensitivity analyses for 5 add-on substances in 10 of the 22 identified economic analyses, the probability of getting an ICUR below the profitability threshold for comparisons with a standard comparator were estimated. For 50% of the comparisons, the probability was 0% and for 50% was low and ranged between 0-30%. No probability higher than 30% was obtained. In addition, the percentage deviation from the established profitability threshold of ICUR compared to the standard comparator was analyzed. An average was equal 175%, with the range between 32%-397%.

**CONCLUSIONS:** Regardless of the clinical value and drug price, almost all innovative AOT, available in the market, has no chance to meet legal requirements (thresholds of cost-effectiveness) and to be available for patients. There is need for different approach for assessing AOT in reimbursement process, particularly in countries such as Poland, where rigid thresholds of cost-effectiveness exists.

**PCN184: PHARMACOECONOMIC ANALYSIS OF STRATEGIES FOR CERVICAL CANCER PREVENTION AND CONTROL IN INDONESIA**

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**OBJECTIVES:** This study aimed to evaluate the health and economic benefits of strategies for cervical cancer prevention and control in Indonesia using cost utility analysis approach. **METHODS:** A Markov model was adopted to simulate an age-stratified cohort of women in Indonesia. Seventeen strategies consisted of single or combination
strategies of human papillomavirus (HPV) vaccination, screening with visual acetic acid (VIA), and screening with Pap smear were analyzed and compared with existing strategy of treatment for cervical cancer or “do nothing” strategy. The strategies and scenarios varied in combinations of intervention and interval for screenings, coverage of screening and vaccination, and vaccine doses. **RESULTS:** At base case, all screening strategies had incremental cost effectiveness ratios (ICERs) less than per capita GDP of Indonesia in 2013 (IDR 35 million or USD 3,475). The most cost effective strategy with the lowest ICER was screening with VIA every 5 years, which the incremental cost effectiveness ratios (ICERs) were IDR -204,000 (USD -19.77) per quality adjusted life year (QALY), a cost saving strategy in a societal perspective; and IDR 634,000 (USD 61.45) per QALY, in a health system’s perspective. All strategies involving vaccination had ICERs between 1 – 3 times GDP. The ICER for providing HPV vaccination as single intervention revealed from this study were IDR 77.6 million (USD 7,522) per QALY and IDR 46.3 million (USD 4,490) per QALY for 3 and 2 doses assumptions, respectively, in a societal perspective. Meanwhile, in a health system’s perspective, ICER for vaccinations were IDR 77.8 million (USD 7.541) per QALY and IDR 48.4 million (USD 4,689) per QALY for 3 and 2 vaccine dose strategies, respectively. **CONCLUSIONS:** Economic evidence resulted from this pharmacoeconomic analysis support a continuation of VIA program in Indonesia, recommendation of scaling up the screening program for the whole country, and consideration of HPV vaccination implementation.

PCN185: COST UTILITY ANALYSIS OF SINGLE FRACTION VERSUS MULTIPLE FRACTION RADIOTHERAPY IN PATIENTS WITH PAINFUL BONE METASTASES; AN IRANIAN PATIENT’S PERSPECTIVE STUDY

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**OBJECTIVES:** To evaluate two various treatment strategies of bone metastasis including single fraction and multiple fraction radiotherapy **METHODS:** A multistage Markov decision model was applied to assess the incremental costs per quality adjusted life year (QALY) gained of single fraction against with multiple fractions. Model cycles period was monthly in a 10 years time horizon with 1000 hypothetical cohort samples. EQ-5D questionnaire was used to estimate health related quality of life (HRQoL) in patients. To cope with parameters uncertainty we used a probabilistic sensitivity analysis by Monte Carlo simulation technique. Both cost and utilities variables are discounted by 3% in base model. **RESULTS:** The expected mean cost and quality adjusted life years were respectively $1360.77 and 40.41 months for patients receiving single fraction and $2656.95 and 47.60 months for multiple fractions arm. The incremental cost-utility ratio (ICUR) was $180.34 per QALY. Compared with one Iranian GDP per capita (6578 US Dollar) as recommended willingness-to-pay for one gained QALYs, the multiple fraction scenario was a cost effective strategy. **CONCLUSIONS:** Policy makers should advocate the multiple fraction method instead of single fraction in treatment of patients with painful bone metastases.

PCN186: SELECTIVE INTERNAL RADIOTHERAPY (SIRT) IN METASTATIC COLORECTAL CANCER PATIENTS WITH LIVER METASTASES: PRELIMINARY PRIMARY CARE RESOURCE USE AND UTILITY RESULTS FROM THE FOXFIRE RANDOMISED CONTROLLED TRIAL.


**OBJECTIVES:** The FOXFIRE trial aims to assess cost-effectiveness of selective internal radiotherapy, using yttrium-90 resin microspheres, combined with oxaliplatin-based chemotherapy (OxMg+SIRT) compared to OxMgG alone in chemotherapy-naïve metastatic colorectal cancer patients with liver metastases (mCRCLM) not suitable for resection/ablation. (Trial number ISRCTN83867919) **METHODS:** Self-reported information was collected on primary care resource use, alongside trial-recorded secondary care, treatments, diagnostic tests and Quality of Life (QoL) at baseline and yearly until 5 years. QoL was also collected at 2 months. Costs were calculated employing UK-NHS perspective (2016 £s), and QoL utilities using EQ-5D-3L UK-tariffs. Multiple-imputation was used for missing data and results were adjusted for baseline values. Here we present self-reported resource utilisation and utility; quality-adjusted life years and cost-effectiveness results will be reported subsequently. **RESULTS:** 364 patients were randomised; median age 63 years, 120/364 (33%) females, and tumour in colon for 261/364 (72%) patients. We limit the time horizon to 3 years, as response rates thereafter fall below 20%. In year 1, total costs (with imputation) were
£158.85 in the OxMdG group and £209.44 in OxMdG+SIRT patients, a mean difference (baseline adjusted) of £51.79 (95%CI: £18.69, £222.27; p=0.15), primarily due to 0.91 additional GP surgery visits (95%CI: 0.05, 1.76; p=0.027). By 3 years, the cumulative difference was not statistically significant (56.38 (-39.74, 152.5; p=0.24)). The mean difference in utility (with imputation, baseline adjusted) was -0.001 at 2 months (CI95%:-0.05, 0.05), -0.03 at 12 months (-0.16, 0.09), 0.03 at 24 months, (-0.09, 0.16), and -0.03 at 36 months (-0.20, 0.14). Neither complete-case nor unadjusted differences qualitatively changed the results. **CONCLUSIONS:** SIRT did not significantly influence primary care resource use or QoL in the first 3 years. Further analysis of secondary care, treatment and diagnostic test costs is needed to estimate the cost-effectiveness of OxMdG+SIRT.

**PCN187: ECONOMIC EVALUATION OF ABIRATERONE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER IN PATIENTS WITH NONE/MILD SYMPTOMS AFTER FAILURE OF ANDROGEN DEPRIVATION THERAPY**

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**OBJECTIVES:** According to clinical guidelines it is estimated that 55% to 65% of people with prostate cancer will go on to develop metastatic disease (that is, the cancer spreads to other parts of the body). In over 90% of people with metastatic prostate cancer, the disease will initially respond to standard hormonal therapy but eventually become resistant to it. This clinical condition is described as castration-resistant prostate cancer, androgen-independent prostate cancer or hormone-refractory prostate cancer. The rationale intended for this study is to determine impact of sequential abiraterone then docetaxel on enhancing quality of life for patients and resources utilization through cost utility study, over a time horizon of 5 years. **METHODS:** A cost utility analysis from the perspective of the National Fund was conducted. A Markov model was applied with four health states. Utility data were incorporated in the model to make adjusted results. The structure of this model reflects the natural history of prostate cancer and current treatment strategy compared to the medical literature related to the disease. The model conforms to real practice of management of prostate cancer in Egypt. One way sensitivity analysis was conducted Costs used were the local ones according to the national fund list. Discounting was applied at 3.5%. **RESULTS:** During the five-year time horizon, total QALY gained for the abiraterone arm was 295 QALY. Total QALY gained for docetaxel arm was 197 QALY. That yields a difference of QALY was 98 Total cost for the abiraterone arm was 21,668,872 EGP. Total cost for docetaxel arm was 19,051,586 EGP. The ICER is 26,725 EGP per QALY gained. The model is highly sensitive to PFS and cost of abiraterone. **CONCLUSIONS:** The result of this study suggest Abiraterone is the dominant therapy. For efficient allocation of health care system resources and to achieve better health in the Egyptian population.

**PCN188: PHARMACOECONOMIC SYSTEMATIC EVALUATION OF BEVACIZUMAB TREATMENT FOR ADVANCED NON-SMALL CELL LUNG CANCER IN CHINA**

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**OBJECTIVES:** The study aims to systematically review the effectiveness, safety and cost-effectiveness of bevacizumab treatment for advanced non-small cell lung cancer in China. **METHODS:** A systematic review method was performed. Both national and international clinical, quality of life and cost-effectiveness studies were collected mainly from database of Cochrane, Pubmed, EMBASE, CNKI, etc., since 2010. **RESULTS:** With inclusion and exclusion criteria, there were seven meta-analysis studies on clinical efficacy and safety, two studies on quality of life, three pharmacoeconomic systematic review and four cost-effectiveness studies finally recruited for the analysis. Clinical results demonstrated that chemotherapy-based bevacizumab-regimen was effective, well tolerated and no deterioration in quality of life. Compared with chemotherapy-alone, bevacizumab-regimen substantially improved overall-survival (HR 0.91; 95%CI 0.83-1.00; p=0.039), progression-free-survival (HR 0.69; 95%CI 0.61-0.79; p<0.001), objective-response-rate (RR 1.80; 95%CI 1.52-2.13; p<0.001) and disease-control-rate (RR 1.34; 95%CI 1.21-1.48; p<0.001). The pharmacoeconomic studies showed that from the perspective of Italy, Korean, Taiwan and Poland payers, ICERs of bevacizumab-regimen versus chemotherapy ranged from USD23,822/LY to USD 54,317/LY. The ICERs were below the local acceptable threshold, and bevacizumab-regimen was considered as a cost-effective treatment option. While the ICERs of bevacizumab-regimen versus chemotherapy were higher in USA, ranging between USD 308,982/LY and USD337,179/LY, far beyond USD50,000/QALY threshold. Heterogeneous in terms of dosage, drug-price, cost category existed in published studies. **CONCLUSIONS:** Chemotherapy-based bevacizumab-regimen can be considered as a new standard option for advanced non-small lung cancer patients. However, more evidences on cost-effectiveness of bevacizumab are still needed to support local public decision making on health insurance benefits update in China. Additionally, in the era of personalized healthcare, it is suggested to explore new methods and dimensions to evaluate the economic value of oncology drugs for complementary.
**PCN189: HOSPITAL RESOURCE USE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER (mCRPC) IN NATIONAL UNIVERSITY HOSPITALS IN JAPAN**

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**OBJECTIVES:** This study aimed to determine the hospital resource use in metastatic castration resistant prostate cancer (mCRPC) in national university hospitals in Japan. **METHODS:** This was a retrospective study conducted using the CISA platform, a database repository for 13 national university hospitals in Japan. The observation period was from October 1, 2005- March 31, 2016. The study population consisted of prostate cancer patients with bone metastases (patients who were specifically coded as “Castration-resistant prostate cancer” (ICD-10, C61) and “8848040” (Japan MEDIS-DC), who had been treated with ADT and a CRPC-targeted treatment (according to approved indication). **RESULTS:** 276 patients were identified, with a mean age of 71.0 y.o (S.D. 8.7). Visceral metastasis was present in 43.8% of the patients, with the most common site being the lungs (34.4%). The mean treatment period for mCRPC was 34 months. 87.4% had undergone medical Androgen Deprivation Therapy (ADT), with 5.8% undergoing surgical ADT. Radiation therapy was given to 29.3% of patients, and 40% had been treated with opioids. 89.5% of the patients had undergone bone scanning. There were an average number of 67 outpatient visits and 2.8 inpatient admissions per patient during the treatment period. A mean of 9.9 laboratory and imaging examinations in the year prior to CRPC diagnosis was observed, increasing to a mean 28.6 one year post-diagnosis. The most common diagnostic and imaging combination done prior to mCRPC diagnosis was bone scintigraphy, CT, PSA, and blood biochemistry test. Mean per patient monthly costs increased 6-fold from prior to CRPC to post-CRPC diagnosis. **CONCLUSIONS:** Metastatic castration-resistant prostate cancer brings about increased resource use for patients in Japan, with a three-fold increase in diagnostic and monitoring tests, increased hospital visits, and increased monthly per patient costs as a result of diagnosis.

**PCN190: CHARACTERIZING THE UTILIZATION OF THE TRILLIUM DRUG PROGRAM BY AN ONCOLOGY PATIENT POPULATION.**

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**OBJECTIVES:** The Trillium Drug Program (TDP) is a provincial government program for residents of Ontario, Canada for whom prescription medications pose a large burden on their annual income. An oncological patient population is of particular interest due to rising cost of antineoplastic medications. There is little published information on recipients of TDP and the costs to the program. The aim of this study was to characterize the demographics and to investigate the cost for this population. **METHODS:** Individuals age < 65 with a cancer diagnosis from 2000-2009 were ascertained from the Ontario Cancer Registry. The Ontario Drug Benefit database was used to identify prescription medication claims to the TDP. We examined baseline demographics and claims-related characteristics for the study cohort. **RESULTS:** 19,029 cancer patients with a TPD claim were included in the study, 63% of whom enrolled following their diagnosis. Nearly 60% of the patients were female, half were in the poorest two income quintiles and the majority resided in urban areas. Total TDP expenditure for the cohort increased from $3.4 million in 2000 to $22.2 million in 2009. Antineoplastic drug expenditures increased from $130,000 (4% of total) in 2000 to $11 million (50% of total) in 2009, far outpacing the rise in cancer incidence. Though most cancer types had similar pre-diagnosis TDP expenditures, average costs following cancer diagnosis differed: lung, colorectal and breast cancer patients averaged <$200/month; prostate, kidney, myeloma and lymphoma patients averaged <$400/month; and leukemia patients averaged over $1,500/month, dominated by imatinib which accounted for $5.4 million among only 173 patients. **CONCLUSIONS:** Our study is one of the first attempts characterizing TDP utilization in an oncology population, and results show that utilization increased over time and differed across cancer diagnoses. These results have public health and policy implications as antineoplastic drug costs continue to rise and place burden on patients.

**PCN191: COSTS OF GRADE 3 AND 4 ADVERSE EVENTS ASSOCIATED WITH CURRENT CANCER TREATMENTS - COST ESTIMATIONS FOR SWEDEN, NORWAY, FINLAND AND DENMARK**

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**OBJECTIVES:** The development of a database to ensure a transparent approach to costing of adverse effects included in cost-effectiveness analysis for HTA reimbursement submissions. **METHODS:** A list of adverse events (AEs), for different types of cancer therapies was identified through a review of phase 3 randomized clinical trials
OBJECTIVES: To describe the real-world rate, and health care resource use associated with neutropenic sepsis (NS) in patients with relapsed advanced non-small cell lung cancer (NSCLC) treated with single-agent docetaxel. To compare the outcomes with those previously published by the National Institute of Health and Care Excellence (NICE) in technology appraisals for NSCLC. METHODS: A retrospective observational study in seven UK centres of 121 patients with locally advanced/metastatic NSCLC; aged ≥18 years; docetaxel monotherapy post-progression or intolerance to 1 line of chemotherapy. Microcosting analysis of resource use data performed using British National Formulary for medicines, and NHS National Tariff Payment System/Department of Health reference costs for hospital admissions/attendances. [ClinicalTrials.gov: NCT02658747]. RESULTS: Eleven patients (9.1%) had an episode of NS confirmed by ANC ≤1×10⁹/L and temperature >38°C or other signs or symptoms consistent with NS, and 10 (8.3%) an episode of suspected NS. Twenty-four patients (19.8%) received prophylactic granulocyte colony-stimulating factor. Twenty-one (17.4%) patients were treated for NS, 9 (7.4%) for anaemia, and 5 (4.1%) for neutropenia without sepsis. All NS episodes (100.0%) required unplanned hospital admission; mean (standard deviation [SD]) admission cost: £2,233.65 (£2,310.01). Mean (SD) cost of managing patients with confirmed NS: £3,163.23 (£2,921.00); suspected NS: £1,789.81 (£1,585.32). CONCLUSIONS: There has been limited to no consensus on the true rate and cost of NS in NICE technology appraisals historically, with costs ranging from £1750–£7332; and rates from 2.9%–12.7%. This real world study identified a higher rate of NS than previously reported through meta-analyses of clinical trials, and most NICE appraisals. Further, it found all patients with suspected/confirmed NS required an unplanned admission to manage the episode, resulting in a higher cost of management than reported in most NICE appraisals. These results should be considered for use within cost effectiveness analyses in future submissions to health technology assessment bodies.

OBJECTIVES: Nivolumab demonstrated survival, HRQoL, and HCRU benefits versus single-agent therapy of IC (methotrexate, docetaxel, or cetuximab) in patients with platinum-refractory R/M squamous cell carcinoma of the head and neck (SCCHN) (RTC) in PubMed. AEs classified as grade III or IV and that occurred in more than 5% of patients were included in the final list in order to capture AEs that may affect the outcome of an economic analysis. Costs were estimated by a systematic approach based on reimbursement value of a suitable Diagnosis Related Group (DRG) and treatment recommendations for grade 3/4 AEs in the U.S. Department of Health and Human Services’ Common Terminology Criteria for Adverse Events (CTCAE). RESULTS: Cost estimates of a total of 78 AEs were collected in local currencies (2016) for four Nordic countries using a structured methodology and were collated in a database with detailed information on how they were estimated. The structure of the database enables easy update to current clinical practice and price levels. The database allows for easy and transparent population of cost-effectiveness models in cancer for Denmark, Norway, Sweden, and Finland. CONCLUSIONS: This database provides cost estimates for adverse effects that were sourced using a transparent and consistent methodology. Thus, the database has simplified the HTA submission process and hopefully aided the decision maker in the understanding of the potential impact of adverse effects and detail regarding how their costs were estimated.

OBJECTIVES: To examine the impact of neutropenic sepsis (NS) in head and neck squamous cell carcinoma (HNSCC) and to explore the impact on health-related quality of life (HRQoL) and healthcare resource utilization (HCRU) in CheckMate 141, a phase 3 study of nivolumab monotherapy versus investigator’s choice (IC) in patients with recurrent or metastatic (R/M) platinum-refractory squamous cell carcinoma of the head and neck (SCCHN). METHODS: We conducted a retrospective observational study in seven UK centres of 121 patients with locally advanced/metastatic NSCLC; aged ≥18 years; docetaxel monotherapy post-progression or intolerance to ≥1 line of chemotherapy. Microcosting analysis of resource use data performed using British National Formulary for medicines, and NHS National Tariff Payment System/Department of Health reference costs for hospital admissions/attendances. [ClinicalTrials.gov: NCT02658747]. RESULTS: Eleven patients (9.1%) had an episode of NS confirmed by ANC ≤1×10⁹/L and temperature >38°C or other signs or symptoms consistent with NS, and 10 (8.3%) an episode of suspected NS. Twenty-four patients (19.8%) received prophylactic granulocyte colony-stimulating factor. Twenty-one (17.4%) patients were treated for NS, 9 (7.4%) for anaemia, and 5 (4.1%) for neutropenia without sepsis. All NS episodes (100.0%) required unplanned hospital admission; mean (standard deviation [SD]) admission cost: £2,233.65 (£2,310.01). Mean (SD) cost of managing patients with confirmed NS: £3,163.23 (£2,921.00); suspected NS: £1,789.81 (£1,585.32). CONCLUSIONS: There has been limited to no consensus on the true rate and cost of NS in NICE technology appraisals historically, with costs ranging from £1750–£7332; and rates from 2.9%–12.7%. This real world study identified a higher rate of NS than previously reported through meta-analyses of clinical trials, and most NICE appraisals. Further, it found all patients with suspected/confirmed NS required an unplanned admission to manage the episode, resulting in a higher cost of management than reported in most NICE appraisals. These results should be considered for use within cost effectiveness analyses in future submissions to health technology assessment bodies.
a differential effect of baseline HRQoL score by treatment group. Higher baseline QLQ-C30 global health status, cognitive functioning, and social functioning were significantly associated (P<0.05) with lower total HCRU event frequency. Higher symptom frequency (ie, QLQ-C30 symptoms of dyspnea and diarrhea as well as speech problems, social eating problems, social contact problems, coughing, feeling ill, and weight loss as measured by the QLQ-H&N35) were significantly associated (P<0.05) with more frequent total HCRU events. Baseline EQ-5D-3L scores were not associated with HCRU event frequency. Baseline HRQoL was associated with hospital admission frequency. There was no clear association of HCRU event frequency with time to HRQoL deterioration. CONCLUSIONS: In CheckMate 141, worse baseline HRQoL was associated with higher HCRU regardless of treatment arm, suggesting that baseline HRQoL scores may be useful to identify patients that may utilize healthcare resources more frequently.

PCN194: RATE OF HOSPITALIZATION DUE TO ADVERSE EVENT AND LENGTH OF STAY FOR ATEZOLIZUMAB IN SECOND AND THIRD LINE METASTATIC NON-SMALL LUNG CANCER (NSCLC) USING PHASE 3 OAK STUDY
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OBJECTIVES: The OAK study is a randomized phase III trial of atezolizumab vs. docetaxel in prior treated NSCLC. The analysis population is the primary analysis population (425 subjects per arm, datcut: 7 Jul 2016). This work evaluates the rate of adverse events leading to hospitalizations per month, as well as the total length of hospitalization stay per patient normalized with respect to the time on treatment per patient. METHODS: A negative binomial model is applied to the number of hospitalizations per patient, using time on treatment (plus a 30-day safety window) as offset. Similarly, a negative binomial model is applied to the total hospitalization duration per patient. One subject in the atezolizumab arm, hospitalized for over 200 days was considered an outlier; hence, excluded from the analysis. RESULTS: The monthly rate of hospitalization, normalized with respect to the time on treatment per patient in the docetaxel arm is 0.14; whereas, the monthly rate of hospitalizations in the atezolizumab arm is 0.08, with a 40% reduction in the rate of hospitalizations (p-value = 0.0004). The mean length of hospitalization stay for the docetaxel arm is 10.63 days for the docetaxel arm and additional 1.3 days on average for the atezolizumab arm (p-value = 0.005). CONCLUSIONS: atezolizumab statistically significantly reduced the rate of hospitalizations due to adverse events compared to docetaxel. In addition, after being hospitalized the length of stay in the atezolizumab arm is shorter than the length of stay for the docetaxel arm.

CANCER - Patient-Reported Outcomes & Patient Preference Studies

PCN195: INDICATORS OF PARTICIPATION IN CERVICAL CANCER SCREENING AMONG ROMANY WOMEN
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OBJECTIVES: Reviewing the statistical indicators of mortality we see that cancer is in second most common cause of death after cardiovascular diseases. Cervical cancer is the seventh most common type of cancer (among women) in Europe. According to current estimations, there are 58,373 new diagnosed out of 3,257 million women older than 15 years, from which 24,404 ends with death. There is an organized screening system in Hungary since 2003. Most women participate “traditionally”, out of this system or ignore invitation and do not accept the opportunity. This behaviour is typical among Romany population, which is Hungary’s largest ethnic group. Many stereotypes live in our society about Romany people, like starting sexual activity early, giving birth to many children. METHODS: A quantitative, cross-sectional study was carried out. Our sample consisted of Romany women from Zala, Baranya and Somogy county, Hungary (N=368). The main topic was reasons for staying away from cervical cancer screening in our self-made questionnaire. During statistical analysis we calculated descriptive statistics, χ2-test and t-test (p<0.05). RESULTS: Mean age of responders was 36.43±11.27 years. 17.39% never attended gynaecological screening. Mean age of participants in screening (82.34%) was 21.14±6.97 at their first time. Educational attainment is an influencing factor in participation (p<0.05). The non-participation rate of those who: have finished only elementary school is 22.6%, hold vocational training certificate is 11.9%, have finished high school is 9.1%, while 100% of women with higher education attended. CONCLUSIONS: It is important to make Romany women aware of process of screening, it’s possible gain, barriers and accidental side effects, and most importantly the risks of staying away from screening. It is also crucial to evolve such a health-conscious behaviour, which allows them to identify cervical cancer before the occurrence of symptoms therefore lowering mortality rate.

PCN196: PREDICTING EQ-5D UTILITY INDEX SCORES FOR GASTRIC CANCER PATIENTS IN JAPAN: A PRELIMINARY MODEL
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OBJECTIVES: As some clinical trials may not capture utility data, the objective of this analysis was to explore various statistical approaches and identify the best algorithm to predict EQ-5D utility index scores for patients in Japan with advanced gastric cancer. METHODS: Gastric cancer patients, currently treated and with at least two prior treatment regimens, were identified from the Adelphi Gastric Cancer Disease Specific Programme (DSP), a global (Canada, France, Germany, Italy, Spain, UK, Korea, Japan) cross-sectional observational study, and CheckMate 032, a multicentre, open-label phase 1/2 trial of nivolumab or nivolumab combined with ipilimumab in patients with advanced or metastatic solid tumors. Predictive models for Japanese EQ-5D utility scores based on global and Japanese data only were generated. Covariates identified a priori were age, gender, BMI, years since diagnosis, ECOG performance score, presence of liver metastases and country (Japan/not-Japan). Model performance was assessed by cross-validation with mean absolute error (MAE), root-mean squared error (RMSE) and proportion of predicted EQ-5D further than 0.2 from recorded EQ-5D (PFR). RESULTS: When validated against observed Japanese EQ-5D utility scores, global models all had similar error metrics (approximately 0.17 MAE, 0.20 RMSE and 33.33%-37.50% PFR) and performed better than models based on Japanese data only. In a model assuming a Gaussian distributional family and identity link function, significant predictors were ECOG performance score (p<0.001) and presence of liver metastases (p=0.015). Predicted EQ-5D values had a Pearson correlation of 0.413 with observed values. CONCLUSIONS: A preliminary algorithm was developed to generate predictions of EQ-5D utility scores for gastric cancer patients in Japan. The applied modelling approach may be useful not only for clinical trials in gastric cancer where utility data are lacking but also for other settings and tumor types.

PCN197: COMPARISON OF UTILITY VALUES IMPLEMENTED IN DISEASE MODELS OF METASTATIC MELANOMA

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OBJECTIVES: The purpose of this study is to compare the methods employed in the estimation of utility values in health technology assessments (HTAs) for treatments for metastatic melanoma submitted to the National Centre for Pharmacoeconomics (NCPE) in Ireland. METHODS: HTA submissions were identified via the NCPE submissions database. A review template was created based on the NCPE submission template to assess compliance with NCPE requirements. Methodology in each submission was compared and critically appraised. RESULTS: Nine HTAs were included in the study. All studies presented a cost utility analysis in line with the Irish reference case. Three submissions did not present systematic reviews for published quality of life (QOL) data; 2 of these used values from the literature in their submission. Eight submissions used generic QOL instruments in the pivotal clinical trials to estimate utilities for the economic model; 7 used EQ-5D data in line with NCPE reference case. The impact of adverse events on utility was assumed to be captured within trial based QOL estimates in 7 submissions. Only 1 submission directly considered the relevance of the trial based QOL data to the Irish population. Mapping of utility values and addition of age-related utility decrements were employed in only 2 submissions. The level of detail provided on response rates, missing data and the analysis undertaken to produce the utility values was generally inadequate and required further clarification by the NCPE in almost every case. The utility values implemented in the HTAs differed greatly between submissions, and sensitivity analyses showed significant impact on model outcomes in some cases. CONCLUSIONS: Submissions did not address all of the requirements for health outcome data specified in the NCPE submission template. Greater adherence to the NCPE submission template could reduce requests for clarification by the NCPE and reduce delays in the review process.

PCN198: MINIMAL IMPACT ON PATIENTS’ HEALTH UTILITIES ASSOCIATED WITH ADVERSE EVENTS IN METASTATIC MERKEL CELL CARCINOMA PATIENTS ON TREATMENT WITH AVELUMAB

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OBJECTIVES: The anti-PD-L1 avelumab is the first FDA-approved treatment for metastatic Merkel cell carcinoma (mMCC), a rare, aggressive skin cancer. Avelumab has a safety profile that includes infusion reactions and a low incidence of immune-related adverse events (AEs). This research aims to explore the association between different types of AEs and EQ-5D utility in avelumab-treated patients. METHODS: EQ-5D data from a phase 2 single-arm trial
(NCT02155647) of 88 patients with mMCC after failing first-line chemotherapy were analyzed. Date of data cutoff was 12 months after enrolment of the last subject. EQ-5D was assessed at baseline, week 7, every 6 weeks thereafter, and at the end-of-treatment visit. For each assessment, presence of ongoing AEs was based on start and end dates of all AEs reported in the trial. Linear mixed models were fitted to estimate reductions in utility for various AE types, adjusted for disease progression (using RECIST 1.1; determined by an IERC). RESULTS: Among 70 evaluable patients, 322 observations were analyzed. Mean utility at baseline was 0.799 (SD: 0.155) for the US, and 0.823 (SD: 0.196) for the UK tariff, respectively. In 37 of 322 observations, patients completed the EQ-5D while experiencing a treatment-emergent grade 3/4 AE. Mean reduction in utility for treatment-emergent grade 3/4 AEs was -0.024 (95% CI: -0.066; 0.018) and -0.017 (95% CI: -0.065; 0.031) based on US and UK value sets, respectively. These utility reductions and those for treatment-related or treatment-emergent AEs of any grade, and immune-related AEs, were not clinically relevant based on published estimates of minimally important differences (US, 0.06; UK, 0.07-0.09). Only serious AEs (13 observations) were associated with clinically meaningful reduction in utility (-0.061 for US; -0.098 for UK). CONCLUSIONS: The impact on health utility from patients’ perspective during avelumab treatment was minimal for all AEs evaluated and marginal for serious AEs.

**PCN199: ESTIMATING UTILITIES / DISUTILITIES FOR HIGH RISK METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (MHSPC) AND TREATMENT-RELATED ADVERSE EVENTS**

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**OBJECTIVES:** Patients with metastatic hormone-sensitive prostate cancer (mHSPC) have widespread disease and are responsive to hormone therapy. Patients classified as ‘high-risk’ have more aggressive disease (at least two of the following: Gleason score ≥8; ≥3 bone lesions; visceral metastasis). Symptoms of mHSPC and treatment burden can substantially impact patients’ health-related quality of life (HRQL), however, health utility data in this setting are scarce. This study aimed to capture UK societal utility values for high-risk mHSPC and burdensome treatment-related adverse events (AEs). METHODS: Literature review and interviews with mHSPC patients (n=4) and oncology specialists (n=5) informed AE selection and health-state wording. Three base-states described a high-risk mHSPC patient: receiving androgen deprivation therapy (ADT) [BS1]; receiving docetaxel+ADT [BS2]; completed docetaxel treatment, still receiving ADT [BS3]. Descriptions of six severe AEs were combined with BS2. Health-states were validated with additional oncology specialists (n=6) and piloted with UK participants (cognitive debrief). A UK general public sample (n=200) valued health states using visual analogue scale (VAS) rating and Time Trade-Off (TTO) interview methods. Disutility of AEs on BS2 were calculated using Generalised Estimating Equation (GEE) model to account for correlating data. RESULTS: Mean TTO values for BS1-3 were 0.71 (SD=0.26), 0.63 (SD=0.29) and 0.68 (SD=0.26) and for BS2+AEs were 0.58 (fluid retention), 0.58 (alopecia), 0.54 (fatigue), 0.48 (reduced immunity), 0.41 (nausea+vomiting), and 0.40 (diarrhoea). Subtraction of means showed BS2+diarrhoea (-0.23) had largest decline in mean utility. GEE model found significant disutility for all AEs, with BS2+nausea+vomiting having the largest impact (GEE model coefficient -0.21; CI: -0.24, -0.16). CONCLUSIONS: In this study, utility values across mHSPC health-states showed a clinically plausible trend and significant impact of AEs, underlining the importance of accounting for impaired HRQL when assessing treatments for mHSPC. Disutility weights associated with severe AEs quantify their HRQL impact for use within economic modelling.

**PCN200: HEALTH STATE UTILITIES ASSOCIATED WITH TREATMENT OPTIONS FOR ACUTE MYELOID LEUKEMIA (AML)**

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**OBJECTIVES:** AML treatment typically involves initial remission induction therapy (usually chemotherapy with cytarabine plus an anthracycline, such as daunorubicin [e.g., 7+3 regimen]) followed by post-induction consolidation therapy (additional chemotherapy and/or blood/marrow transplant [BMT]). CPX-351 is a novel dual-drug liposomal encapsulation of cytarabine and daunorubicin that delivers a synergistic drug ratio. Compared with 7+3, CPX-351 improves overall survival in older adults with untreated high-risk or secondary AML and differs in its mode of administration. The purpose of this study was to estimate health state utilities associated with AML treatment strategies. METHODS: In time trade-off interviews with a 1-year time horizon, participants from the UK general population (London, Edinburgh) valued 12 health states drafted based on literature and clinician interviews. To identify disutility associated with chemotherapy, two types of induction and four types of consolidation were added to an otherwise identical health state describing AML in temporary remission. The decrease in utility when adding these
treatment regimens represents the disutility of each type of induction/consolidation. Five additional health states were valued to estimate utilities associated with other AML treatments. RESULTS: 200 participants completed interviews. Mean (SD) utilities were 0.55 (0.31) for pre-treatment AML and 0.66 (0.29) for AML in temporary remission. The addition of any chemotherapy to one year of temporary remission significantly decreased utility (P <0.0001). Induction had a mean disutility of –0.11 with CPX-351 and –0.15 with 7+3. Mean disutility for consolidation ranged from –0.03 with outpatient CPX-351 to –0.11 with inpatient 5+2. Utilities were also assessed for other AML treatments (e.g., BMT, low-intensity regimens).

CONCLUSIONS: Induction and consolidation chemotherapy were consistently associated with decreases in health state utility values, but consistently less disutility was seen with CPX-351 versus 7+3 across treatment phases. These utilities may be useful in cost-utility models comparing the value of AML treatments.

PCN201: NO EQ-5D? ANALYSIS OF ALTERNATIVE UTILITY VALUE SOURCES USED IN NICE APPRAISALS FOR ONCOLOGY INDICATIONS

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OBJECTIVES: The National Institute for Health and Care Excellence (NICE) reference case states that utility values should be based on health-related quality of life (HRQoL) measures reported directly by patients and valued with public preferences, preferably using the EuroQol-5 dimensions questionnaire (EQ-5D). We investigated the health state utility values (HSUVs) used in oncology appraisals submitted to NICE, the extent to which EQ-5D data were available, and views of the NICE Committees on alternative approaches of sourcing HSUVs. METHODS:NICE oncology appraisals published between January 2015 and April 2017 were reviewed: details of the drug, indication, source of base case HSUVs, Evidence Review Group (ERG) and Committee comments on the HSUVs, and final recommendation were extracted. Multiple technology appraisals, Cancer Drugs Fund reappraisals, or appraisals not using a typical 3- or 4-health state oncology health economic model were excluded. RESULTS: Of the 30 appraisals reviewed, 17/30 (57%) used EQ-5D data from the intervention’s pivotal trial to inform at least one HSUV; 5/30 (17%) mapped HRQol data from the intervention’s pivotal trial to EQ-5D, 5/30 (17%) used EQ-5D data from an alternative source (e.g. a comparator clinical trial), and 3/30 (10%) did not use EQ-5D data to inform any HSUVs. Mapping to EQ-5D was generally well-received by the Committee; validated mapping algorithms from large datasets were preferred. Alternative sources of HSUVs were also accepted if HSUVs were derived from an appropriate patient population and used in previous NICE appraisals; failure to convert US-valued EQ-5D data to the UK and double-counting of adverse event disutility were strongly criticised. CONCLUSIONS: The majority of oncology appraisals had EQ-5D data collected from the intervention’s pivotal trial. Whilst HSUV sources deviating from the NICE reference case attracted criticism from the ERG, there are measures manufacturers may take to mitigate such feedback, and Committees appear willing to accept alternative HSUV sources.

PCN202: FACTORS CONTRIBUTING TO THE CEILING EFFECT AMONG PATIENTS WITH PROSTATE CANCER WHO WERE JUDGED TO HAVE “FULL-HEALTH” BY EQ-5D-5L

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OBJECTIVES: The first Japanese guidelines for the economic evaluation of drugs and medical devices were officially approved in 2016. These guidelines recommend using utility values, especially those evaluated with EuroQol Five-Dimensional Questionnaire (EQ-5D). Recently, a Japanese version of the EQ-5D five level (5L) value set was developed. However, the ceiling effect that can be judged as full health (utility value = 1) was not fully improved comparing to the previous 3L version. We aimed to identify the factors that contributed to the ceiling effect among patients with prostate cancer by using EQ-5D-5L. METHODS: A cross-sectional study utilized self-administered EQ-5D-5L as the generic health-related QOL and the Functional Assessment of Cancer Therapy-Prostate Cancer (FACT-P) as the disease-specific instrument. Two hundred Japanese patients with prostate cancer in two hospitals were recruited (100 patients in each). Utility values were calculated, and the correlation of values between EQ-5D-5L and FACT-P was checked using least-square method. The physicians in charge reported the patient characteristics. Stepwise selection and logistic regression analysis were used to identify demographic and medical factors associated with subjective judgment of full health. RESULTS: Self-administered questionnaires and medical characteristics were obtained from 161 patients. The EQ-5D-5L utility value was positively correlated with FACT-P score (r=0.57, p<0.001). The EQ-5D-5L utility values (standard deviation) for localized, advanced, and castration-resistant prostate cancer (CRPC) were 0.86 (0.16), 0.87 (0.14) and 0.80 (0.18), respectively. Of the patients, 47.8% were judged to be at full health by EQ-5D-5L, although only one patient showed the maximum FACT-P score. Regression analysis suggested that full health was affected by age (β=0.10, p<0.001) and months since the last treatment (β=0.01,
p=0.004). **Conclusions:** The age of patients and months since the last treatment significantly contributed to the ceiling effect of EQ-5D-5L utility values. We obtained the utility values of localized, advanced, and CRPC.

**PCN203: UK UTILITY ELICITATION IN PATIENTS WITH FOLLICULAR LYMPHOMA**

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**Objectives:** Follicular lymphoma (FL) is the most common indolent lymphoma with approximately 1,860 new cases diagnosed in the UK each year. Clinical management ranges from immediate treatment with chemotherapy and/or radiotherapy, to observation (“watch-and-wait (W&W)”), with treatment initiated if/when symptoms develop. Once a patient has achieved a response to therapy, they are considered to be in remission. Numerous cost-utility analyses on FL management have been conducted over the years; however, the utilities used in these studies were either not derived from published studies or were not specific to FL. The objective of this study was to bridge this gap and present the robust utility values specific to FL for use in future economic evaluations. **Methods:** 181 FL patients from the UK’s population-based Haematological Malignancy Research Network (www.hmrn.org) newly diagnosed from 2012 to 2016 completed a EQ-5D-5L questionnaire at diagnosis, at 6 month and at 12 monthly intervals thereafter. Two value sets were used to calculate utility: the EQ-5D-5L value set and the EQ-5D-5L crosswalk index value (mapping to EQ-5D-3L values). Descriptive statistics on utility values were summarized using three aggregated disease states on the treatment pathway: W&W, undergoing treatment, and remission. **Results:** Utility score differed with disease state: 0.85 (W&W), 0.83 (Treatment) and 0.88 (Remission) using the EQ-5D-5L value set, and 0.79, 0.74 and 0.83 respectively using the crosswalk value set. Patients in remission had a higher QoL compared to those on W&W (p=0.182 and p=0.139 for EQ-5D-5L and EQ-5D-3L values, respectively) and those on treatment (p=0.016 and p=0.002 for EQ-5D-5L and EQ-5D-3L values, respectively). **Conclusions:** Based on “real-world” contemporary data, this is the first study to measure utility for different phases of the FL pathway, confirming the impact of disease state on QoL. Such robust data should be used in future economic evaluation studies designed to support policy decision making.

**PCN204: MAPPING FROM SF-36 TRIAL DATA TO EQ-5D UTILITIES IN ADVANCED BASAL CELL CARCINOMA**

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**Objectives:** Vismodegib is a Hedgehog (Hh) pathway inhibitor indicated for the treatment of adult patients with advanced basal cell carcinoma (aBCC). ERIVANCE included measurements of health-related quality of life using the SF-36 questionnaire at various timepoints. The objective of this study was to map the SF-36 data onto EQ-5D utilities for use in health economic evaluations. The resulting EQ-5D values were then validated against published utility estimates in aBCC. **Methods:** Patient level SF-36 data were used to generate EQ-5D utilities for pre-and post-progression, based upon the best performing algorithm (model 3) reported in a study by Rowen et al (2009). Results were compared to a study by Shingler et al. (2013) which reported utilities associated with various health states in aBCC, stratified by response status and by diameters of lesion. Although the Shingler publication was a vignette study it was believed to be the best available evidence on patients with aBCC. **Results:** Mapped utilities [95% CIs] in the locally advanced population amounted to 0.839 [0.810, 0.867] and 0.757 [0.684, 0.830] for PFS and PD (n= 63 at baseline visit), respectively. The mapped PFS utility (0.839) was very close to the raw average of complete response and partial response values reported in Shingler et al. (0.836). The mapped PD utility was considerably lower than the raw average of PD utilities from Shingler et al. (0.705 versus 0.757). **Conclusions:** Mapped utilities produce similar estimates to those seen in published literature, though results should be interpreted with caution due to the different methods and small sample sizes. This study is limited by the small sample size of the SF-36 data collected during ERIVANCE - n=95 at baseline visit.

**PCN205: QUALITY-ADJUSTED LIFE YEARS (QALYS) FOR INOTUZUMAB OZOGAMICIN VERSUS INVESTIGATORS CHOICE (IC) FOR RELAPSED/REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKAEMIA (R/R B-ALL)**

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**Objectives:** Inotuzumab ozogamicin (InO) is an anti-CD22 antibody-calicheamicin conjugate that has demonstrated superior efficacy in patients with r/r B-ALL compared to IC in the pivotal Phase III INO-VATE ALL trial.
A UK-based Markov model has been developed based on this study to estimate the mean life year (LY) and QALY gains associated with InO compared to IC. Using a 1.5% discount rate, we explored key QALY drivers and factors influencing long-term survival following haematopoietic stem cell transplant (HSCT). METHODS: Using trial data, parametric survival curves were generated based on patient’s remission status and whether they received a HSCT. Patients alive 3 years post-HSCT were considered cured and followed general population mortality. Utilities were based on trial EQ-5D scores, and utilities for both post-HSCT and progression states were from the literature. Three scenarios were used to explore post-HSCT survival: (1) using the INO-VATE ALL post-HSCT data split by treatment to estimate treatment effect; (2) pooling the data from both treatment arms and applying survival post-HSCT independent of treatment; and (3) applying a covariate for minimal residual disease negativity, which was shown to be key in determining long-term post-HSCT survival in the treatment of de novo disease and is under investigation as a prognostic factor for survival following relapse. RESULTS: InO increased survival by 5.18 LYs and 2.23 QALYs versus IC. One-way sensitivity analysis showed utility values in progressive disease and those used 5 years post-HSCT to be most influential. Probabilistic sensitivity analysis showed a large spread in QALYs gained which was a result of post-HSCT survival estimates. The first post-HSCT scenario indicated the largest LY and QALY gains for InO in comparison to IC. CONCLUSIONS: InO was shown to increase survival and QALYs compared to IC demonstrating it to be an effective treatment for rit B-ALL; this was demonstrated in all three scenarios explored post-HSCT.

PCN206: UTILITY VALUES ACROSS LINES OF THERAPY IN IMMUNO-ONCOLOGY TREATMENTS: AN EXAMPLE FROM ADVANCED MELANOMA

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OBJECTIVES: Cost utility analyses of oncology treatments are most commonly performed using partitioned survival models, applying health state utilities to progression-free and progressive disease and relative to a specific line of therapy. The objective of this study was to assess utility values across treatments and lines of treatment using data in advanced melanoma for two immuno-oncology agents, nivolumab and ipilimumab. METHODS: Utility values from 1st line (1L) and 2nd line (2L) advanced melanoma populations treated with nivolumab and ipilimumab were extracted from three randomised controlled clinical trials: CheckMate-067 (1L nivolumab and 1L ipilimumab), CheckMate-037 (2L nivolumab) and MDX010-20 (2L ipilimumab). Visual assessment of QoL over time as well as comparisons of baseline and change from baseline values were performed using summary statistics. RESULTS: Baseline values for 1L and 2L were similar for nivolumab (0.80 vs 0.75, p=0.001) and ipilimumab (0.79 vs 0.81, p=0.123). Across all lines of therapy nivolumab use resulted in improvements in utility whilst patients remained progression free. Ipilimumab treatment regimens showed initial declines in utilities in the first 3 months followed by improvements over the remainder of time on treatment. The change in utility from baseline to 12 months was similar for 1L and 2L nivolumab (0.050 v 0.047, p=0.930). Both these changes were greater than that observed for 1L ipilimumab at 12 months (0.035, p=0.533 v 1L nivolumab and p=0.767 v 2L nivolumab). 2L ipilimumab results were limited to short term follow-up, however utility values were comparable to 1L ipilimumab at 5 months (-0.023 v 0.014, p=0.091). CONCLUSIONS: The quality of life of patients on immune-based therapies appears to be independent of therapy line. Furthermore, economic modelling in an immune-oncology setting should reflect that quality of life looks to be a function of time on treatment.

PCN207: REPORTED UTILITIES FOR PATIENTS WITH UNTREATED ADVANCED/METASTATIC RENAL CELL CARCINOMA – A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Renal cell carcinoma (RCC) is the most common form of kidney cancer. The aim of this research was to systematically collect quality-of-life (QoL) evidence expressed as utility values for patients with untreated advanced or metastatic RCC. METHODS: A systematic literature review was performed with a pre-defined search strategy and review criteria. Embase, Medline, and the Cochrane Library were included as databases. Conference and Health Technology Assessment (HTA) organization websites were also searched. No language or time limits were applied, except for conference abstracts (≥2015). RESULTS: A total of 2,967 citations were obtained via Embase, Medline, and Cochrane Library, and 362 via conference and HTA organization websites. The review process resulted in the inclusion of 37 publications reporting on utility values. These publications were cost-effectiveness analyses (13 studies), clinical trials (10 studies), HTA reviews (7 studies), and utility studies (7 studies). First-line RCC treatment-specific utilities are those most frequently reported in the included studies, which assigned a specific utility value to treatments such as sunitinib, pazopanib, IFN-α, and temsirolimus. Disease states (pre/post progression), being on or off systemic treatment, and adverse events were also commonly presented as either health-state utilities (e.g., stable...
difference in mean overa
with nivolumab compared with IC in patients with R/M SCCHN. Results appeared to be related to a between
vs 0.37 months; P<0.0001). 3.30 months) compared with the IC group (P<0.0001). Mean time in TOX was shorter for nivolumab versu

OBJECTIVES: The aim of this study is to analyse the correlation of health state values using EQ-5D-5L and visual
analogue scale using EQ-VAS as quality of life (QOL) scores in Japanese breast cancer patients. METHODS: A total
of 148 patients were enrolled in this study. Of these patients, 120 were primary breast cancer patients, and 28 were
metastatic breast cancer patients; data for a total of 612 points of visiting were collected. The study was a longitudinal
cohort study conducted from May 2016 to June 2017 in St. Marianna University Hospital. We compared the mean
utilities and EQ-VAS scores of primary and metastatic breast cancer patients by using ANOVA. Then, we conducted
a correlation analysis between the utilities derived from EQ-5D-5L and the QOL derived from EQ-VAS. All analyses
were performed with JMP 13 (SAS Institute., Cary, NC, USA). The study protocol was approved by the Institutional
Review Committee of St. Marianna University School of Medicine. RESULTS: The utilities of primary breast cancer
patients were 0.87±0.006, and those of metastatic breast cancer patients were 0.808±0.011 (p<0.0001). The VAS
scores as a QOL indicator of primary breast cancer patients were 78.52±0.742, and those of metastatic breast
cancer patients were 71.47±1.464 (p<0.0001). The corresponding correlations between utilities and VAS scores in
primary breast cancer patients were 0.25, whereas those for metastatic breast cancer patients were 0.50. CONCLUSIONS:
We identified that both health state values and the VAS scores of metastatic breast cancer patients were lower than those of primary breast cancer patients. However, the correlation of utilities and the VAS
scores of metastatic breast cancer patients was higher than that of primary breast cancer patients.

OBJECTIVES: Nivolumab provided survival, health-related quality-of-life, and healthcare resource utilization benefits
versus single-agent therapy of IC (methotrexate, docetaxel, or cetuximab) in patients with platinum-refractory R/M
SCCHN in CheckMate 141 (NCT02105636). Here we compared between-treatment differences in overall benefit
using a Q-TWIST analysis. METHODS: Overall survival was partitioned into 3 health states: toxicity (TOX), time
without symptoms of disease progression or toxicity (TWIST), and relapse (REL). TOX was defined as time spent
with all-cause grade 3–4 adverse events after randomization, prior to disease progression. TWiST was defined as the
time not in TOX or REL. REL was defined as the time between progression and death. Mean duration of each state
was calculated for each treatment group using Kaplan-Meier analysis. Utility values from the 3-level EQ-5D (EQ-5D-
3L) questionnaire collected in the trial were used to calculate Q-TWIST as the utility-weighted sum of the mean health
state durations. Bootstrapping (500 samples) was used to estimate time in each health state and to compare
estimates between treatment groups. A threshold analysis was conducted across ranges of TOX and REL values
from 0 to 1 to illustrate the full range of possible results. RESULTS: A total of 361 patients (nivolumab, n=240; IC,
n=121) were included in the analysis. Median duration of follow-up for survivors was 15.7 months. The between-
group difference in Q-TWIST score was 1.23 months (95% CI: 1.18, 1.28) favoring nivolumab, P<0.0001. The
nivolumab group experienced a significantly longer mean time in TWiST (3.82 vs 2.78 months) and in REL (4.02 vs
3.30 months) compared with the IC group (P<0.0001). Mean time in TOX was shorter for nivolumab versus IC (0.30
vs 0.37 months; P<0.0001). CONCLUSIONS: In this analysis, quality-adjusted survival was significantly improved
with nivolumab compared with IC in patients with R/M SCCHN. Results appeared to be related to a between-group
difference in mean overall survival.
PCN210: UTILITY META-REGRESSION; FREQUENTIST VS BAYESIAN APPROACHES IN MULTIPLE MYELOMA

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OBJECTIVES: Utility values are used in health technology assessment to measure the health-related quality of life impacts of new products, typically taken from a single source. In contrast, meta-analysis synthesizing all available information is a requirement for clinical data. Consequently, utility values currently used to inform health technology assessments lack consistency by ignoring data from the other sources. This analysis presents a standard frequentist meta-regression and a novel and Bayesian approach to the synthesis of utility values. METHODS: A literature review for all published utility data in multiple myeloma was conducted, in conjunction with analysis of patient registries across all stages of disease (2,445 patients, over 9,000 completed EQ-5D questionnaires), and of a clinical trial including 669 patients. This information was then synthesized using two distinct approaches – frequentist meta-regression and Bayesian statistical modelling. These approaches were compared in terms of the results produced, internal validity, and efficiency of estimation. RESULTS: The systematic review identified 13 papers giving 27 utility values across multiple lines of treatment including some values not linked to a specific disease stage. Analysis of the two datasets produced 9 further values. Both frequentist and Bayesian meta-regression produced similar overall results; low utility on diagnosis (0.53), increasing to approximately 0.65 on first treatment then decreasing with each subsequent treatment class to approximately 0.50 after four classes of treatment. In all analyses, strong evidence was found to suggest an association between stem cell transplant and an increase of 0.06 in patient utility. CONCLUSIONS: Both Bayesian and frequentist approaches produced internally consistent utility estimates across the treatment pathway. However, the Bayesian approach more accurately represents the uncertainty in the clinical data, and allows non stage specific utilities to be used as prior beliefs. This exemplifies how Bayesian analyses can be performed using a simple and flexible framework.

PCN211: HEALTH RELATED QUALITY OF LIFE IN CANCER IMMUNOTHERAPY: PREVIOUSLY TREATED, LOCALLY ADVANCED OR METASTATIC NON-SMALL-CELL LUNG CANCER

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OBJECTIVES: To assess the different methodologies utilised to present Health Related Quality of Life (HRQoL) of patients with metastatic cancer, and to compare the impact of such methodologies for an immunotherapy in the treatment of second line non-small-cell lung cancer (NSCLC). METHODS: The 10 most recent published technology appraisals in oncology were taken from the National Institute of Health and Care Excellence (NICE) website, and reviewed to determine the approach taken to elicit and present HRQoL data. From this, 4 methodologies were tested on atezolizumab, an anti-programmed death-ligand 1 (PD-L1) antibody for the treatment of NSCLC after prior chemotherapy using data collected from the OAK trial: PFS/PD, time-to-death, on treatment/off treatment, and a combination of on treatment/off treatment and time-to-death. RESULTS: The 10 published NICE technology appraisals spanned a multitude of different indications in oncology, including lung cancer, breast cancer, pancreatic cancer, colorectal cancer, renal cell carcinoma, multiple myeloma and chronic lymphocytic leukaemia. Several appraisals utilised a traditional Progression-Free Survival (PFS)/Stable Disease and Progressed Disease (PD) approach to implement health state utility values (HSUV’s). However, others incorporated a time-to-death, “time lived with disease”, or an on treatment/off treatment approach. The different methodologies generated different cumulative quality of life gain for atezolizumab versus docetaxel, up to a difference of 0.04 QALYs, or 2 weeks of perfect health: a significant period of time for a patient with a median overall survival of 13.8 months. CONCLUSIONS: The methodologies used to determine total quality of life gain in the appraisal of treatments can impact outcomes considerably. Therefore it’s important to ensure methodologies are clinically accepted, validated, and representative of the disease area and treatment under consideration.

PCN212: QUALITATIVE EXPLORATION OF THE REAL-WORLD EXPERIENCES OF MEN RECEIVING OR REFUSING CHEMOTHERAPY (DOCETAXEL) FOR THE TREATMENT OF METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (mHSPC)

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OBJECTIVES: Evidence from recent studies highlighted that administration of docetaxel plus androgen deprivation therapy in men with metastatic hormone sensitive prostate cancer (mHSPC) can prolong survival. As docetaxel is a cytotoxic therapy, however, there is a need to understand the experiences of men with mHSPC receiving docetaxel,
and those of their carers, in a real-world setting. METHODS: Semi-structured qualitative interviews were conducted with men with mHSPC (n=26) and carers (n=14) to elicit in-depth data concerning their experiences of docetaxel. Men were also asked to record their experiences in a diary for 7 days. Interviews were also conducted with men who refused treatment with docetaxel (n=5). Participants were recruited from five European countries (France, Germany, UK, Italy and Spain) and all interviews were conducted in the local language by trained qualitative interviewers. Data was analysed using thematic analysis. RESULTS: At the outset of therapy, men reported a willingness to take docetaxel to prolong their life, despite being fearful of the potential side effects and impacts on their daily lives. Those refusing to take docetaxel cited concerns regarding side effects and negative experiences of other men, as reasons for their decision. The majority of men experienced benefits associated with docetaxel, evident by reduced prostate-specific antigen levels. However, a wide range of side effects and impacts on daily life were reported, such as nausea, diarrhea, fatigue and others. Variations in individual experiences and their ability to tolerate side effects were evident. Carers were also negatively impacted by docetaxel treatment, despite their efforts to stay positive and support the patients. CONCLUSIONS: Men with mHSPC and their carers were largely satisfied with the perceived efficacy of docetaxel but reported concerns regarding side effects and associated impacts. Informed by this study, the experiences of men with mHSPC receiving docetaxel are currently being explored in a larger quantitative study.

PCN213: PREFERENCES FOR SURVIVAL IN NON-SMALL CELL LUNG CANCER: SWINGING FOR HOME RUNS OR BASE HITS?

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OBJECTIVES: Studies of outcome preferences in oncology have presented the value that patients and physicians place on improvements in mean or median progression-free or overall survival. Furthermore, a recent study showed that patients with metastatic melanoma or breast cancer prefer treatments with greater potential for long-term survival, even when expected survival is no different, a phenomenon termed the “value of hope.” Our objective was to evaluate oncologist and patient preferences for advanced non-small cell lung cancer (NSCLC) treatments, defined by mean expected overall survival (ES), best-case survival (BCS), worst-case survival (WCS), and treatment toxicities. METHODS: A discrete-choice experiment (DCE) was administered online to oncologists and patients with NSCLC. Each treatment profile in the DCE was defined by different levels of ES, BCS, and WCS, along with fatigue, nausea, and risk of febrile neutropenia. BCS and WCS were defined as the expected survival for the top and bottom 15% of patients, respectively. In separate surveys, physicians and patients chose among pairs of profiles representing possible second-line treatments for advanced NSCLC. Data were examined using random parameters logit analysis. RESULTS: A total of 102 physicians completed the survey. The preference weight for each 1-month improvement in BCS was positive, independent of the effect of all other attributes. The preference weight for ES was also positive and statistically significant, but the preference weight for WCS was not statistically significant. Severe nausea and severe fatigue were statistically significantly (negatively) more important to treatment choice than mild-to-moderate nausea or fatigue, respectively. A 10% risk of febrile neutropenia was statistically significantly preferred to a 40% risk. The patient data collection is ongoing. CONCLUSIONS: ES, BCS, and toxicities impacted physicians’ choice of advanced NSCLC treatments. Strong preference for longer BCS, holding ES, WCS, and toxicities constant, confirms that the “value of hope” matters to oncologists in the advanced NSCLC setting.

PCN214: PATIENT EMPOWERMENT FOR HEALTHCARE DECISION-MAKING ASSESSING ONCOLOGY INNOVATION THROUGH MULTICRITERIA DECISION ANALYSIS

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OBJECTIVES: Develop a value based framework using the Multi-Criteria Decision Analysis (MCDA) to evaluate oncology innovation from patient’s perspective. METHODS: A Systematic Literature Review (SLR) was done focusing in four main questions: criteria used to assess the value of oncology innovation in general and from patient’s perspective, criteria used by HTAs and criteria used in previous MCDA projects from patient’s perspective. The EVIDEUM framework was used to adapt the criteria gathered from the SLR into the Domains included in the framework. A working group composed by 8 patient’s representatives from General and Specific (disease) was asked to do the following task: 1. To assess and validate the criteria in the SLR, 2. To decide which criteria and definition of the criteria would be included or excluded from the proposed framework based on a general qualitative discussion among the panelist and 3. To weigh the agreed criteria in a 5-points scale from (1 no important to 5 most important). RESULTS: We retrieved 757 articles and 47 were included. Only 2 additional criteria were included to
EVIDEM framework (“cost-effectiveness” and “technological innovation”). Thus, we included 15 quantitative criteria and 7 contextual. The validation by patients excluded 4 quantitative (“technological innovation”, “cost effectiveness”, “quality of evidence” and “clinical practice guidelines”) and 2 contextual (“environmental impact” and “political, historical & cultural context”) and adapted the definitions of 3 quantitative ones. Ratings showed that most important criteria from patient’s perspective were “comparative patient-reported outcomes” (4.6) and “comparative efficacy/effectiveness” (4.6), the less important were “type of preventive reduction of risk” (2.9) and “comparative cost of intervention” (2.9). CONCLUSIONS: A pilot MCDA framework was obtained with 11 quantitative and 5 contextual criteria to assess oncological innovation from patient’s perspective. Further research is ongoing to apply this scale in a pilot evaluation of oncology innovative therapies.

**PCN215: WHAT MATTERS TO SPANISH PATIENTS AND PHYSICIANS WHEN FACING DECISIONS FOR GEP-NET? AN EXPLORATION USING A REFLECTIVE MULTICRITERIA SHARED-DECISIONMAKING FRAMEWORK**

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**OBJECTIVES:** Patients with slow-growing, unresectable, well/moderately-differentiated asymptomatic gastroenteropancreatic-neuroendocrine tumors (GEP-NETs) may have to decide between initiating treatment with somatostatin analogs (SSAs) or pursuing watchful-waiting. We explored drivers of decision among Spanish patients and physicians using a shared-decisionmaking multicriteria framework. METHODS: The framework, designed based on EVIDEM structure, literature review and input from GEP-NET patients and clinicians, consisted of benefit-risk criteria pertaining to effectiveness, patient-reported and safety outcomes and modulating criteria, related to type of benefit, need, costs, evidence, and feasibility. During a Chatham-House session, patients and physicians made individual reflections on the relative importance of the criteria explicit by assigning weights using Hierarchical Point Allocation and Direct Rating Scale (alternative analysis). Subsequently, informed by synthesised evidence, participants assigned a score for each criterion from -5 (Much in favor of SSA treatment [reference case lanreotide]) to -5 (Much in favor of watchful-waiting) and shared insights and knowledge. Value contributions for each criterion (NormWeightXScore/5) were calculated. RESULTS: Among benefit-risk criteria, participants attributed greatest weights to Impact on health-related quality of life (HRQoL) (0.15±SD0.06), Fatal adverse events (0.13±SD0.06) and Overall survival (0.12±SD0.07); among modulating criteria, to Feasibility/System capacity (0.15±SD0.07), Type of therapeutic benefit (0.14±SD0.07) and Quality of evidence (0.10±SD0.08). Exploring SSA treatment versus watchful-waiting based on benefit-risk criteria, at the group level, consideration of Progression-free survival contributed most in favor of treatment (+0.11±SD0.07), followed by Fatal adverse events (+0.06±SD0.08) and Impact on HRQoL (+0.04±SD0.04). When adding modulating criteria into considerations, Type of therapeutic benefit (+0.10±SD0.08), Quality of evidence (+0.08±SD0.06) and Disease severity (+0.07±SD0.04) contributed most towards treatment. None of the criteria favored watchful-waiting. Wide SDs reflected variability across participants. Alternative weighting yielded similar results. CONCLUSIONS: The comprehensive multicriteria framework supported patients’ and physicians’ reflection on the diverse aspects impacting GEP-NET management decisions and helped them identify and share what matters most to them.

**PCN217: PATIENT PREFERENCES REGARDING TREATMENT OPTIONS FOR RELAPSED REFRACTORY MULTIPLE MYELOMA (RRMM)**

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**OBJECTIVES:** New treatment options for relapsed refractory multiple myeloma (RRMM), such as combination regimens including proteasome inhibitors (PIs), are constantly evolving. However, no study has been conducted to elucidate patient preferences regarding different novel treatment options for RRMM so far. METHODS: A cross-sectional multicentre study based on computer-assisted telephone or face-to-face interviews with RRMM patients was undertaken. A Discrete-Choice-Experiment (DCE) with four attributes (drug administration: application 1 (tablet once/day+once/week, 2-hour physician visit once/month), application 2 (tablet once/day+twice/week, 2-hour physician visit once/month) or application 3 (tablet once/day+once/week, physician visit twice/week lasting 3-4 hours incl. infusion); time without disease progression: 26/20/17 months; possibility of side effects affecting the blood: 12%/19%; probability; possibility of heart failure: 2%/4%) was implemented. Preferences were analysed based on conditional logit regression models. RESULTS: Analysis was conducted for 84 patients (mean age: 62.75 years; 63.10% male; mean disease duration: 5.51 years). Drug administration was the most important attribute for patients’ choices (relative importance 38.83%). Patients strongly preferred application 1 (utility: 1.79; p<0.001), followed by application 2 (1.46; p<0.001), both compared to application 3. The second most important attribute was disease-
progression-free time (38.63%) with utilities of 1.78 for 26 months (p<0.001) and 0.81 for 20 months (p<0.001), both compared to 17 months. Possibility of heart failure occurrence had an importance of 13.92% (utility of 2% vs. 4%; 0.64; p<0.001), and possibility of side effects affecting the blood had the lowest importance (8.62%; utility of 12% vs. 19%; 0.40; p<0.001). Derived utilities for currently available RRMM treatment options were 3.21 for Ixazomib+Lenalidomide+Dexamethasone, 2.75 for Lenalidomide+Dexamethasone and 1.89 for Carfilzomib+Lenalidomide+Dexamethasone. **CONCLUSIONS:** RRMM patients prefer treatment options with an all-oral application mode, a longer disease-progression-free time and a lower probability of side effects. In order to receive a more convenient therapy, patients are willing to accept slightly less efficacy.

**PCN218: PATIENT PREFERENCES IN COLORECTAL ADENOMA SURVEILLANCE**

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**OBJECTIVES:** Colorectal cancer (CRC) is the second most common cancer worldwide and has poorer prognosis when metastasised, tackling this is the main driver of prevention programs which have focused on early detection and removal of adenomatous polyps. As more is known about the influences dietary and lifestyle factors on development of CRC, efforts are moving towards primary prevention as a means of optimising cancer prevention. We set out to elicit how patients with adenoma consider trade-offs and weigh up their choices between different surveillance options; to examine the patient and healthcare-related characteristics that could influence these choices; to determine whether preferences of patients with adenoma vary by literacy or other non-health related factors; to examine the concordance of these preferences with studies of adherence to exercise programs for individuals with pre-cancerous detected lesions. **METHODS:** Pilot online discrete choice experiment, n=231 participants (of 1200 invitees with known intermediate or high risk polyps removed during CRC screening test,) completed 8 sequential choice grids, containing information about 5 attributes related to risk reduction; diet & lifestyle program options combined with clinical testing information, estimated out-of-pocket costs for participation in primary prevention programs added to surveillance. **RESULTS:** Predominantly male, married respondents, with 25.13% university educated, and self reported comorbidities, 27.6% with high blood pressure, 25.4% with high cholesterol, 10.1% with cardiac problems, demonstrate risk aversion preferences. 37.1% of participants were unaware of their own risk status following polypectomy, despite 41% receiving their results on the day of their procedure by their treating health professional. 38.3% were willing to make changes to diet and lifestyle, with 35.1% already making changes to reduce their risk of cancer. **CONCLUSIONS:** Participants report preferences for risk minimisation and are willing to engage in diet and lifestyle programs which may optimise cancer prevention efforts following removal of adenomatous polyps in cancer screening programs.

**PCN219: IS WILLINGNESS TO PAY HIGHER FOR CANCER PREVENTION AND TREATMENT?**

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**OBJECTIVES:** It is often assumed by health economists that the principal objective of health care is to maximise population health. However, people may be willing to sacrifice overall health in order to direct resources towards high priority disease areas, such as cancer. This presentation examines whether society is willing to pay more for cancer prevention and treatment than for other types of health care. **METHODS:** The policy context in the UK, where special assessment criteria and funding arrangements are currently in place for certain cancer drugs, will be described. A review of the stated preference literature on support for a ‘cancer premium’ will also be presented. This review covers: (1) studies examining the special weighting of quality adjusted life years (QALYs) in the cancer context; and (2) studies examining cancer as a ‘dread disease’ in the literature on the value of a statistical life (VSL). **RESULTS:** Overall the evidence in relation to a cancer premium is mixed, with some studies reporting results consistent with higher QALY weights / VSL in cancer and others finding no difference in QALY weights / VSL estimates when comparing cancer and non-cancer scenarios. Conceptual overlap with other factors, such as severity, ‘end of life’ and rarity, has been identified. There is a dearth of research on the societal value of treatments that seek to improve the quality of life of cancer patients. **CONCLUSIONS:** The evidence available is not sufficiently strong to conclude whether or not willingness to pay is higher for cancer prevention and treatment. A challenge facing policy makers is to determine whether societal preferences should form the basis for a policy that prioritises investments in cancer interventions.

**PCN220: PSYCHOLOGICAL IMPACT OF CANCER: MORE GOOD THAN BAD**

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OBJECTIVES: Past research has focused on cancer’s negative consequences. Recent research has paid increasing attention to the more positive side of psychosocial adjustment to illness. The PROMIS Illness Impact (II) scale contains 46 positive II (PII) and 40 negative II (NII) items that are classified into four sub-domains: Self-Concept (SC), Social-Impact (SI), Stress-Response (SR), and Spirituality (Sp). The purpose of this study was to investigate PII and NII in cancer survivors. METHODS: Cancer survivors (n=509; age: 59.5±1.4; 51.5% men) completed the PROMIS PII and NII items comparing current and premorbid perspectives. We calculated change scores as the discrepancy between participants’ ratings of recalled experiences before cancer diagnosis and their ratings of post-cancer experiences. Descriptive statistics and agreement (Weighted kappa (κ)) were calculated on change scores. Effect sizes (ES) provided standardized change scores. Coefficient of variation (CV) was also calculated for each item. RESULTS: The largest mean change scores appeared on PII-SI items and NII-SR items (absolute mean > 0.5). The CV results showed that items from PII-SC and from NII-SR and NII-SP have better discrimination power among survivors (CVs>10). As demonstrated by ES values, participants tended to report more positive than negative impacts after cancer (mean: 0.30 vs.0.23). Across NII and PII, there were 25 of 86 (29.1%) areas where significant negative change was reported, and 32 of 86 (37.2%) areas where significant positive change was reported. CONCLUSIONS: Cancer survivors reported more positive than negative psychosocial illness impact after diagnosis. Future research should examine how the perceived change captured by the PII and NII items correspond to reported change over time.

PCN221: MOVING PRO MEASURES FROM THE PROMISE TO IMPACT IN ONCOLOGY CLINICAL PRACTICE: RESULTS FROM A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To explore existing evidence on the impact of incorporating patient-reported outcomes (PRO) into routine oncology clinical care on patient outcomes and work flow using a systematic literature review (SLR). METHODS: A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol was developed and used to guide the SLR conducted in Medline and Embase databases for studies published from 2006 to 2017. An additional search was completed following the initial search to include references of identified articles and prior SLRs. A theoretical framework based on ISOQOL PRO Implementation Guidelines was used to guide data synthesis. RESULTS: After screening 4,417 abstracts, 36 studies met the eligibility criteria (44% from US). The majority of studies reported PRO intervention trial evaluations (n=22, 61%) or feasibility assessments (n=13, 36%); only three studies reported real-world PRO implementation. Of the 22 studies with an intervention component, three reported no intervention effects on study outcomes. PRO intervention effect was documented for patient centered communication (n=8), changes in PRO score (n=8), chart documentation (n=3), and satisfaction with treatment (n=3). The EORTC QLQ-C30 was most commonly-used across studies (n=10, 28%) with an additional 38 measures also reported. Most elements of the ISOQOL PRO Implementation Guidelines were followed, with a notable gap in providing interpretation guidelines. Fewer than 20% of studies reported information on interpretation of PRO scores and 25% discussed strategies for addressing issues identified by PROs. CONCLUSIONS: Existing evidence is mixed, but suggests that the use of PROs in clinical care may be effective for symptom monitoring, improving quality of care, and/or increasing patient-centered communication. Yet, reports of real world PRO implementation are scarce. Factors that can facilitate implementation include: 1) increased focus on interpretation guidelines for PROs; 2) addressing existing implementation barriers; 3) early engagement of diverse stakeholders and 4) systematic implementation approach.

PCN222: PATIENT EXPERIENCE ASSESSMENTS IN ADVANCED GASTRIC, ESOPHAGEAL, AND GASTROESOPHAGEAL JUNCTION CANCER STUDIES

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OBJECTIVES: The objectives of this research were to identify signs, symptoms, and impacts of advanced gastric, esophageal, and gastroesophageal junction cancers (GC/EC/GEJC) and map these to the patient-reported outcomes (PRO) instruments frequently used to assess patient experience. METHODS: A structured, targeted literature and clinical trial search of HRQoL and PRO studies in English for GC/EC/GEJC from was conducted. Results were supplemented with patient blogs and message-boards discovered through an internet search to identify and corroborate the symptoms and impacts. A preliminary conceptual model was developed, summarizing the signs, symptoms, and impacts frequently mentioned by the existing literature or patient websites. RESULTS: 39 concepts (24 symptoms, 15 impacts) were identified. Symptoms related to dysphagia, nausea and vomiting, pain, and satiety were most important; impacts related to weakness and weight loss were frequently mentioned. Previous
gastrectomy/esophagectomy was associated with worsening symptoms. Of the PRO instruments identified, the EORTC QLQ-C30 was most frequently cited; however, it does not capture all concepts in our conceptual model and it was often supplemented by a disease-specific module (e.g., STO22, OES18, OG25). The OG25 was developed most recently and captures important concepts for GC/EC/GEJC patients; the most comprehensive capture of general and disease-specific symptoms and impacts most important to patients is the combination of the QLQ-C30 and OG25. **CONCLUSIONS:** In patients with advanced GC/EC/GEJC, the most important symptoms and impacts were disease-specific (e.g., dysphagia) and general (e.g., satiety), indicating that a general instrument supplemented by a disease-specific module can best represent patient experience. The QLQ-C30 and OG25 used together comprehensively assess the most important patient symptoms and impacts. The OG25 is validated to measure concepts in both GC/EC/GEJC, and covers more concepts. Further research through patient concept elicitation interviews is warranted to elucidate priority symptoms of advanced GC/EC/GEJC, based on frequency and disturbance to patients.

**PCN223: PRO-CTCAE IMPACT ON PAYER EVALUATIONS OF ONCOLOGIC THERAPIES: A QUALITATIVE RESEARCH STUDY**

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**OBJECTIVES:** The Patient-Reported Outcomes (PRO) version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) was developed as a companion to the standard lexicon for AE reporting utilized by clinical investigators. The objective of this research was to understand payers’ perceptions of the PRO-CTCAE tool and its potential impact on formulary and coverage decision-making for new oncologic therapies. **METHODS:** This double-blind qualitative research included individuals with formulary or reimbursement decision-making responsibility in the US and Europe. Respondents were provided background materials on the PRO-CTCAE. A semi-structured guide was developed to facilitate discussion during telephone interviews to elicit spontaneous reactions to the usefulness of PROs in decision making and reactions to the PRO-CTCAE in particular. The sample included 8 medical directors from the US and 2 medical/pharmacy directors each from the UK, France, Germany, Italy, and Spain with experience in evaluating oncologic therapies. Data were summarized descriptively and evaluated for geographical differences. **RESULTS:** Variables considered in evaluating a new oncologic therapy in the US and EU were similar with highest relative importance assigned to efficacy versus standard of care, followed by safety considerations, then costs. Respondents viewed the PRO-CTCAE positively, noting direct patient input as an important perspective of the patient experience. However, the combination of newness of the tool, variability in subjective ratings, lack of understanding of meaningful scale changes, and difficulty comparing responses with investigator-reported CTCAE evaluations were noted relative to potential utilization for purposes of new formulary or reimbursement decision making. **CONCLUSIONS:** Payers considered the PRO-CTCAE a useful tool adding supplemental informative data on new oncologic therapies, but in the near term, until the tool and its data are better understood, it is not anticipated that these data will significantly influence current reimbursement or access decision making.

**PCN224: UNDERSTANDING PATIENTS’ ABILITY TO FUNCTION IN ORDER TO INFORM CLINICAL BENEFIT IN ONCOLOGY STUDIES**

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**OBJECTIVES:** Demonstration of clinical benefit in oncology typically focuses on the impact of treatment on survival and tumour progression. However, as survival benefit data are difficult to obtain in oncology drug development programmes, additional endpoints are needed to complement the evidence of treatment effect on the tumour. To date, little is known of the changes patients experience in day-to-day function due to cancer and/or treatment. We set out to understand the concept of ‘function’ in order to inform its assessment as a patient-relevant endpoint for clinical benefit. **METHODS:** Twenty semi-structured interviews were conducted to explore how cancer patients describe their daily functioning. Patient interviews and the literature were then used to develop a conceptual framework of function. **RESULTS:** Patients interviewed were diverse: eight cancer types (all solid tumours, 65% metastatic, 50% with active disease), ECOG status 0–1 (55%) and 2–3 (45%), and 35% having previously received taxanes. The term ‘function’ was not easily understood by patients and 35% did not provide a definition. When describing function, 60 unique concepts were discussed. Four categories of function emerged (mobility, cognition, activities, roles), and later a conceptual framework was developed. Impairments in function were often described as limitations in mobility and/or cognitive abilities. Patients also described 20 different concepts of ‘adaptation’ to overcome cancer or treatment-related impairment and resume their day-to-day function, including change in frequency/intensity, precaution, use of external aids or proactive behaviour changes. **CONCLUSIONS:** ‘Function’ from patients’ perspective is a complex concept; further research is needed to understand the assessment of mobility, cognition, activities and roles as
individual concepts for measuring function. In addition, selecting the most appropriate dimension of measurement (e.g., frequency, ability to perform, difficulties completing a task) for each concept is paramount to reliable and meaningful capture of cancer- and/or treatment-related functional impairment.

PCN225: PRO INSTRUMENTS USED IN STUDIES OF SKIN CANCER 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 skin cancer, the geographical settings in which these studies were conducted and the interventions assessed. METHODS: We searched the heoro.com database (www.heoro.com) for PRO studies on skin cancer published between 1960 and May 15 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 79 abstracts that reported the use of 45 different PRO instruments. Of these, nine instruments were specific for skin cancers, four were designed for other cancers or cancer in general, 18 were general instruments used to evaluate quality of life or utilities, seven assessed the impact of treatments, and seven assessed symptoms or comorbidities of people with skin cancer. The most frequently used tool was the EORTC QLQ-C30 (12 abstracts), followed by the SF-26 (9), then Skindex, DLQI and visual analogue scales (7 each) and Skin Cancer Index (5). Studies generally recruited patients with melanoma (35 abstracts), basal cell carcinoma (13), squamous cell carcinoma (7), all non-melanoma skin cancers (13) or skin cancer in general (15). The USA was the most frequent location for the studies, with 27 abstracts, followed by the UK (11) then Italy (5). The main interventions assessed were surgery, including Mohs microsurgery (17 abstracts), interferon (7), photodynamic therapy (5) dacarbazine (4) and screening or surveillance (12). CONCLUSIONS: A wide range of PRO tools have been used in studies of skin cancer from a wide range of locations, but only six tools and three countries were cited in five or more abstracts.

PCN226: SYMPTOMS AND IMPACTS IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: QUALITATIVE STUDY FINDINGS

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OBJECTIVES: To understand the signs and symptoms experienced by chemotherapy-naïve patients with metastatic castration-resistant prostate cancer (mCRPC) and how both disease- and treatment-related factors impact patients’ lives. METHODS: Qualitative structured interviews with chemotherapy-naïve patients with mCRPC identified the most frequently experienced signs, symptoms and impacts of prostate cancer, and the degree of disturbance these had on patients’ lives. Patients rated the disturbance of their symptoms and impacts on a scale of 0 (not at all disturbing) to 10 (extremely disturbing). Responses were analysed through ATLAS.ti software and summarised to include frequency of prompted versus unprompted responses, and mean disturbance. RESULTS: Nineteen patients were interviewed to reach concept saturation. Ninety-five percent of patients were on continuous hormonal therapy; 68% were on some anti-androgen therapy. The majority of patients reported some form of prostate cancer-specific symptoms with moderate mean disturbance, including pain (74%; disturbance=6.3) and fatigue (89%; disturbance=6.4). Nearly one-half of patients experienced some form of muscle deconditioning (48%; disturbance=6.7). Much of the additional symptom burden experienced by patients, including sexual dysfunction and urinary and hormonal symptoms, was attributed to previous or ongoing treatment. A substantial proportion (≥60%) of patients reported depression (68%; disturbance=4.9), interference with daily activities (74%; disturbance=7.7) and frustration (63%, disturbance=8.1). Patients rated treatment dissatisfaction (16%; disturbance=9.5) and inability to perform extracurricular activities (16%; disturbance=8.3) as most the disturbing impacts of mCRPC. CONCLUSIONS: Chemotherapy-naïve patients with mCRPC reported a variety of symptoms that may be due to their underlying disease and previous and ongoing treatments. The reduced ability to physically function on a day-to-day level and satisfaction of care were the most disturbing elements to these patients. Understanding patients’ experience and satisfaction with mCRPC treatments may allow for the use of tailored patient-reported outcome measures in clinical trials.

PCN227: DIGITAL REAL-WORLD EVIDENCE PLATFORM: TAKING THE BURDEN OUT OF MELANOMA PAIN REPORTING

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OBJECTIVES: Our aim was to assess, in the context of melanoma real-world evidence, the value of participants reporting pain via a mobile application. Our focus was twofold: how would the data compare with the literature and
what value does the app hold for the participant? METHODS: We developed a melanoma-specific mobile app, featuring a pain NRS question adapted from the Brief Pain Inventory (SF) and EuroQol’s EQ-5D 5L. Data were gathered from stage IV melanoma participants, recruited in collaboration with patient advocacy group MelanomaUK. Quantitative data focused on participant demographics, frequency of access to app, and regularity of reporting. Qualitative surveys elucidated: the value of using the data at consultations; whether anxiety related to recall-based pain-reporting was alleviated; and if participant burden of reporting over longer time periods was reduced. A scoping literature review was carried out to evaluate the published real-world evidence on pain in melanoma, and modalities of data capture. Feedback was evaluated to understand the everyday experience of living with melanoma and the impact of participants using an electronic application to report their pain within their real-life context rather than within clinical surroundings. RESULTS: The benefits of a flexible and intuitive reporting app solution were highlighted, including: greater accuracy and granularity in reporting over longer periods; usefulness of instant access to data during consultations; and a reduction in participant anxiety and burden related to verbal recall. CONCLUSIONS: In the context of melanoma, technology that allows participants to generate and record regular pain and QoL data in real-time and in the real life setting, has several benefits, not only for the participant, who experiences decreased burden in reporting and increased satisfaction in interactions with their healthcare professional, but also for carers, clinicians and stakeholders, who can instantly access accurate and granular pain data in order to offer improved treatment options and care.

PCN228: IMPACT OF ISOCITRATE DEHYDROGENASE (IDH) STATUS ON THE PERFORMANCE STATUS AND QUALITY OF LIFE (QOL) OF Glioblastoma Multiforme (GBM) Patients

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BACKGROUND: In 2016 WHO reclassified diffuse gliomas, incorporating new entities defined by histological and molecular features, such as IDH-wildtype and IDH-mutant, hoping to improve patient outcome predictions and guide individualized treatment OBJECTIVES: To assess GBM patient’s performance status and QoL by IDH classification. METHODS: Cross-sectional data were gathered using Adelphi’s Disease-Specific Programme in Canada, France, Germany, Italy, Spain and the UK (May - Sept 2016). Physicians provided patient level data on 1,747 GBM patients; 420 of those patients completed a questionnaire containing the 3L-EQ-5D and EORTC Quality of Life Questionnaire (C30 and GBM-specific BN20). Summary statistics are reported, differences assessed using pairwise t-tests and chi-square analysis. RESULTS: IDH status of 682 (39%) patients was provided, 31% confirmed IDH-mutant. Performance status, assessed using ECOG, showed IDH-wildtype patients as significantly more disabled than IDH-mutant at diagnosis (p<0.01) and time of reporting (p=0.01). Mean life expectancy at diagnosis (weeks) for IDH-wildtype patients was 62.6 vs. 78.1 for IDH-mutant (p<0.01); medians show a similar trend (52.0 and 65.0 respectively). Physician subjective classification of patient GBM status showed significant differences in the proportion of patients considered ‘responding to treatment’ (IDH-wildtype 26%, IDH-mutant 35%, p<0.01) and stable (IDH-wildtype 50%, IDH-mutant 41%, p=0.02). No significant difference was noted in patients classified as progressing. PRO data were provided from 26 IDH-mutant and 109 IDH-wildtype patients. QoL was poor, indicated by an overall mean EQ-5D index score of 0.54 with no significant difference noted by IDH status. Similarly no significant difference was noted by IDH status for the EORTC Global health status score (overall mean 44.5). CONCLUSIONS: With limited existing data, our data demonstrated IDH-wildtype patients were likely to have poorer performance status, shorter life expectancy and not be considered as responsive to treatment as IDH-mutant patients reinforcing the decision to reclassify GBM entities to guide patient management strategies.

PCN229: HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH METASTATIC COLORECTAL CANCER USING EQ-5D-5L

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OBJECTIVES: New treatments in metastatic colorectal cancer intend to reduce side effects and improve quality of life. The aim of this study was to estimate health related quality of life of patients with metastatic colorectal cancer undergoing conventional chemotherapy in a tertiary university hospital in Brazil. METHODS: Prospective cohort study was conducted from July 2013 to June 2014. All patients that were diagnosed with metastatic colorectal cancer answer the EQ-5D-5L and then went to conventional chemotherapy as recommended by their doctor. They also answered the questionnaire at all outpatient visits and chemotherapy sections in a university hospital in Ribeirão Preto. The value set used to calculate the EQ-5D-5L index was the one from United Kingdom because Brazil doesn’t have the value set for this version of the questionnaire. RESULTS: There were 46 patients that answered the questionnaire in 174 interviewers. Median age was 64 years (34-81) and 52.2% were women, 52.2% married and
30.4% had fundamental school incomplete, 71.7% the colon was the primary site of the tumor, 67.4% had hepatic metastasis and 56.5% had already done some surgery because of the tumor. When stratified by the chemotherapy we had the utility scores: XELOX = 0.799 (SD 0.241); FOLFOX = 0.855 (SD 0.320); FOLFIRI = 0.780 (SD 0.200); FOLFIRI + BEVACIZUMAB = 0.890 (SD 0.111); IRINOTECAN + CETUXIMAB = -0.667 (SD 0.161). Among all the observations, 36.6% showed no problems, 44.8% slight or moderate problems and 19.0% severe or extreme problems. The most affected dimensions were, usual activities (37.9%), pain/discomfort (36.2%), mobility and anxiety/depression (25.9%) and self care (15.5%). The mean Visual Analogue Scale was 75.71. CONCLUSIONS: This study helps in discussing the benefits and quality of life of these patients with metastatic disease undergoing different chemotherapy regimens.

PCN230: QUALITY OF LIFE (QOL), FUNCTIONAL STATUS (FS), AND SURVIVAL IN TRIPLE NEGATIVE BREAST CANCER (TNBC): Discordance of Definitions Among a Targeted Literature Review and Stakeholder Interviews

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OBJECTIVES: To understand the relationship between QoL, FS and survival in women with TNBC via available literature and key stakeholders’ (payer, physician and patient) perspectives. METHODS: A targeted literature review (2006-2016) was conducted focusing on studies in the US and EU. Studies were selected for evaluation if the title indicated relevance to the research questions. Telephone interviews were conducted with 8 US payers, 9 EU HTA advisors, 6 US and 9 EU oncologists, and 6 US and 3 UK TNBC patients, to understand how QoL and FS are defined and valued relative to survival. RESULTS: A total of 375 studies were identified (with potential overlap between databases): 175 from Medline and 200 from Embase. No publications directly assessed the relationship between QoL, FS and survival in women with TNBC. Nine publications evaluated general QoL in breast cancer (BC) patients: 6 in patients with brain metastases and 1 in a patient with leptomeningeal metastases. In one study of 118 BC patients (40.5% TNBC+), Karnofsky PS (≥70 vs <70) was significantly associated with survival (HR, 0.485; P=0.015). Stakeholder telephone interviews revealed that survival is the most important factor in treatment selection. Key variables impacting stakeholders’ perceived value of QoL and FS are line of therapy and disease progression. Adverse events (AEs), side effects (SEs) and toxicities were also critical. Stakeholders assumed FS and QoL are related to AEs, SEs and drug toxicities; therefore, FS and QoL data may be linked to these drug-specific experiences as well. Stakeholders did not know how to precisely define the connection between constructs. CONCLUSIONS: Many gaps exist in understanding the relationships between QoL, FS and survival in TNBC; AEs, SEs and toxicity also need to be considered. Future patient-focused quantitative research is necessary to further explore and prioritize outcomes in TNBC.

PCN231: Health-related Quality of Life after Major Lower Extremity Amputation Due to Musculoskeletal Tumors

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OBJECTIVES: Major amputation may be required when limb-sparing surgery is not possible for musculoskeletal tumors, or has failed. The authors aimed to assess the function and health-related quality of life (HRQoL) after major lower extremity amputation due to musculoskeletal tumors. METHODS: Thirteen non-consecutive adult patients (two men and 11 women; mean age 66 years) who had been fitted with a prosthesis after having undergone major lower extremity amputation due to a tumor. Participants completed a general health survey on a 0-100mm (best-worst) visual analog scale, the Locomotor Capabilities Index 5, and the 15D HRQoL instrument at a median of five years after amputation. Twenty-four major lower extremity trauma patients who had their amputated limb fitted with a prosthesis served as HRQoL controls. RESULTS: The mean (SD) general health was 23/100 (13), 15D Mobility dimension was 2.2/5 (0.8) and locomotor capability was 44/100 (13). The mean 15D index was 0.85 (0.11) and that of the control group 0.87 (0.11). Both scores were somewhat lower than those usually observed in similar aged general population (around 0.90). CONCLUSIONS: Function after major lower extremity amputation due to musculoskeletal tumors is good among patients who had undergone successful prosthetic fitting, and the HRQoL is slightly lower than similar aged general population but comparable to that of major lower extremity trauma amputees.

PCN232: A Qualitative Interview Study to Explore the Patient Experience of Locally Advanced or Metastatic Pancreatic Cancer and Explore the Content of Patient-reported Outcome Measures
OBJECTIVES: This study aimed to a) understand the lived experiences of patients with locally advanced or metastatic pancreatic cancer and b) develop a conceptual model to guide future outcomes measurement. Patient-reported outcome (PRO) instruments (EORTC QLQ-C30 & PAN26; FACT-Hep) were assessed for their suitability in this population. METHODS: Patients with locally advanced or metastatic pancreatic cancer who had received treatment in the past 12 months participated in an interview. A semi-structured interview guide was developed, based on published literature and medical expert interviews (n=6). Interviews were thematically analyzed in ATLAS.ti.v7; quotes were coded to identify concepts. Concepts arising from interviews were grouped into domains to form a conceptual model. Framework analysis was applied to identify PRO conceptual relevance, comprehension, and interpretation. RESULTS: Twenty-four patients were interviewed (62.5% female, aged 35-84). Before diagnosis, patients experienced pain (n=21) including in the abdomen (n=9) or back (n=6) and jaundice-associated symptoms e.g., yellow skin/eyes (n=8). Treatment included Whipple surgery, chemotherapy and radiation regimens. Surgery was associated with acute pain and gastrointestinal symptoms; chemotherapy/chemo radiation with cyclical side effects including fatigue/tiredness (n=21), appetite loss (n=15), bowel problems (n=15), nausea and vomiting (n=15). Radiation was also associated with skin problems at the radiation site. Patients experienced significant impairment to physical function and daily activities (e.g. tiredness, difficulty walking), sleep, socializing, work, and wellbeing. Patients generally found the QLQ-C30 & PAN26 and FACT-Hep to be understandable and conceptually relevant. CONCLUSIONS: Pancreatic cancer and its treatment are associated with significant symptoms, side effects, and impact on patient lives. PRO instruments included in clinical trials should assess the effect of therapies on pain, gastrointestinal symptoms and fatigue. The QLQ-C30 & PAN26 and FACT-Hep appeared relevant and suitable to capture symptoms and impacts in clinical trials but FACT-Hep assesses additional distal impacts. Items in both PRO instruments could be amended/added to ensure conceptual comprehensiveness.

PCN233: TREATMENT SATISFACTION AND BURDEN OF ILLNESS WITH ORAL VS INJECTABLE MULTIPLE MYELOMA THERAPY IN PATIENTS WITH NEWLY DIAGNOSED DISEASE (NDMM)

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OBJECTIVES: We compared patient-reported satisfaction, productivity, and burden of illness with oral vs injectable therapy in NDMM. METHODS: Patients were recruited from PatientsLikeMe, MyelomaCrowd, and Facebook. Eligible US patients were: ≥ 18 years; on current treatment without any prior change in therapy due to progression, without amyloidosis, and without other cancers. The cross-sectional electronic survey included: Treatment Satisfaction Questionnaire for Medication (TSQM), Work Productivity and Activity Impairment – Specific Health Problem, and Burden of illness questions. Outcomes of interest were compared between all-oral (oral users) or injectable therapy with or without oral medication (injectable users). Adjusted analyses were controlled for age, gender, race and frailty. RESULTS: Among 176 patients, mean age was 61 years, 38% were male, 86% were Caucasian, and 27% had ECOG-PS: 2+. Patients using oral vs injectable agents comprised 44% (78/176) and 56% (98/176), respectively. Baseline characteristics were balanced between the groups. Adjusted means were comparable for treatment effectiveness (72 vs 71, p=0.72), and global satisfaction (54 vs 57, p=0.18) of the TSQM, but a trend toward greater convenience of treatment among patients using oral vs injectable agents was observed (81 vs. 76, p=0.06). Patient activity impairment was lower among patients using oral vs injectable agents (33% vs. 43%, p < 0.05). Lower adjusted mean number of monthly clinic visits (1.2 vs 3.4, p<0.001), adjusted mean monthly travel and clinic visit time (minutes; patient: 185 vs 456, p<0.01; and caregiver: 58 vs 326, p<0.05) and estimated monthly per patient cost (sum of patient/caregiver travel and clinic visit value of time, and visit copay/parking) $150 vs $322 (p<0.01) were reported among patients using oral vs injectable agents. CONCLUSIONS: In NDMM, an all-oral regimen is associated with lower economic burden of illness and less activity impairment than an injectable regimen, and a trend towards greater treatment convenience.

PCN234: WORK PRODUCTIVITY IN HER2 POSITIVE BREAST CANCER: A COMPARISON OF PATIENTS ACROSS STAGES OF EARLY AND METASTATIC DISEASE.

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OBJECTIVES: While the clinical impact of HER2+ breast cancer (HER2+BC) is well described, data on the societal impact are lacking. This study compared work productivity in three HER2+ patient groups: early (E)BC during adjuvant treatment, EBC post-treatment, and metastatic (M)BC. METHODS: A cross-sectional, observational study of 299 consenting female patients recruited from 14 secondary care centres. Group1 (n=89): receiving targeted HER2 therapy±chemotherapy for EBC; Group2 (n=108): in follow-up post-targeted treatment for EBC; Group3 (n=102): MBC on treatment. Patients completed questionnaires including the Work Productivity and Activity Impairment (WPAI) measure and EQ-5D-5L; clinical staff collected patient and disease characteristics from medical records. Associations and inter-group differences were assessed using correlation analysis and univariate analysis of variance (ANOVA). [NCT03099200]. RESULTS: Fewer Group3 patients were employed (n=28) compared to Group1 (n=45) and Group2 (n=55) (p<0.003), with more reporting an inability to work (Group3: n=27, Group1: n=7, Group2: n=5) (p<0.003). Of employed patients, Group2 reported lower mean (SD) levels of work absenteeism (9% [24%]) and overall work impairment (26% [31%]), compared to Group1 (38% [44%]; p<0.001 and 49% [40%]; p=0.015, respectively), and marginally lower mean (SD) levels of absenteeism than Group3 (31% [44%]; p=0.068). Across all patients (including unemployed), mean (SD) activity impairment in Group1 (34% [28%]) and Group2 (28% [26%]) was lower than in Group3 (48% [31%]; p<0.005). Across groups, higher work and activity impairments were associated with lower EQ-5D-5L health utility: r=-0.3950; p<0.001, and r=-0.6670; p<0.001, respectively. CONCLUSIONS: The relatively low levels of absenteeism and work impairment reported by employed patients suggest that those who were able to work remained productive. However, a higher proportion of MBC patients were unable to work, and reported significantly higher levels of overall activity impairment compared to those with EBC. Impairment was related to health utility, reflecting the overall impact of advanced disease.

PCN235: THE HUMANISTIC BURDEN OF MICROSATELLITE INSTABILITY-HIGH (MSI-H) COLORECTAL CANCER (CRC) AND METASTATIC CRC (mCRC) PATIENTS TREATED WITH SUBSEQUENT LINE THERAPY: A SYSTEMATIC REVIEW

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OBJECTIVES: To summarize the impact of subsequent line pharmacotherapy on the humanistic burden of patients with MSI-H CRC and mCRC. METHODS: A systematic literature review was conducted, searching MEDLINE form January 2007 through April 2017; manual backward-citation tracking was also employed. Searches used disease-specific terms for MSI-H CRC and mCRC combined with terms for "humanistic burden." Humanistic burden encompassed health state utilities, quality of life (QoL), and other patient-reported outcomes (PROs). English-language studies of patients with MSI-H CRC or mCRC who received subsequent line pharmacotherapy and provided data on humanistic burden were included. RESULTS: The search yielded 621 non-duplicate citations. Following title/abstract and full-text screening, no MSI-H CRC studies met inclusion criteria. Fifteen mCRC studies were included; 7 reported on both utilities and QoL/PROs while 8 studies reported outcomes individually. All utility studies used EQ-5D and 9 QoL studies used QLQ-C30. Reported utilities ranged from 0.68-0.84; most utility studies reported no differences between treatments or lacked statistical analyses. Improved QoL was seen with cetuximab when compared to best supportive care (BSC) or added to irinotecan. Similar QoL improvements were also observed when panitumumab was compared to BSC or added to irinotecan. However, a randomized controlled trial (RCT) comparing cetuximab to panitumumab revealed no significant differences between these treatments. RCT-data evaluating ramucirumab+FOLFIRI vs. placebo+FOLFIRI and regorafenib+BSC vs. placebo+BSC showed similar results between cohorts. CONCLUSIONS: While published research assessing QoL or PROs in MSI-H CRC patients receiving subsequent line pharmacotherapy is limited, patients with mCRC reportedly experience significant humanistic burden. With the emergence of immunotherapies for MSI-H CRC, there is a need to better understand the humanistic burden associated with this population, including the association between humanistic and clinical outcomes.

PCN236: HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND DISEASE SYMPTOMS IN PATIENTS WITH UNRESECTABLE HEPATOCellular CARCINOMA (HCC) TREATED WITH LENVATINIB (LEN) OR SORAFENIB (SOR)

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OBJECTIVES: A recent phase 3, randomized, open-label, noninferiority trial compared efficacy and safety of LEN to SOR as first-line systemic treatment in unresectable HCC (954 patients). The study included analyses to evaluate the impact of therapy on HCC on HRQOL. METHODS: HRQOL was assessed using the EORTC QLQ-C30, the HCC-specific module (EORTC QLQ-HCC18), and the European Quality of Life (EQ-5D-3L) at baseline, Day 1 of each cycle, and off-treatment visit. Changes from baseline in both treatment arms were assessed using linear-mixed models with selected covariates (baseline score, geographical region, macroscopic portal vein invasion and/or extrahepatic spread, ECOG-PS, body weight). Time to worsening for each domain was represented as months to deterioration defined by a minimally important difference (MID). RESULTS: 954 patients (LEN n=478; SOR n=476) were randomized and included in the intent-to-treat population. Baseline HRQOL scores were similar for patients receiving LEN or SOR across all domains. Significant changes from baseline HRQOL scores were noted for Nutrition, Diarrhea, Role Function (RF), Pain, and Body Image (BI). In the QLQ-HCC18 Nutrition domain, lower adjusted mean scores in favor of LEN were reported at most time points with significant differences at Cycle 6 and Cycle 9 (p<0.05). SOR was associated with worsening Diarrhea symptoms with lower adjusted mean scores in favor of LEN reported at Cycles 3, 6, 9, and 12 (p<0.01). Median months to clinically meaningful worsening among each treatment group was statistically significantly favoring LEN for the QLQ-C30 domains of RF (2.0 vs 1.9; p=0.0098), Pain (2.0 vs 1.8; p=0.0060), and Diarrhea (4.6 vs 2.7; p=0.0011), and in the QLQ-HCC18 domains of BI (2.8 vs 1.9; p=0.0041), and Nutrition (4.1 vs 2.8; p=0.0060). CONCLUSIONS: Most domains met the noninferiority assumption between LEN and SOR. The additional evidence of significant HRQOL benefits further support LEN in terms of functional deterioration delays.

PCN237: HEALTHCARE PROFESSIONALS’ PREFERENCES FOR THE TREATMENT SELECTION OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): THE PRELIC STUDY

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OBJECTIVES: To explore the preferences of Spanish healthcare professionals (haematologists and hospital pharmacists) for the treatment selection of active CLL patients at first relapse. METHODS: Preferences for attributes were measured using a discrete choice experiment (DCE). A literature review and focus group of 5 experts determined 7 attributes that defined 36 scenarios included in the DCE: four patient-related attributes (age, functional status, comorbidities, and risk of the disease [risk; Del17p/mutTP53 and relapse]), and three treatment-related attributes (hazard ratio of progression-free survival [HR-PFS], rate of discontinuations due to adverse events and treatment cost). Data were analyzed using the mixed logit model. Relative importance (RI) of attributes was calculated and compared between healthcare professionals. Willingness to pay (WTP) was estimated using two questions ad-hoc. RESULTS: A total of 130 participants, 72 haematologists [mean (SD) time of practice (yrs)= 16.8 (7.7), chief of department= 20.8%] and 58 hospital pharmacists [mean time of practice= 16.3 (9.3), chief of department= 44.8%] answered the DCE. Higher RI was obtained for treatment-related attributes, the highest rated being ‘cost’ (23.8%) followed by ‘HR-PFS’ (20.9%). Regarding patient-related attributes, the highest RI was obtained for ‘age’ (18.1%). No significant differences (p>0.05) in RI between haematologists and pharmacists were found. Ad-hoc questions showed a WTP of €41,923/year and €36,769/year for a gain of 1 year-PFS when treating a patient aged 70 and ≥80, respectively, considering a reference annual treatment cost of €20,000/year. CONCLUSIONS: This is the first DCE including age and cost as attributes for CLL treatment selection. ‘Cost’ and ‘HR-PFS’ (treatment-related attributes) and age (patient-related attribute) were the main factors that determine treatment selection at first relapse. WTP decreases with increasing patients’ age. Similar research in other onco-haematological diseases is recommended.

PCN238: ASSOCIATION BETWEEN TUMOUR LESION SIZE AND HEALTH-RELATED QUALITY OF LIFE OUTCOMES IN PATIENTS WITH METASTATIC MERKE CELL CARCINOMA TREATED WITH AVELUMAB

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OBJECTIVES: In patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive skin cancer,
changes in tumour size during treatment may be associated with an impact on functioning and health-related quality of life (HRQoL). This research aimed to investigate this association. METHODS: Patients (N=88) with stage IV chemotherapy-refractory MCC receiving avelumab in a single-arm, open-label, multicentre, international phase 2 trial (NCT01865747) completed FACT-Melanoma (FACT-M) and EQ-5D-5L questionnaires at baseline, week 7 and then every 6 weeks until week 25. FACT-M has been shown to perform adequately in the mMCC population. Tumour size was determined from radiological assessment every 6 weeks based on RECIST 1.1, and mapped onto HRQoL assessments occurring within 7 day proximity. Associations were evaluated by linear regression of change in HRQoL on percent change in sum of target lesion size (SLD) at week 7 and all subsequent timepoints. Mean HRQoL score changes corresponding to a 30% reduction in tumour size were predicted and interpreted in the context of published minimally important differences. RESULTS: All patients with tumour evaluations and FACT-M data at baseline and week 7 (n=39), week 13 (n=27), week 19 (n=20) and week 25 (n=19) were analysed. One additional patient was included in EQ-5D analyses. Median SLD at baseline was 83mm (range: 16–404mm). Regression analyses showed associations between change in HRQoL outcomes and SLD at week 7. Specifically, a 30% SLD reduction at week 7 was associated with clinically meaningful improvements (mean change) in Functional Well-being (1.89), FACT-M Trial Outcome Index (4.20), FACT-G total (3.84), FACT-M total (5.52) and EQ-5D-5L utility index (0.06). Gain in EQ5D-5L utility index remained at week 13 (0.03) but no other associations were observed at subsequent timepoints. CONCLUSIONS: Reducions in tumour size after 7 weeks of avelumab treatment were associated with clinically meaningful improvements in functioning and HRQoL.

PCN239: SYMPTOM DETERIORATION IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA TREATED WITH CABOZANTINIB OR EVEROLIMUS

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OBJECTIVES: In the phase 3 METEOR trial (NCT01865747) cabozantinib significantly improved OS, PFS and ORR over everolimus in previously-treated patients. A priori between-treatment analysis showed cabozantinib maintained symptoms and HRQoL similarly to everolimus. Here, we report post-hoc within-treatment analysis of symptoms and impact on HRQoL. METHODS: Patients completed FACT Kidney Symptom Index (FKSI-19) and EQ-5D-5L at baseline, every 4 weeks (first 6 months), then every 8 weeks and end of treatment (EOT). Repeated-measures regression of EQ-5D VAS on FKSI-19 symptoms was used to assess impact on HRQoL. Time until definitive deterioration (TUDD) using Kaplan-Meier/Cox methods was assessed for the FKSI-19 total and Disease-Related Symptoms 9-item subscale (FKSI-DRS9). Sensitivity analyses included a smaller minimal important difference (MID) and including disease progression and death as events. For time until FKSI-19 symptom impact, a patient report of “quite a bit/very much” was the event. RESULTS: TUDD analyses included 615 (93.5%) ITT patients providing baseline and ≥1 post-baseline FKSI-19 value before EOT. Symptom analyses included 648 ITT patients providing ≥1 FKSI-19 value before EOT. Higher symptom frequency was associated with lower HRQoL for all FKSI-19 symptoms except ‘blood in urine’. No difference in time until FKSI-19 total deterioration was found between cabozantinib and everolimus; however, time until FKSI-DRS9 deterioration was longer for cabozantinib (5.6 vs 3.8 months, HR=0.79, 95%CI:0.64–0.99), Sensitivity analyses had consistent results and interpretation. Time until symptom impact was longer for most FKSI-19 symptoms (12/19) for cabozantinib versus everolimus but was shorter for diarrhea (HR=3.91, 95%CI:2.05–7.43). After post-hoc multiple testing adjustment, significant improvements remained with longer time to lack of energy (HR=0.50), fatigue (HR=0.57), pain (HR=0.47), shortness of breath (HR=0.26), coughing (HR=0.32), and HRQoL items relating to ability to work (HR=0.67) and contentment with HRQoL (HR=0.54). CONCLUSIONS: Cabozantinib exhibited longer disease-related symptom control with an associated impact on quality of life.

PCN240: PATIENT’S JOURNEY THROUGH ACUTE MYELOID LEUKEMIA (AML): UNDERSTANDING AML’S HUMANISTIC IMPACT THROUGH AN INTERNATIONAL PATIENT-CENTRIC QUALITATIVE STUDY

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OBJECTIVES: To document patients’ experiences with diagnosis, symptoms, impacts, side effects (SE), unmet needs and treatment pathways for acute myeloid leukemia (AML) across 3 countries. METHODS: Following a comprehensive literature review, patient and expert input, and IRB approval, face-to-face interviews were conducted with adults with AML in Canada, Denmark, and the United Kingdom. Using a semi-structured interview guide, trained qualitative interviewers explored patients’ diagnosis and treatment pathways to elicit spontaneous responses on symptoms and impacts of AML. Interviews traced patients’ journey from diagnosis through last treatment received.
Treatment phases included induction, consolidation, maintenance, and transplant. Healthcare utilization resources were also collected. Interview transcripts were analyzed using Atlas.ti. RESULTS: Data were available from 25 AML patients (mean age [range], 53 years [28-75]; 60% women; 40% Canadian; 28% Danish; 32% English). A total of 81 symptoms/SE and 48 impacts were reported. These concepts differ across the treatment phases. The most frequently reported symptoms/SE at induction (i.e., fatigue (88%), hair loss (64%), weakness (80%), diarrhea (80%)) overlapped somewhat to those reported at consolidation (i.e., fatigue (79%), hair loss (50%), muscle loss (46%)), but differed slightly from those described after transplant (i.e., fatigue (100%), GVHD (80%), infections (73%)). Only 7 symptoms/SE were reported at maintenance (including fatigue (100%) and nausea/vomiting (100%)). Patients described more emergency room visits at diagnosis in Canada and shorter periods of hospitalization in Denmark. Patients also reported a variety of unmet needs such as care and communication issues. CONCLUSIONS: Living with and being treated for AML has a significant impact on patients’ life from diagnosis until treatment end. Symptoms/SE experienced during induction and transplant had the strongest impact. Diagnosis and treatment pathways vary across countries, leading to different patient experiences. Better understanding of patients’ experiences can help optimize patient management and treatment whilst alleviating disease and treatment burden.

PCN241: RELATION OF QLQ-C30 AND QLQ-CR29 HEALTH RELATED QUALITY OF LIFE SCALES AND BIOCHEMICAL INDICATORS OF NUTRITIONAL STATUS

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Patients undergoing treatment for colorectal cancer (CRC), can develop multiple alterations in patient’s life. A common symptom in these patients is appetite loss, which is the main cause of nutrient deficiency and therefore nutritional amelioration. In addition, the association of serum albumin with quality of life (QoL) has been reported. OBJECTIVES: To determine the relation of the QoL and total serum protein, albumin, globulin, globulin/albumin ratio, in patients with CRC treated at the Hospital de Especialidades Centro Médico Nacional de Occidente del Instituto Mexicano del Seguro Social (HE CMNO IMSS) in 2016. METHODS: EORTC QLQ-C30 (version 3) and QLQ-CR29 colorectal cancer module quality of life questionnaires were applied to 113 patients with CRC treated in the Coloproctology Clinical Department at HE CMNO IMSS in Guadalajara, Mexico. Biochemical indicators of nutritional status of 65 patients were determined. Statistical analysis included mean, standard deviation, and the Pearson correlation coefficient. To calculate the QoL scores, a linear transformation was used according to the EORTC QLQ-30 scoring manual instructions. RESULTS: Global health status/QoL scores in women and men were 79.4±19.04 and 78±18.8, respectively. No significant difference was found in biochemistry nutritional indicators by clinical stage. Physical functioning had a positive correlation with the albumin serum level (Rp=0.490), and total serum proteins (Rp=0.372). Emotional functioning correlated positively with albumin serum level (Rp=0.313) and total serum proteins (Rp=0.308). Relation of role functioning with albumin serum level and total serum proteins were Rp=0.352 and Rp=0.254 respectively (p<0.05). There was a negative correlation between the following symptoms score: nausea and vomiting (Rp=0.481), fatigue (Rp=0.329), appetite loss (Rp=0.418), diarrhea (Rp=0.420), pain (Rp=0.331), and constipation (Rp=0.352), and serum albumin level (p<0.05). CONCLUSIONS: The adequate levels of serum albumin and total serum proteins are related with improved physical and emotional functioning and decreased symptoms in patients with CRC.

PCN242: HEALTH-RELATED QUALITY OF LIFE AFTER ONCOLOGICAL RESECTION AND RECONSTRUCTION OF THE CHEST WALL

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OBJECTIVES: Chest wall resection and reconstruction is a surgical challenge. There is limited information on the long-term health-related quality of life (HRQoL) after surgical treatment of chest wall tumors. We assessed the long-term HRQoL in patients after chest wall reconstruction following oncological resection. METHODS: Seventy-eight patients who had undergone the resection and reconstruction during 1997-2015 were invited to fill in the 15D and QLQ-C30 HRQoL instruments and answer questions about sociodemographic and clinical characteristics. Primary outcomes were the 15D and QLQ-C30 scores. We hypothesized that these patients would have an impaired HRQoL compared to age- and gender-standardized general population. RESULTS: A total of 17 men and 38 women (response rate, 69%) with a mean (SD) age of 68 (14) years completed the questionnaires. Respondents had been operated because of soft tissue sarcoma (n= 16), advanced breast cancer (n=15), osteo- or chondrosarcoma (n=
14), or other tumor (n= 10). The patients' mean 15D score (0.878, SD 0.111) was comparable to that of the general population (0.891, SD 0.041). However, patients were worse off on the dimensions of “Breathing” (p= 0.05) and “Usual activities” (p= 0.03), and better off on “Mental function” (p= 0.03). Most substantial difference in the mean 15D score was between soft tissue sarcoma and advanced breast cancer patients (0.829 and 0.917, respectively). Among all patients QLQ-C30 Global health status (HRQoL) was 72 points (0-100, worst to best). Scores in the QLQ-C30 Functional scales ranged from 78 (Physical) to 91 (Social). Scores in the Symptom scales (0-30, best to worst) ranged from 2 (Nausea/vomiting) to 23 (Fatigue).

**CONCLUSIONS:** Long-term HRQoL in patients after chest wall reconstruction following oncological resection is fair and comparable to that of the general population. Limitations in breathing and usual activities can occur.

**PCN243: ARE THERE DIFFERENCES IN FACT-G SCORES BETWEEN DIFFERENT TUMOUR TYPES FOR AN EU POPULATION USING REAL WORLD DATA?**

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**OBJECTIVES:** The main objective of this analysis was to assess FACT-G scores from an EU sample of cancer patients to test for differences between tumour types. **METHODS:** Data was collected through the Adelphi Real World Disease-Specific Programmes (DSPs) across breast, gastric, melanoma, non-small cell lung and prostate cancers. Data were collected between January 2015 and March 2017, resulting in a total sample of 4899 patients. Analysis included comparisons between the tumour types using minimum important differences (MIDs) of 3 points for FACT-G sub-scales and 7 points for FACT-G total score. General linear models were used to identify significant differences between tumour types while adjusting for key covariates (age, sex and ECOG status) on quality of life (QoL) within tumour type.

**RESULTS:** The results from the linear mixed model indicate significant differences between tumour type, ECOG status, and age group for the FACT-G total score. Patients with gastric cancer reported the poorest QoL (FACT-G total score, 49.4), NSCLC (53.1), breast (53.7), melanoma (54.7) with prostate reporting the highest (56.5), based on the least squares (LS) predicted means. Comparing predicted LS means based on the MID estimates, patients with gastric tumours have lower FACT-G scores than patients with prostate cancer (difference=-7.1). Patients with ECOG 0 also achieved change greater than MID compared to ECOG 1-3. **CONCLUSIONS:** Tumour type, age and ECOG status have a significant impact on FACT-G total score. Those with gastric cancer have worst quality of life compared to other tumour types and patients in the age group 18-34 have the lowest QoL across all sub-scales. Although not significant, females tend to have a lower FACT-G total score than males. Sub-scale analysis will also be presented.

**PCN244: APPLICATION STUDY OF THE EQ-5D-5L IN ONCOLOGY: LINKING SELF-REPORTED QUALITY OF LIFE OF PATIENTS WITH METASTATIC COLORECTAL CANCER TO CLINICAL DATA FROM A GERMAN TUMOR REGISTRY**

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**OBJECTIVES:** Approximately one out of eight cancers in Germany affects the bowel and more than 6% of the population are diagnosed with colorectal carcinoma during their lifetime. The EuroQoL EQ-5D questionnaire is widely used in oncology to generate quality of life (QoL) weights and corresponding health states. Aim of this study is to generate EQ-5D utilities by linking clinical data of a German colorectal cancer registry to self-reported QoL measures from the EQ-5D-5L to explore the relationship between disease-specific health states and health-related QoL (hrQoL).

**METHODS:** The study sample included metastatic colorectal cancer patients currently recruited in the German Tumor Registry Colorectal Cancer. The EQ-5D-5L was administered once as paper version to patients who were at the start or at later stages of treatment. Potentially relevant comorbidities, disease-specific health states (e.g. metastases) and symptoms (e.g. nausea), and treatment status were defined by literature review and medical experts. Data was drawn from the clinical registry and the EORTC QLQ-C30 questionnaire. Multivariate regression models will be calculated to explore the health state specific and comorbidity dependent decrements on QoL.

**RESULTS:** In total, n=758 questionnaires were sent to patients, n=535 were returned, and n=503 were finally included in the data analysis. Mean age was 66.76 years and 62.23% were male. 70.68% of patients had at least one comorbidity and the most frequent comorbidity was hypertension (42.37%). The overall mean hrQoL based on EQ-5D-5L for patients with metastatic colorectal cancer was 62.12 with the Visual Analog Scale (VAS).

**CONCLUSIONS:** This pilot study linking clinical registry data to hrQoL data shows a new opportunity for a
cross-sectional study design. The implementation of EQ-5D-5L in metastatic colorectal cancer patients showed reduced hQoL compared to the general population (mean VAS 85.15). Results from the regression analyses will be presented.

PCN245: HEALTH-RELATED QUALITY OF LIFE IN ONCOLOGY – ARE WE GETTING BETTER?

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OBJECTIVES: With recent advances in the treatment of cancer we would hope to see improvements in survival rates and greater health-related quality of life (HRQoL). The main aim of this analysis was to examine HRQoL scores across a sample of EU cancer patients. Comparisons were made between existing norms based on a US cancer population. METHODS: HRQoL data across breast, gastric, melanoma, non-small cell lung and prostate cancers were collected through the Adelphi Real World Disease-Specific Programmes (DSPs). All data were collected from EU patients between January 2015 and March 2017 and included the FACT instrument, resulting in a total sample of 4899 patients. Analysis included comparisons between the DSP and existing US cancer population norms. RESULTS: The EU sample had similar population characteristics to the published population norms with respect to age, gender and ECOG status but consisted of a wider sample of cancer types (including haematological cancers). Using minimum important difference (MIDs) of 3 points for FACT domain and 7 points for total FACT-G score, comparisons between the DSP data and US population norms identified several differences in domain and FACT-G scores between the EU and population norms based on MIDs. Exceeding MIDs were noted across social well-being (SWB), emotional well-being (EWB), functional well-being (FWB) and overall FACT-G, but not for physical well-being (FWB). In all these cases the EU data were consistently lower than the cancer population norm data. CONCLUSIONS: Two potential reasons for the observed differences are identified; one reason that may account for the differences is that HRQoL of cancer patients has decreased since the norm data was published, the other reason may be that the population norms may be region-specific. Further work comparing specific cancer types will also be presented. These reasons are further explored with respect to the changing therapeutic environment within oncology.

PCN246: IMPORTANT GROUP DIFFERENCES ON THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY–KIDNEY SYMPTOM INDEX DISEASE-RELATED SYMPTOMS (FKSI-DRS) IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

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OBJECTIVES: The Functional Assessment of Cancer Therapy–Kidney Symptom Index Disease-Related Symptoms (FKSI-DRS) is useful tool to gauge clinical benefit in metastatic renal cell carcinoma (mRCC). This study aimed to estimate important difference (ID) in FKSI DRS scores that is considered to be meaningful when comparing treatment effect between groups, using mRCC trial data. METHODS: Data were derived from two pivotal phase III mRCC trials comparing sunitinib versus interferon-alpha (N=750) in first-line mRCC, and axitinib versus sorafenib (N=723) in second-line mRCC. The change from baseline in FKSI-DRS score was examined as a function of an adverse event (AE) grade using a longitudinal repeated measures model (RMM); several types of adverse events were analyzed. In sensitivity analyses, using the same methodology, we examined the relationship between change in FKSI-DRS score as an outcome and two additional anchors: the FKSI item “I am bothered by side effects of treatment” score and change from baseline in EuroQoL (EQ-5D) utility score. Also, in sensitivity analyses, we averaged all available values of the outcome and predictor across time, effectively creating one observation per subject, and then a linear regression analysis was applied to those data. RESULTS: Using the RMM with AE as an anchor, the FKSI-DRS ID generally ranged between 0.74 (AE as a continuous predictor variable) and 1 point (AE as a categorical predictor variable); results of sensitivity analyses were generally consistent. When item “I am bothered by side effects of treatment” score was used as an anchor, FKSI-DRS ID ranged between 1.2 and 1.39 points (depending on the model). When EQ-5D utility score was used as an anchor, the FKSI-DRS ID ranged between 0.63 and 1.0 point. CONCLUSIONS: Among patients undergoing treatment for mRCC, the evidence suggests that FKSI-DRS between-group differences as low as 1 point may be meaningful.
PCN248: FEASIBILITY OF PRECISION ONCOLOGY VIRTUAL TUMOR BOARDS TO OPTIMIZE DIRECT POINT-OF-CARE MANAGEMENT AND CLINICAL TRIAL ENROLLMENT OF ADVANCED CANCER PATIENTS

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OBJECTIVES: Precision oncology encompasses the implementation of high level of evidence disease-specific and biomarker-driven diagnostic and treatment recommendations for optimized cancer care. Telemedicine and value-based care may optimize clinical trial enrollment and overall cost-benefit. We evaluated the feasibility and clinical utility of a precision oncology virtual tumor boards (VTB) program, and its clinical impact on community-dwelling patients with advanced solid tumors to facilitate point-of-care management and clinical trial enrollment, as well as the financial impact and potential outcomes of the intervention. METHODS: We report the results on the initial 10 VTB-evaluated patients of an ongoing prospective qualitative case study screened between October/2016 and March/2017. Eligibility required written informed consent. Cases were evaluated by a patient-activated multidisciplinary VTB. A Markov model by incorporating clinical, utility and cost data was developed to evaluate economic outcome of VTB regarding survival and cost-of-care. Using a proprietary knowledge-base, parametric survival analyses of patient-level progression-free (PFS) and overall survival (OS) data from reported clinical trials in known sources were performed. Average Sales Prices public data sources were used to estimate unit treatment costs and duration of subsequent active therapies. Oncology-modeled patient pathways, expert opinion and Delphi panel methods were used for assumptions. RESULTS: The VTB identified clinical trials for 80% of these heavily treated patients, and 50% of patients decided to pursue a clinical trial. VTB resulted in data that impacted clinical decisions in 100% of cases. VTB achieved 88% cost reduction compared to standard therapies due to clinical trial enrollment (517,000USD vs 61,000USD). Treatment options as prioritized by VTB also provided an estimated reported PFS advantage (6.3 months) compared to standard therapy (3.6 months). CONCLUSIONS: These results demonstrate the feasibility and benefits of incorporating precision oncology VTB into clinical practice, including its value as clinical trial recruitment engine and as a cost-effective, value-based measure for innovative care delivery models.

PCN249: SUBJECTIVE FINANCIAL BURDEN AMONG GERMAN CANCER PATIENTS - RELATIONSHIP OF THE PATIENTS’ ECONOMIC SITUATION AND SUBJECTIVE DISTRESS

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OBJECTIVES: The diagnosis of cancer imposes a number of burdens on patients – physical, emotional, and financial. So far, evidence on the socio-economic impact of cancer for patients in Germany is scarce. The aim of the project is to provide an overview of financial losses and risk for poverty in patients with neuroendocrine neoplasms (NEN) and colorectal cancer (CRC) as well as possible psychosocial effects. METHODS: This prospective quantitative study recruited 249 cancer patients (n=123 NEN/ n=126 CRC) from 11/2016 to 3/2017 at the National Center for Tumor Diseases, University Hospital of Heidelberg. They completed a survey on patients’ income, cancer-related out-of-pocket costs, subjective distress (Distress Thermometer), quality of life (EORTC-LQ 29/30), health status (EQ-5D) as well as demographic data. RESULTS: Overall, 86.7% (n=216) of the patients reported that their financial situation has deteriorated, due to cancer-related out-of-pocket costs and/or income losses: 82.7% (n=205) stated to have higher out-of-pocket costs because of their disease. Higher cancer-related out-of-pocket costs per month were associated with a lower reported quality of life (.002) and higher distress levels (.02). Using poisson regression, the correlation of the subjective distress with selected items on income and expenditure since diagnosis was examined. Under the control of cancer and the age group, the amount of expenditure due to the disease (.09) as well as the overall worsening of living conditions (.26) have a significantly positive effect on the stress experienced by a patient. CONCLUSIONS: Although the number of studies investigating the subjective financial burden of cancer patients is constantly rising, this is one of the first studies within the German health care sector. Further research is required to develop both, validated instruments on the subjective financial burden that address health service conditions in Germany and targeted measures that could prevent financial problems and reduce emotional burdens.

PCN250: APPLYING NICE END OF LIFE CRITERIA IN THE ERA OF DRUG APPROVALS BASED ON SINGLE-ARM TRIAL DATA

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE) recommends public reimbursement of health technologies deemed cost-effective at an upper threshold of £20,000–£30,000 per additional Quality Adjusted Life Year (QALY). In 2009, NICE issued supplementary ‘End of Life’ (EoL) guidance for technologies that may extend
the life of people with incurable illnesses to be assessed at a higher threshold (£50,000/QALY). One key eligibility criteria is that the treatment offers an extension to life (normally ≥3 months) versus current NHS treatment. The European Medicine Agency (EMA) is increasingly authorizing medicines for such patients at earlier stages of their clinical development, without Phase 3 data. This research analyses how NICE have evaluated the eligibility of such therapies for consideration under EoL criteria. METHODS: NICE single technology appraisal (STA) guidance for oncology drugs was screened (01/01/2009-31/05/2017) and data on the supportive trial package and EoL consideration extracted. RESULTS: 95 STA-recommendations were identified (60% recommended, 16% optimized, 2% only in research, 22% not recommended). EoL criteria were discussed in 66% (63/95) of appraisals and were deemed to apply in 63% of cases (40/63, 93% of which were recommended/optimised). Six technologies lacking supportive Phase 3 data were identified. EoL criteria were considered in 5/6 instances and applied in 4/5 cases (osimertinib, bosutinib, trabectedin, and ceritinib - but not for ofatumumab). Successful strategies to meet the 3-month OS gain criterion included indirect treatment comparisons and estimations/extrapolations. However, the small non-comparative study of ofatumumab with immature PFS/OS data was deemed insufficiently robust. CONCLUSIONS: NICE EoL criteria has been a positive access driver for treatments for patients with severe unmet needs. Such therapies are increasingly being approved on trial packages lacking Phase 3 data. Nevertheless, NICE have been quite flexible to date in their interpretation of the additional 3-month extension to life requirement, enabling their consideration under EoL criteria.

PCN251: NICE AND SINGLE? RECOMMENDATION RATES OF ONCOLOGY THERAPIES APPROVED ON CLINICAL TRIAL PACKAGES LACKING COMPARATIVE PHASE 3 DATA


OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on the reimbursement of new medicines based upon their clinical and cost-effectiveness (as defined by their incremental cost per additional Quality Adjusted Life Year [QALY]). Historically, oncology therapies have had lower recommendation rates than those for other therapy areas, driven by their comparatively high costs and small incremental QALY gains. The European Medicines Agency is increasingly approving therapies for patients with life-threatening diseases with high unmet needs (encompassing many oncology therapies) at earlier stages of their clinical development, without any supportive comparative Phase 3 data. This research aims to investigate NICE appraisal outcomes of oncology therapies approved based on such data. METHODS: NICE single technology appraisal (STA) guidance for systemic anti-cancer therapies was screened (01/01/2009-31/05/2017) and the recommendation and supportive trial package extracted. RESULTS: 95 oncology therapies were identified (60% recommended, 16% optimized, 2% only in research, 22% not recommended). Six therapies were approved on trial packages lacking any comparative Phase 3 data. 66% (4/6) were recommended (1 under the CDF), 17% (1/6) optimized, and 17% (1/6) not recommended. 66% (4/6) were appraised in June 2016 or later. 80% (4/5) of such recommended therapies were subject to a patient access scheme or managed access agreement. CONCLUSIONS: NICE have recommended 5/6 oncology STAs supported by a clinical trial package lacking comparative data. The trend for such appraisals is increasing with most having been conducted in the last 12 months. The clinical benchmark of EMA approval for oncology drugs on such a data package seems sufficient to enable acceptance under NICE’s clinical criteria. Nevertheless, NICE’s recommendations are further conditional on cost-effectiveness being adequately demonstrated. Additional price discounts and/or innovative contracting may frequently be required to offset the inherent uncertainties on conducting economic modelling based on such limited clinical data package.

PCN252: INTERNATIONAL HTA EXPERIENCE WITH TARGETED THERAPY APPROVALS FOR LUNG CANCER

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OBJECTIVES: In the field of cancer, Health Technology Assessment (HTA) evaluations can be restricted, with the result of limited comparative clinical effectiveness evidence of cancer therapies. In addition, the high cost of cancer treatment raises the stakes and may further complicate the HTA appraisal process. Thus, the aim of this analysis was to compare the access success rates of recently approved lung cancer medications across three countries (Australia, Canada and England) based on HTA documents. Major uncertainties and limitations that compromise HTA recommendations were identified. METHODS: A comparison between the three countries was performed with respect to the listing status, time incurred for access and differences in recommendations made for cost-effectiveness. RESULTS: The access success rate of lung cancer treatment was found to be low across all three countries at 33% for Canada, 17% for England and 8% for Australia. In general, Canada was ahead in terms of the listing rate and number of submissions appraised and had a shorter HTA review process (less than one year) compared to England and Australia. Across the HTA agencies’ reviews, comparators were either dissimilar or altered...
for effectiveness and/or economic analysis for the same indication. Overall, limited evidence was found for all indications, and uncertainties were found to be formed due to indirect analyses (70%) and survival extrapolation (100%). HTA agencies in all three countries frequently proposed readjusting the time horizons and recalculating the incremental cost-effectiveness ratios in economic evaluations. As most of the indications were concluded to be non-cost-effective, some were subsequently listed (47%) at a reduced price and/or with a specific access programme. **CONCLUSIONS:** Major uncertainties that are resistant to the available solutions, such as managed access programmes, seem to be common across different countries; thus, international solutions would be beneficial.

**PCN253: ARE ACCELERATED APPROVAL MECHANISMS A PREDICTOR TO EARLY ACCESS AND COVERAGE? A GLOBAL STUDY OF CANCER DRUGS**


**OBJECTIVES:** To explore the interrelationship between accelerated approval schemes for cancer drugs and national HTA processes across thirteen jurisdictions globally, by investigating the impact HTA and value assessment has on drugs approved through accelerated pathways. **METHODS:** 15 drug-indication pairs with cancer indications (melanoma, lung and haematology) were selected based on whether they received accelerated approval in the US or Europe via an early access mechanism (one of the FDA Accelerated Approval pathways or the EMA Conditional Marketing Authorisation [CMA], or both) until December 2015. In-depth analysis was conducted to assess the impact HTA and value assessment had on coverage and funding pathways in 13 countries (Australia, Brazil, England, Canada, France, Germany, Italy, Japan, the Netherlands, Scotland, Sweden, Spain and USA). The analysis relied on an analytical framework investigating in-depth: (a) Similarities and differences in clinical and economic evidence submitted; (b) Evidence interpretation; (c) Uncertainties; (d) Other considerations, drug or therapeutic-area related; and (e) Time difference between MA and HTA recommendation. **RESULTS:** Preliminary analysis indicates that market access for drugs authorised under an early access mechanism continues to rely heavily on HTA requirements. Additionally, HTA for these drugs does not necessarily lead to positive recommendations and may result in longer HTA review processes than drugs approved under standard MA. Moreover, some countries often resort to special funding arrangements to enable access to cancer drugs. **CONCLUSIONS:** Accelerated approval pathways do not guarantee coverage or early market access at population level and may result in delays in access. Alternative data sources and evidence to meet HTA requirements are important, including real world data generation or managed entry schemes, in order to enable access to new cancer therapies.

**PCN254: SURVIVAL EFFECT, DEMAND EFFECT AND POLICY EFFECT AS DRIVERS FOR PRICING OF INNOVATIVES ANTICANCER DRUGS**

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**OBJECTIVES:** The objective of this study is to assess how the survival, the demand (cancer disease) and the pricing policy can affect the prices of anticancer drugs in the OECD countries. **METHODS:** In order to investigate both the impact of the survival (added value), the demand (cancer disease) and the regulation in the pricing of the anticancer drugs, we used an econometric approach: From linear regression two fixed effect were performed in the model in order to estimate a country fixed effect and disease cancer effect. (Stata was used). **RESULTS:** A total of 305 drugs prices were observed across all countries in the study. Our model evaluated the impact of twelve variables considered most likely to impact the prices setting. The model fitted the data well (R2=62%). As expected the added survival had a significant effect on the prices, the demand effect is demonstrated by each cancer disease, and the country effect is significant. **CONCLUSIONS:** This study demonstrates that the level of pricing disparities, in most cases reflect the therapeutic added value (survival), the demand (explained by the severity and the burden disease) play an important role and the prices mechanisms have the major effect in the pricing.

**PCN255: THE ROLE OF GENERAL PRACTITIONERS IN DIAGNOSTIC DELAY IN CASE OF CUTANEOUS MALIGNANT MELANOMA PATIENTS**

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**OBJECTIVES:** The aim of the present study was to determine the role of general practitioners, self-medication, alternative therapies and self-examination in diagnostic delay in case of malignant melanoma patients. **METHODS:** We carried out a survey including medical record analysis and questionnaire survey in patients diagnosed within five years with cutaneous malignant melanoma at the Pécs Dermatological Clinic (n=362). The investigation involved: delay rate, clinical characteristics of the tumor, sociodemographic factors, oncology vigilance of the general practitioner, application of self-medication, alternative therapies and self-examination. Logistic
RESULTS: The mean age was 54.5. Breslow tumor thickness was above 4 mm in 12.2% of patients. The mean delay was 8.1±15.6 months, median: 6 months. In case of patients who were undressed up from waist in some occasions (53.3%, OR=1.9 [95%CI:1.08-3.5]), or never (25.7%, OR=2.9, 95%CI:1.4-5.9) during medical visits in the period prior to the diagnoses, Breslow tumor thickness was more likely above 1.01 mm, but did not affect the patient delay. Skin of 75.4% of patients were never examined by the practitioner, however it did not affect delay. In case of 69.9% of the respondents GP never asked whether they recognize any skin lesions, the long delay in their case was more likely (OR: 3.4, 95%CI:1.2-9.4). 76% have never heard from the GP about skin problems. The frequency of self-medication and alternative therapy use before visiting the physician did not affected the delay and tumor parameters. Among patients who have never been conducted self-examination (50%) the chance of longer delay was higher (OR=3.2, 95%CI:1.8-6.1). CONCLUSIONS: GPs play an important role in the early detection of melanoma lesions, propagation of self-examination, awareness raising in the recognition of signs. The vigilance of GPs is especially important in case of patients with higher-risk and disorders in less visible places.

PCN256: THE CLINICAL BURDEN OF HEAD AND NECK CANCER TO THE BRAZILIAN SOCIETY

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OBJECTIVES: To estimate the clinical burden of head and neck cancer (HNC) to the Brazilian society through the calculation of disability-adjusted life years (DALY). METHODS: DALY were calculated considering the estimated years of life lost (YLL) and years lived with disability (YLD) related to the disease. YLL was calculated based on the population life expectancy presented by the Brazilian Institute of Geography and Statistics (IBGE) for each age (Complete Mortality Table for Brazil 2014), and the mortality from HNC by age group (Brazilian Mortality Information System 2014). Age-weighting and a discount rate of 5%, as recommended by the Brazilian Ministry of Health, were used. YLD were calculated by multiplying incidence of HNC in 2014 (GLOBOCAN), length of disability and weight of disability, related to disease stages and their respective duration of a conceptual model of HNC developed based on literature and specialists’ opinion. Disability weights were derived from the Global Burden of Disease Study (2013). RESULTS: Considering the discount rate and age-weighting, there was a total loss of 216,356 years due to premature death from HNC, of which 175,354 years corresponded to male patients and 41,002 years to females. Based on an estimated incidence of 26,091 HNC cases in 2014, the YLD value was 47,502. Total DALY due to HNC in 2014 was 263,858. CONCLUSIONS: As expected, due to cancer location and treatment pattern, HNC has an important clinical impact on population health, not only because of high mortality, but also considering the disease related functioning health loss, since years lived with disability were responsible for almost 20% of total DALY.

PCN257: CLINICAL EFFICACY AND SAFETY OF LICENSED DRUGS AND POTENTIAL NEW THERAPIES FOR NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To review the published literature on the efficacy and safety of licensed drugs and therapies currently in phase 3 development for the treatment of adults with non-metastatic (M0) castration-resistant prostate cancer (CRPC). METHODS: A systematic literature review (SLR) of the clinical evidence was conducted in the PubMed and Cochrane databases, and the key relevant congress websites. No time-frame or geographic restrictions were applied. RESULTS: Twelve publications reporting data from nine different studies were reviewed. The active interventions compared in these studies were apalutamide (SPARTAN trial), atrasentan (NCT00365556), bicalutamide plus dutasteride (TARP), darolutamide (ARAMIS), subcutaneous denosumab (NCT00286091), enzalutamide (PROSPER and STRIVE), poxviral vaccine (NCT00020254) and zibotentan (ENTHUSE 0). Atrasentan, dutasteride, poxviral vaccine and zibotentan appear to no longer be in clinical development for M0 CRPC due to the lack of efficacy in this setting. The ARAMIS, SPARTAN and PROSPER studies were still ongoing at the time of review. With the exception of STRIVE and NCT00286091, none of the other four completed studies demonstrated efficacy of the assessed interventions. In NCT00286091, denosumab significantly increased median metastasis-free survival versus placebo (29.5 versus 25.2 months). In STRIVE, enzalutamide significantly delayed disease progression of M0 CRPC patients with a hazard ratio versus bicalutamide of 0.24 (95% confidence interval 0.14, 0.42; p<0.001) for progression-free survival and a hazard ratio of 0.18 (95% confidence interval 0.10, 0.34; p<0.001) for time to prostate-specific antigen progression. However, STRIVE is a phase 2 study and M0 CRPC patients
constituted only 35% of the total study population. CONCLUSIONS: The SLR highlights the limited available evidence on treatment efficacy in the M0 CRPC setting. Ongoing clinical trials (ARAMIS, PROSPER, SPARTAN) may provide important evidence of clinical benefit in treating patients with M0 CRPC.

PCN258: THE CLINICAL BURDEN OF BLADDER CANCER TO THE BRAZILIAN SOCIETY

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OBJECTIVES: To estimate the clinical burden of bladder cancer (BC) to the Brazilian society through the calculation of disability-adjusted life years (DALY). METHODS: DALY was calculated considering the estimated years of life lost (YLL) and years lived with disability (YLD) related to the disease. YLL was calculated based on the life expectancy presented by the Brazilian Institute of Geography and Statistics (IBGE) for each age (Complete Mortality Table for Brazil, 2014) and the mortality data from BC by age group presented (Brazilian Mortality Information System 2014). Age-weighting and a discount rate of 5%, as recommended by the Brazilian Ministry of Health, were used. YLD were calculated by multiplying incidence of BC in 2014 (Brazilian National Institute of Cancer), length of disability and weight of disability, related to disease stages and their respective duration of a conceptual model of BC developed based on literature and specialists' opinion. Disability weights were based on the Global Burden of Disease Study (2013). RESULTS: Considering the discount rate and age weighting, in 2014 there was a loss of 27,738 years due to the premature death of patients with bladder cancer, of which 17,701 years corresponded to male patients and 10,037 to female patients. Based on the incidence of 8,940 patients in 2014, the total YLD was 12,402. Total DALY due to bladder cancer in 2014 was 40,140. CONCLUSIONS: BC is responsible for a high clinical burden in patients, both due to disability resulting from treatment and from premature mortality. This data can support strategic actions of public health policies aimed at the prevention and early diagnosis of BC, as well as on the decision-making process for choosing preferential treatment.

PCN259: Navigating the Road to Reimbursement and Optimizing Uptake for Oncology Agents in the EU5: Payer and Prescriber Perspectives on the Power of Pivotal Trial Design

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OBJECTIVES: The health technology assessment (HTA) bar is rising across the EU5 (France, Germany, Italy, Spain, UK). As payers' balance clinical need with budgetary constraints, proving added benefit over currently available therapies is vital for new agents entering high-cost therapeutic markets. Focusing on key oncology indications, this study examined payer and physician perspectives on the importance of clinical trial design in HTA, reimbursement and prescribing. METHODS: Across the EU5, 250 medical oncologists were surveyed regarding their current and expected prescribing patterns, and 15 payers who influence reimbursement nationally or regionally were interviewed. RESULTS: For interviewed payers, robust head-to-head overall survival (OS) data showcasing benefit over appropriate existing agents are key to optimal reimbursement. They stress that crossover design frequently confounds OS data, leading to suboptimal HTA, and that agents with weak or marginal OS benefits, or with surrogate end-point data only, will likely require discounts/rebates/lowering of list prices to compete favorably in the EU5 markets. These payers advise that focusing on biomarker-defined subpopulations can be an effective means of optimizing clinical benefit to meet HTA demands in competitive markets. This study also finds clinical trial design to influence the prescribing of almost all surveyed oncologists to some extent. Approximately 75% of surveyed oncologists in Italy and Spain, and at least 60% in France and the UK indicate a strong impact of clinical trial design on their prescribing decisions. Specifically, OS and progression-free survival (PFS) as co-primary end points, appropriate comparator choice, and robust safety data are the key clinical trial design-related prescribing drivers identified by physicians surveyed. CONCLUSIONS: Meeting well-considered end-points, ideally improvement in OS versus existing standard-of-care, is crucial for favorable reimbursement and strong uptake of oncology agents in the EU5. Drugmakers must ensure their clinical trials are designed to showcase unequivocal superiority over the right comparator to secure optimal market access.

PCN260: Incidence, Mortality and Treatment of Melanoma in Poland in the Years 2012-2016

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OBJECTIVES: To assess the incidence and number of deaths from melanoma each year as well as the number of patients pharmacologically treated according to the type of drug they were treated with. METHODS: A retrospective study was performed on the Polish population treated for advanced melanoma between January 2012 and October 2016. This period reflects the time since new drugs for melanoma, other than chemotherapy, have been reimbursed in Poland. The data on drugs usage was obtained from the Polish NHF. Melanoma incidence and number of deaths from this cancer were acquired from National Oncology Registry. Regression analysis was performed to predict the missing data for years 2015-2016. RESULTS: The National Cancer Registry data indicate a permanent increase in both the incidence and number of deaths from melanoma. The highest increase in incidence was observed in the age group over 55 years old for both sexes. There is also a stable growth in the number of patients pharmacologically treated for advanced melanoma (in 2015 almost 40%). Dacarbazine was most commonly used drug in chemotherapy (89% and 93% respectively as first and next lines). However, introducing vemurafenib to reimbursement in 2013, and then ipilimumab in 2014 resulted in a significant decline in dacarbazine usage, from 84% in 2012 to 75% in 2016. CONCLUSIONS: 1) An ageing population may be the reason for the increasing incidence and mortality in melanoma. Due to the fact that the highest increase was observed in older patients, special interest should be paid to the safety of the therapy. 2) Systematic growth in the number of patients pharmacologically treated for advanced melanoma is noted, which may be related to availability of the new treatment options, as well as earlier diagnosis. 3) Reimbursement of the new drugs has shifted dacarbazine from first to the next lines of therapy.

PCN261: ROLE OF CHEMOTHERAPY IN THE CURRENT TREATMENT OF METASTATIC MELANOMA

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OBJECTIVES: With recent approvals of immuno-oncology (IO) and targeted therapies (TT) that demonstrated improved efficacy versus chemotherapy comparator for metastatic melanoma (MM), the role of chemotherapy for this disease is less well defined. We aimed to describe current treatment patterns for MM in real-world. METHODS: A retrospective observational study was conducted using a large US claims database to identify adult patients with ≥1 claim of melanoma and ≥1 claim of metastasis between 1/1/2015 and 3/31/2017. Patients included had both pharmacy and medical enrollment with ≥3 months follow-up from start of first line (1L) metastatic treatment. Patients with a second primary cancer diagnosis, in a clinical trial, pregnant, or diagnosed with HIV/AIDS during the study were excluded. Patients were classified by 1L treatment: PD-1 inhibitor, ipilimumab, ipilimumab + nivolumab (I/N) combination, BRAF/MEK monotherapy, BRAF/MEK combination therapy, or chemotherapy. Treatment patterns were summarized using descriptive statistics for each treatment group by year. RESULTS: 307 patients with MM initiated 1L systemic therapy during the study period: 88 (29%) ipilimumab, 85 (28%) chemotherapy, 68 (22%) PD-1, 26 (8%) I/N, 25 (8%) BRAF/MEK combination, and 15 (5%) BRAF/MEK monotherapy. 2L was observed among 96 (31%) MM patients; the most common 2L therapies were PD-1 monotherapy (n=40; 42%) and chemotherapy (n=26; 27%). Among those who received 2L chemotherapy (n=26), half received different chemotherapy regimen in 1L, followed by ipilimumab in 1L (23%) and PD-1 monotherapy in 1L (12%). 1L chemotherapy use remained consistent across the 2 years at 28% and 27%, putting it in the top two most common treatments for both years of the study period. CONCLUSIONS: Despite the introduction of IO and TT for the treatment of MM, almost one third of patients are treated with chemotherapy in 1L and 2L. Improved overall survival with IO and TT warrants further research to understand use of chemotherapy in melanoma.

PCN262: OPIOID USE OUTCOMES AMONG FEMALE BREAST CANCER PATIENTS USING ADJUVANT ENDOCRINE THERAPY REGIMENS

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OBJECTIVES: Opioids could be used effectively as a pharmacotherapy for severe cases of Adjuvant Endocrine Therapy (AET)-associated musculoskeletal and joint pain. This study explored differences in opioid use across different AET regimens, factors associated with opioid use, and the impact of opioid use on overall survival in female breast cancer patients treated with AET. METHODS: We retrospectively analyzed 2006-2012 SEER-Medicare datasets, following patients for at least two years from the index date, defined as the first date they filled an AET prescription. The study included 10,773 Medicare-enrolled (Parts A, B, D) adult women with incident, primary, hormone-receptor-positive, stage I-III breast cancer. They were also required to be first-time AET users, alive for at least two years following AET initiation. The main independent variable in multivariate Cox-proportional hazard regression models was the AET regimen. The regimens included in this study were tamoxifen only, aromatase inhibitor(AI) only, AI switching to tamoxifen and vice versa, and mixed groups. We measured whether patients used opioids during follow-up and opioid use for at least 90 days during follow-up. RESULTS: The results of the causal
countries. Average healthcare related cost per patient ranged from (2017 values) $75,617 to $136,350 in high-income countries. CONCLUSIONS: GC and GEJC are diseases with marked epidemiological differences across the globe,
The objective of this study is to describe the evolution of the inpatient use ATU drug spending from 2012 to 2016. METHODS: We included 2012-2016 ATUs data for inpatient use (unit price, volume of prescriptions) extracted from the French DRG based information system (PMSI). For each year the numbers of hospitals prescribing ATUs and medicinal products funded were studied. Therapeutic area repartition was assessed for 2016. RESULTS: From 2012 to 2016 inpatient use ATU drug spending increased more than 10-fold from €35.4 to €471.4 million. The number of hospitals prescribing these medicines rose by more than 2-fold (190 to 481). The number of ATU drugs increased by 40% (105 to 148). In 2016, the expenditure was mainly due to hematological and/or oncology drugs (85%) followed by gastroenterological drugs (19%). CONCLUSIONS: From 2012 to 2016 the expenditure of inpatient use ATU drug drastically increased as well as the numbers of medicinal products covered and prescribing hospitals. In 2016, hematological and/or oncology drugs represented the major portion of the expenditure.

PCN267: THE ARRIVAL OF THERAPEUTIC BIOSIMILARS IN ONCOLOGY: THE CASE OF TRASTUZUMAB

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OBJECTIVES: With the patent expiration of the reference product trastuzumab in Europe in 2014, several companies are developing biosimilar versions of trastuzumab. In the near future, these lower priced products can contribute to significant cost savings in the heavily burdened healthcare budgets. The market access and uptake of these biosimilars will predominately depend on price and the clinical evidence submitted for registration. The number of authorized biosimilars in turn may affect the level of competition, the magnitude of savings and the number of patients treated. Therefore, this study aims to provide an overview of the clinical trial evidence for biosimilars to trastuzumab in an advanced stage of development. METHODS: A literature review was carried out in a systematic way using databases Embase and Medline between February and June 2017. Additionally, the ClinicalTrials.gov website, abstracts, conference posters and press releases were consulted. RESULTS: In June 2017, at least seven potential trastuzumab biosimilars have completed phase I clinical trials. Six of these subsequently completed phase III trials and four dossiers were submitted for approval to EMA. The reported phase I and phase III clinical trial data are indicative for biosimilarity of the proposed biosimilars to the reference product. Of note is the considerable variation in the phase III clinical development programs of these biosimilars in terms of selected endpoints, patient population (disease stage) and trial design. CONCLUSIONS: Several trastuzumab biosimilars are expected to enter the market in the following months. Their introduction will drive significant cost savings as well as improve patient access to essential treatment. A first-to-market advantage has been demonstrated for biosimilars in the past, potentially resulting in a higher uptake of the first trastuzumab biosimilar entering the market. The identified variation in the clinical development of the different trastuzumab biosimilars may influence healthcare professionals' decision-making and may therefore impact their uptake.

PCN268: TIME TO MARKET ACCESS FOR ONCOLOGY MEDICINES IN GREECE: HAS IT CHANGED DURING THE CRISIS?

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OBJECTIVES: Timely access to medicines, especially for patients with life-threatening diseases, is a major goal for pharmaceutical policy internationally. However, policy regulations, technology assessment requirements as well as financial constraints for the third-party payers, tend to increase the necessary time until a patient reaches a new treatment alternative. The aim of the present study was to estimate the time from the centralized authorization to the actual availability for oncology medications in Greece, during the years of the financial crisis. METHODS: The study sample included all medications with an indication for oncology that received centralized authorization from the European Medicines Agency (EMA) during 2009-2015 and entered the Greek pharmaceutical market. Time to market access (in days) for a medication was defined as the period spanning from the centralized approval until its official market entry in Greece, i.e., the first announcement of the medicine’s price (inclusion in an official price bulletin). RESULTS: The study included 48 medications, of which 13 were approved during 2009-2011, 12 during 2012-2013 and 23 during 2014-2015. The average time to market access for an oncology medication was 530 days (range: 162 – 1394 days). For medications that received EMA authorization in 2009, 2010, 2011, 2012, 2013, 2014 and 2015, the respective time was 721, 705, 873, 328, 434, 536 and 404 days. CONCLUSIONS: Time to market entry for an oncology medication in Greece exceeds the European average and shows an increase compared to previous estimates for the country. Regulatory processes that combine appropriate health technology assessments as well as timely access for patients are imperative.

PCN270: ONE YEAR REPORT CARD FOR THE CANCER DRUGS FUND REFORMS – FROM ABSURDITY TO IRRELEVANCE?


OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access oncology therapies that are not routinely publically funded. In April 2016, the CDF became a temporary reimbursement fund under the remit of NICE with the aim of collecting observational data to inform subsequent technology appraisals. This research aims to evaluate how the reformed CDF has been utilised in the year since its implementation. METHODS: NICE Final Appraisal Determinations for Single Technology Appraisals of oncology drugs from (29/07/2016-16/06/2017) were identified and key data extracted. RESULTS: 35 oncology drug appraisals were identified, 27 (77%) were recommended/optimised. 4 (11%) were not recommended, only 4 (11%); osimertinib, brentuximab vedotin [BV], pembrolizumab, and olaratumab) were referred to the CDF. For osimertinib, pembrolizumab, and olaratumab, the greatest uncertainty in its cost-effectiveness analysis related to its long-term survival extrapolations, intended to primarily be resolved through the subsequent availability of clinical trial data. For BV, the key uncertainty was the proportion of patients bridging to stem cell transplant from BV. This is to be investigated through a prospective analysis while BV is CDF-funded; in parallel, a retrospective analysis of patients
previously-treated with BV under the ‘old’ CDF will be undertaken. CONCLUSIONS: The newly reformed CDF has only been utilised in a small minority of appraisals to date. Collecting uncontrolled observational data may not be a suitable mechanism to address most key uncertainties in the appraisal of oncology drugs (often related to long-term survival extrapolations and [if based on a single-arm study] suitable comparator data). The BV example illustrates where the CDF can address a key area of uncertainty. However, in practice, the CDF may act as a temporary access mechanism for oncology treatments that receive market authorization based on early/single-arm trial data until longer-term and/or Phase III data are available.

PCN271: THE IMPACT OF CANCER DRUGS FUND REFORMS ON REIMBURSEMENT OF ONCOLOGY DRUGS IN THE UK


OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 to enable cancer patients in England to access therapies that are not routinely publically reimbursed. Initially, inclusion was based on clinical criteria only with free-pricing for CDF-included therapies. However, due to escalating costs, in October 2014, economic criteria were introduced. In 2016, the original fund was closed and the CDF became a temporary reimbursement fund under the remit of NICE to collect observational data to inform subsequent technology appraisals. This research aims to evaluate what effect the introduction and reform of the CDF has had on NICE recommendation rates. METHODS: All NICE Single Technology Appraisal (STAs) guidance for oncology drugs were screened up to 24/05/2017 and the date and outcome were extracted and were stratified by CDF status. RESULTS: 118 STAs were identified, 68% had recommended outcomes (defined as ‘recommended’ or ‘optimised’) and 32% had not recommended outcomes (defined as ‘only in research’ or ‘not recommended’). Of 37 STAs prior to the introduction of the CDF, 68% were recommended. Of 28 STAs during the initial free-pricing phase of the CDF, only 43% were recommended. Of 21 STAs whilst the CDF incorporated economic evaluations, 76% were recommended. Of 32 STAs following the 2016 CDF reforms, 84% were recommended (one through the newly reformed CDF). CONCLUSIONS: After the CDF was initially introduced there was a notable drop in the NICE recommendation rate. This suggests that the CDF provided an alternative market access route with free-pricing that companies preferentially entered (versus obtaining a NICE recommendation). Indeed, since economic evaluations were introduced there has been a prominent corresponding increase in NICE recommendation rates, which has been further pronounced since the CDF closed in 2016, reflecting the renewed importance of NICE recommendations for national reimbursement in oncology.

PCN272: EXPERIENCES WITH PRICE COMPETITION OF BIOSIMILAR DRUGS IN HUNGARY

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OBJECTIVES: The aim of our study is to analyse the biosimilar bids of the Hungarian National Health Insurance Fund Administration in case of colony-stimulating factor (CSF). METHODS: The data used in this analysis was derived from the financing database of Hungarian National Health Insurance Fund Administration, and they covered the interval between July 1, 2011 and June 30, 2014. RESULTS: Owing to the first price bidding, two biosimilars were awarded the status of preferred drugs. One biosimilar drug still obtained reimbursement, and it was available to the patients for a refund of 1500 HUF. Another biosimilar and an original drug lost their reimbursement. Owing to second price bidding, three biosimilar drugs became available for the patients, but it was for a unified refund of 300 HUF/box. During the 12 months prior to the bid process, 13974 patients received G-CSF treatment and 13352 and 13185 patients received it during the first and second year after the bid process, respectively. This shows a decrease of 4.5% in the number of patients during the first year after the bid process, followed by a further decrease of 1.3% during the second year relative to that before the bid process. The total amount of money spent on the reimbursement of G-CSF drugs during the year before bid process amounted to 7.49 billion HUF. This amount was reduced by 44% to 4.49 billion HUF in the first year following the bid process. In the second year, the amount of subsidization amounted to 3.6 billion HUF, indicating a 51.9% decrease relative to that before the bid process. CONCLUSIONS: The analyses of the Hungarian price competition bid of biosimilar products showed a minimal decline in the number of patients under treatment by colony-stimulating factor while the health insurance reimbursement of these drugs significantly decreased.

PCN273: TREATMENT PATTERN OF PATIENTS DIAGNOSED WITH PROSTATE CANCER IN KOREA: A TREND ANALYSIS USING NATIONWIDE HEALTH INSURANCE DATABASE

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OBJECTIVES: As the average life expectancy of Koreans increases, the prevalence of prostate cancer (Pca) is increasing in men aged 70 years or older. But, in the absence of pattern data of primary treatment for elder patients was unable to healthcare policy for prostate cancer. This study aims to examine the medical patterns of major for prostate cancer. METHODS: The treatment patterns of Pca were analyzed by using the linked data of the Korea Central Cancer Registry and National Health Insurance Service (NHIS), using International Classification of Diseases, 10th diagnosis codes. To analyze the status of medical use of Pca, the database of NHIS claims in 2002–2014 was used. The treatment pattern due to Pca were investigated according to year based on the details of age, insurance type, primary treatment type, hospital type, comorbidity and cancer stage. RESULTS: Overall 71,223 patients were identified and 45,197 new medical users were selected. In terms of the stage of cancer, the proportion of “Localized” group increased from 46% in 2005 to 58% in 2013. Patients that the Charlson’s Comorbidity Index is 1 point at the time of the first diagnosis had the most proportion at 26.78%, and the proportion of 4 points or more tended to increase annually for 11 years from 2003 to 2013. However, there was a continuous increasing trend in surgery (including robot surgery) from 23.7% in 2003 to 48.5% in 2013. Among those who received hormone therapy as a first treatment in patients aged 75-79 increased annually from 20.8% in 2003 to 27.3% in 2013, and patients aged 80 or more tended to increase. CONCLUSIONS: Considering the increased prevalence of elder patients with Pca, it is important to understand the real-world status of medical treatment and to generate evidence for support decision-making of national health policy in Korea.

PCN274: PAYER MANAGEMENT OF HIGH-COST BRAND-ON-BRAND COMBINATION THERAPIES IN ONCOLOGY

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OBJECTIVES: In recent years, brand-on-brand combinations of high-cost therapies have become a reality in the oncology space, particularly in areas such as multiple myeloma. The synergistic value of combining drugs with complementary mechanisms of action is expected to considerably bolster the benefit to the patient; however, the cost of using branded combinations increases exponentially due to the longer treatment duration, therefore making the regimen unaffordable. This research aims to explore pricing and market access issues that health systems have encountered during the evaluation of such therapies and potential solutions to make these regimens more affordable. METHODS: In-depth reviews of published sources were conducted, including a thorough analogue assessment. Primary research interviews with fifteen payers in the EU5 markets were conducted to support analysis and conclusions; payers were selected based on their involvement in the pricing and market access processes in their respective country and to reflect the different layers of decision-making (national, regional and/or local). RESULTS: The majority of drugs included within brand-on-brand combinations are already perceived as expensive in monotherapy, therefore, willingness to pay for a combined regimen is low. Payers are increasingly looking to innovative pricing models beyond simple discounts and in agreement with different manufacturers of the various therapies including within combination regimens in order manage budget impact. However, the complexity of the agreements and potentially unfair reflection of the value-based price for individual drugs is problematic. CONCLUSIONS: Aligning the differing priorities of patients, payers and manufacturers is critical for finding mutually beneficial solutions. The operating models of both payers and manufacturers will require innovation in order to meet these increasing needs.

PCN275: CANCER DRUGS IN ALGERIA AND SIX OTHER COUNTRIES: A CROSS-COUNTRY PRICE COMPARISON STUDY

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OBJECTIVES: The objective is to analyze whether cancer drugs are less or more expensive in Algeria than in 7 other countries in the world (Morocco, France, United Kingdom, Brazil, United States and Malaysia). METHODS: Based on the economic situation and the high prices of oncology medicines, we chose to survey official list prices at ex-factory level for 17 originator cancer drugs (breast cancer, lung cancer and prostate cancer) from the in-patient sector in Algeria and 7 countries from inside (France and Turkey) and outside its country basket for IRP as of April 2017. Drug data were provided by official websites except for Algeria where a questionnaire has been completed from representatives of the ministry of health. The prices of these drugs were compared per unit (i.e. per vial). Malaysia turned out to be an unreliable comparator because of the extreme variability of price data. Therefore, we decided to exclude it from our study. RESULTS: The study showed that there is a large disparity between the lowest and the highest priced drug ranging from 31% to 812%. The United States had all drug prices in the fourth quartile (100%), followed by Brazil (57%). Prices ranking most frequently in the first quartile were observed in Algeria (59%), Morocco (44%) and France (20%). Overall, in Algeria prices ranked at low level; whereas US had the most expensive prices. CONCLUSIONS: The large disparity in medicines prices is likely to result from national health policies. However, the prices surveyed do not include discounts because these are confidential. Since IRP is
based on the official list prices, even if Algeria’s prices are the lowest, the funding organizations risk overpaying. Therefore, changes in the Algerian pricing policy by moving to risk sharing agreements may be a serious option to have more attractive prices.

PCN276: GERMAN AMNOG BENEFIT ASSESSMENT: THE TYPE OF APPROPRIATE COMPARATOR MAKES THE DIFFERENCE

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OBJECTIVES: For benefit assessment of new pharmaceuticals in Germany, G-BA defines appropriate comparators of four categories: one specific drug, a list of drugs, patient individualized therapy, and best supportive care (BSC). The aim of the study was to reveal the impact of the category on the added benefit. METHODS: Information on appropriate comparators and benefit assessment were retrieved from a databank containing information on all AMNOG dossiers in the field of oncology. Dossiers were analyzed for data on indication, target population, line of therapy, appropriate comparator, and added benefit. RESULTS: 66 relevant dossiers including 129 separate (sub-)labels were identified. Appropriate comparators assigned by G-BA were distributed as follows: 33 (26%) specific drug, 39 (30%) list of drugs, 23 (18%) patient individualized therapy, and 34 (26%) BSC. About 50% of all assessed sublabels within the categories “specific drug” and “list of drugs” gained an added benefit (45.5% and 46.2%, respectively). In nearly all of these dossiers direct evidence to the assigned comparator was presented. 41.2% (n=14) of the indications in the category “BSC” gained an added benefit. In 3 dossiers no direct evidence to the appropriate comparator was presented. Nevertheless, 2 of these dossiers achieved an added benefit. In contrast, an added benefit was granted for only 30.4% (n=7) of sublabels, which belonged to the category “patient individualized care”. 9 of the dossiers in this category did not show direct evidence to the appropriate comparator; however, 3 of these dossiers achieved an added benefit. CONCLUSIONS: A specific drug or BSC are the most commonly assigned appropriate comparators in oncology dossiers. If a specific drug is the appropriate comparator, it seems inevitable to present direct evidence in order to gain an added benefit. For BSC and patient individualized therapy, G-BA seems to be more permissive regarding the acceptance of evidence not directly matching the appropriate comparator.

PCN277: RATES OF UPTAKE OF NOVEL AGENTS IN CANCER (PROSTATE, MELANOMA, AND LUNG): CONSIDERATIONS FOR FORECASTING IN ECONOMIC EVALUATIONS

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OBJECTIVES: With recent drug approvals in prostate, melanoma and lung cancers, determining the uptake rate is important to understand their budgetary impact for national and private payers. This research describes the patterns in uptake of novel anti-cancer agents in the US and discusses the importance of developing time-dependent budget/cost-effectiveness models. METHODS: Unique patients initiating therapy approved between 01/01/2011-12/31/2016 for prostate, melanoma and lung cancer were counted by quarter (Q) in the Symphony Health pharmacy and medical claims database (≥ 1 Rx claim and ≥ 1 medical claim for indication-specific diagnosis). Mean time to peak utilization was assessed. Trends in utilization were evaluated using linear regression. Model fit was based on r2. Sub-analyses were conducted to describe the influence of clinical and market forces (new clinical data, competitor launch, expanded indications) on utilization. RESULTS: Mean years from approval to peak utilization was: abiraterone(abi)=4, enzalutamide(enza)=4.5, ipilimumab(ipi)=2.3, dabrafeni/trametinib(dab/tra)=3.5, afatinib(afa)=4.5, crizotinib(criz)=4.5. A quadratic model (x2) showed a downward trend in abi use beginning in 2015 Q2 (r2=0.97). A cubic model (x3) for enza showed stable rates since 2016 Q3 (r2=0.98). Expanded indications increased the slope of the uptake curves for both drugs. Use of ipi began to decline in 2014 Q3 (x2,r2=0.84) at the time of approval of nivolumab. Similarly, utilization of dab/tra appears (x3,r2=0.95) to be now declining(42% less dab/tra from 2015 Q1-2016 Q4), approximately 2 quarters following launch of nivolumab. Afa use appeared to begin to decline(x3,r2=0.96) while criz appeared stable (x3,r2=0.96). CONCLUSIONS: This research demonstrates that it takes several years from approval to attain peak market share. Uptake is not a linear process and market forces drive utilization patterns. Payers, whether national or private, should request time-dependent uptake factors in the calculation of budget impact models or forecasts to accurately reflect rates of adoption. Historical data can be used to inform such models.

PCN278: CHARACTERISTICS OF PATIENTS TREATED WITH CETUXIMAB-BASED EXTREME REGIMEN IN 1ST LINE R/M SCCHN CANCER IN REAL LIFE SETTING, IN FRANCE IN 2012-2015.

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OBJECTIVES: The objective of the study was to assess the EXTREME chemotherapy regimen in real life setting. In
this abstract, we present patient characteristics and primary endpoint which was the rate of patients with relative dose intensity (RDI) of cetuximab ≥ 80% in patients with 1st line R/M SCCHN. METHODS: DIRECT is a national, observational, longitudinal, multicenter, cohort-type study performed in adult patients with R/M SCCHN treated in first-line with cetuximab according to the administration schedule of the EXTREME study in usual medical practice. Sociodemographics, clinical and management data were collected through e-CRF, and the analysis of the full sample was defined as all subjects who received at least one dose of cetuximab after the loading dose. RESULTS: Of the prospective population (n=169), 157 patients received at least the loading dose of cetuximab for R/M SCCHN, and 140 received at least one dose of cetuximab in addition to the loading dose. Among them, 96 had received chemotherapy in the LA SCCHN setting, and 30 patients had previously received cetuximab. 139 patients had recurrent disease, whereas 17 metastasis upon initial diagnosis. 29.9% of patients in DIRECT were ≥ 65 years old, 85.4% were males, 18.4% of patients had an Eastern Cooperative Oncology Group performance status (ECOG PS) of ≥ 2. Regarding the primary endpoint, mean RDI for these patients (n=130) for the whole treatment was 86.1% ± 16.1%, and 63.1% had an RDI ≥ 80%. 72 patients (45.9%) continued cetuximab in maintenance phase. CONCLUSIONS: Baseline characteristics of the DIRECT prospective patient population who received at least the loading dose of cetuximab were quite similar to those in the EXTREME trial. Results demonstrated that the EXTREME regimen is a feasible treatment regimen in a real world setting.

PCN279: THE CASE FOR COMBINATION THERAPY - CLINICAL AND ECONOMIC VALUE DIFFERENTIATION STRATEGIES IN SATURATED ONCOLOGY THERAPY AREAS

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OBJECTIVES: Market saturation or commoditisation is an increasingly frequent occurrence in the healthcare industry, and brings with it the challenge of value differentiation. The aim of this research was to analyse value differentiation strategies utilised by a selection of case studies in saturated oncology therapy areas. METHODS: In-depth analysis of national HTA decisions was undertaken for selected oncology case studies in France, Germany, and England; these included novel therapies recently approved in relapsed / refractory multiple myeloma (RMM), advanced melanoma, and non-small cell lung cancer (NSCLC), which have encountered an influx of novel products over the last five years. Descriptive analysis identified key decision drivers behind each appraisal, and an assessment of successful value differentiation strategies was also conducted. RESULTS: Despite perceived ‘market saturation’, most HTA decisions reviewed in RRM, advanced melanoma and ALK+ NSCLC were ultimately positive (11/11, 9/11 and 5/6, respectively). While efficacy / safety outcomes are key decision-drivers in all HTA appraisals, they were the only drivers cited in FRA / GER appraisals, while NICE appraisals also cited cost-effectiveness, end-of-life criteria and treatment variety. Regardless of decision-drivers cited within appraisals, notable value differentiation strategies were employed by manufacturers to ensure a successful outcome. In RRM, fixed drug combinations were a key differentiation strategy implemented, with KYPROLISTM (carfilzomib, AMGEN) seeking approval for a doublet combination in cost-effectiveness markets (ENG) and a triplet combination in clinical-effectiveness markets (FRA / GER). This method was also observed in advanced melanoma with success of the OPDIVOTM / YERVOYTM (nivolumab / ipilimumab, BMS) combination in ENG. Additional value differentiation strategies employed by manufacturers included mechanism of action and mode of administration. CONCLUSIONS: HTA bodies in FRA, GER and ENG remain receptive to novel therapies in saturated therapy areas. However, alternative value differentiation strategies can and have been employed to market improve access success in these scenarios.

PCN280: ANALYSIS OF PHARMACY CLAIMS FOR HIGH COST DRUGS: RUXOLITINIB UTILISATION AND EXPENDITURE IN IRELAND

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OBJECTIVES: To analyse Irish national utilisation and health payer expenditure on ruxolitinib (from January 2015-December 2015 inclusive). To compare this real-world data to the utilisation and expenditure predicted at the time of the decision making process. METHODS: Predicted utilisation and expenditure data was derived from the National Centre for Pharmacoeconomic (NCPE) website. The NCPE considers the cost effectiveness and likely budget impact of all new drugs for which reimbursement by the health payer is sought. Real-world data was derived form a retrospective analysis of the national pharmacy claims database of dispensed ruxolitinib (ATC code LO1XE18). The total number of individuals who had received at least one prescription for the drug over the 12 month study period was determined. The gender/age distribution of the cohort were established. Total expenditure was ascertained. RESULTS: In 2013, the NCPE had evaluated ruxolitinib for the treatment of splenomegaly/disease-related symptoms in primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocytahemia myelofibrosis. The budget impact analysis assumed that there would be 24 patients initiated on treatment in year 1 post reimbursement, and about 11 annually thereafter. The annual gross impact was estimated to
increase from €1.20 million (year 1) to €2.61 million (year 5). The drug was reimbursed in 2014 subsequent to price negotiations. Real-world analysis indicated that, in 2015 (year 2 post reimbursement), 81 (65.4% male) individuals had received at least one dose of ruxolitinib. The mean age of the male and female cohorts were 74 (± 9.3) and 70.7 (± 8.9) years respectively; no significant difference between age distributions was detected. Total expenditure was €2.65 million. **CONCLUSIONS:** Our analysis demonstrates how real-world utilisation can differ from pre-reimbursement estimates and highlights the benefit that this real-world information could bring to the decision making process, particularly in relation to monitoring affordability.

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**PCN281: REAL-WORLD EVALUATION OF PHYSICIAN ATTITUDES TOWARDS THE PRESCRIPTION OF ANDROGEN DEPRIVATION THERAPY FOR PATIENTS WITH PROSTATE CANCER**

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**OBJECTIVES:** We sought to understand drivers for real-world treatment decisions among physicians prescribing androgen deprivation therapy (ADT) in Europe. **METHODS:** A disease specific programme, collected data from 81 urologists across Belgium (n=8), France (n=29), Germany (n=20) and Italy (n=24) between February and May, 2015. Data on physician demographics and prescribing habits were collected through physician-completed online surveys and patient record forms. Opinion questions were scored on a seven-point scale from strongly agree to strongly disagree. All data were anonymised and treated in accordance with national data collection regulations. **RESULTS:** Physicians were grouped by frequency of prescription of the GnRH Antagonist, degarelix, as regular prescribers (n=30), low-prescribers (n=31) or non-prescribers (n=20). Physician demographics showed those who regularly prescribed, tended to be more recently qualified (67% vs 30%), worked at larger university hospitals (56% vs 7%) and were actively involved in clinical trials (43% vs 10%), compared to non-prescribing physicians, respectively. Approximately one-third of physicians thought that current treatments were not controlling the disease, and the majority (≥90%) agreed that drug efficacy claims are factual. Overall, ≤50% considered pharmaceutical companies a valuable source of information and ≤33% thought they would be among the first to prescribe a new treatment. Few physicians thought traditional endpoints were more important than quality of life endpoints (≤13%). Treatment costs did not influence choice of therapy among 40% Degarelix prescribers and 5% of non-Degarelix prescribers, although ≤10% in any prescriber group felt restricted in prescription choice. **CONCLUSIONS:** These real-world data suggest that overall, physicians have realistic expectations of prostate cancer treatments and consider quality of life endpoints to be important. Most physicians consider themselves able to prescribe the treatment of their choice, despite potential differences in costs.

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**PCN282: MANAGEMENT AND COST ANALYSIS OF CANCER PATIENTS TREATED WITH G-CSF: A COHORT STUDY BASED ON THE FRENCH NATIONAL HEALTHCARE INSURANCE DATABASE (ECHANTILLON GÉNÉRALISTE DES BÉNÉFICIAIRES)**

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**OBJECTIVES:** Chemotherapy-induced neutropenia can lead to life-threatening infections and treatment modifications thus compromising the chemotherapy efficacy in cancer patients. The use of granulocyte colony-stimulating factor (G-CSF) to prevent febrile neutropenia is defined by international guidelines. We aimed to describe the management and costs associated with G-CSF therapy in cancer patients in France. **METHODS:** We analyzed a representative random population sample from the French national healthcare insurance database, focusing on 2,284 patients with hematological or solid malignancies who were reimbursed in 2013, 2014 or 2015 for at least one G-CSF treatment dispensed by retail pharmacy (hospital administration being marginal). Patient characteristics and treatment costs were analyzed according to cancer type and G-CSF product. **RESULTS:** Most frequent malignancies were breast cancer (25.5%), hematological malignancies (23.5%) and lung cancer (19.2%). Patients mean age was 61.8 years (SD=14.0), 55% were female. G-CSF was pegfilgrastim in 34% of cases, lenograstim in 26%, filgrastim in 19%. More than one G-CSF product was reimbursed to 21% of patients. Total annual reimbursed health expenses per patient were €27,768, €24,481 and €21,629 for patients treated with filgrastim, lenograstim and pegfilgrastim respectively. The respective ambulatory care costs were €9,748, €8,389 and €8,729 and the G-CSF accounted for 18% (filgrastim), 19% (lenograstim) and 42% (pegfilgrastim) of those costs. Hematological malignancies incurred the highest costs (€35,906) and breast cancer the lowest (€17,642). **CONCLUSIONS:** Daily and pegylated G-CSF are equally recommended by international guidelines. The annual reimbursed costs varied with the type of cancer. The choice of G-CSF can have a significant impact on the total cost of ambulatory care for cancer patients.
PCN283: DEVELOPMENT AND EVALUATION OF ONCONURSE PRACTICE—A SMARTPHONE APPLICATION FOR ONCOLOGY NURSES

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OBJECTIVES: To develop a cancer-focused smartphone app- OncoNurse Practice for oncology nurses for the purpose of drug administration and safe handling of hazardous drugs (chemotherapeutics) and also to assess the acceptability and usage of the app. METHODS: The smartphone app, OncoNurse Practice was designed and developed over a period of 6 months using the Android mobile platform. A multi-centre survey was conducted among 106 oncoNurses working across South India through structured questionnaires. RESULTS: Approximately, 92.5% perceived the need to access cancer-focused smartphone apps and online tools such as drug references. Of these, 18.9% had previously used smartphone apps. This showed that the highest need for its implementation was perceived in cities (62.3%) and villages (47.2%). After installing app into their devices for a month, majority stated the app was good (76.4%), user-friendly (88.7%) and was useful in patient education (95.3%). 99.1% of the surveyed nurses were satisfied with the app. 97.2% recommended its use. 56.6% of the nurses had used the app at least twice per day. Safe handling of chemotherapy was the most frequently searched information. CONCLUSIONS: This study found that the app was widely accepted among oncoNurses. Majority of them accessed the app more than once daily to enhance their knowledge on hazardous drugs and ensure effective handling. It further enabled them to provide improved quality of care for the cancer patients.

PCN284: PERSISTENCE, COMPLIANCE AND BISPHTONATE SWITCHING IN PATIENTS WITH MULTIPLE MYELOMA (MM) IN GERMANY

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OBJECTIVES: This retrospective observational analysis aimed to estimate persistence, compliance and switch patterns in MM patients newly treated with bisphosphonates (BPs) approved in Germany for the prevention of SREs. METHODS: This was a retrospective analysis of German health insurance claims data (including ~4 million patients). The study included newly diagnosed MM patients aged ≥18 with no prior hypercalcemia, undergoing BP treatment for the first time. Descriptive analyses to estimate persistence, compliance and switch rate among first line intravenous BP treatments were performed. Persistence was defined as continuous prescriptions with <90-days gaps. Compliance was defined as ≥12 prescriptions within 12 months after BP initiation. A switch was defined as a change from a prescribed BP to another BP within a <90-day window. Patients were censored at death. RESULTS: The sample included 281 patients (female: 53.0%, mean age: 68.1 [SD 11.2], previous SRE: 31.7%, renal disease: 19.9%). In the first year, BP compliance rates were 35.7% and 28.0% for pamidronate and zoledronate, respectively. Persistence rates [% (95% CI)] at 12 months were 50.9% (44.7-58.0) overall, 52.8% (37.6-74.0) for ibandronate, 44.2% (36.4-53.7) for pamidronate, and 48.4% (37.0-63.2) for zoledronate. Median time to non-persistence [median (95% CI)] after treatment initiation was 53 weeks (40-76) overall, 55 (31-NA) for ibandronate, 45 (28-82) for pamidronate and 41 (32-65) for zoledronate. The switch rates from ibandronate, pamidronate and zoledronate to another BP were 9.8%, 12.5% and 4.8% for ibandronate, pamidronate and zoledronate, respectively. CONCLUSIONS: In MM patients treated with BPs, persistence at 12 months was 50.9%. Compliance was very low: at 12 months only 1 in 3 and 1 in 4 patients had received ≥12 prescriptions of pamidronate and zoledronate respectively. Between 5% and 12% switched treatments within the first 12 months. Overall, patients with MM seem to be sub-optimally treated for the prevention of SREs.

PCN285: DENOSUMAB AND BISPHTONATE PERSISTENCE, COMPLIANCE AND SWITCH IN PATIENTS WITH SOLID TUMORS (ST) AND BONE METASTASES (BM)

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OBJECTIVES: This observational study aimed to provide real-world data on denosumab and bisphosphonate use in patients with ST and BM in Germany. METHODS: This is a retrospective analysis of a German sick-fund claims database (including ~4 million patients). The study population consisted of ST patients aged ≥18 years, newly diagnosed with BM with no prior hypercalcemia, initiating denosumab or bisphosphonates. Persistence was defined as continuous prescriptions with <90-days gaps. Compliance was defined as ≥12 prescriptions in a 12-month period. Switch was defined as change in drug within 90 days. Dying patients were censored on the day of
RESULTS: 1156 eligible patients with breast [BrCa], prostate [PrCa] and lung cancer [LuCa] were analyzed (mean age 65 years for BrCa, 74 for PrCa, 65 for LuCa). Of patients with BrCa, PrCa, and LuCa, respectively, 25%, 17% and 20% had prior skeletal related event (SRE) and 8%, 23% and 16% had renal disease. For BrCa, persistence at 1 year [% (95% CI)] was 78% (70-85) for denosumab and 58% (45-75), 56% (43-72) and 54% (47-61) for ibandronate, pamidronate and zoledronate, respectively. For PrCa, persistence with denosumab and zoledronate were 58% (48-71) and 50% (42-59), respectively. Finally for LuCa persistence for denosumab, pamidronate and zoledronate were 68% (47-99), 34% (15-80) and 60% (50-73), respectively. 1-year compliance [% (95% CI)] for BrCa was 75% (64-84), 42% (25-61), 48% (31-66) and 48% (40-57) for denosumab, ibandronate, pamidronate and zoledronate, respectively. For PrCa, it was 47% (32-62) and 36% (26-47) for denosumab and zoledronate, and for LuCa was 51% (35-67) for zoledronate. Switch rates in BrCa were 5%, 14%, 14% and 19% for denosumab, ibandronate, pamidronate and zoledronate, respectively, with a similar pattern in PrCa and LuCa. CONCLUSIONS: Denosumab had higher persistence and compliance with lower switch rates.

PCN286: WHAT IMPACT DOES NICE’S MODIFIED CANCER DRUGS FUND PROCESS MEAN FOR PATIENT ACCESS TO NEW ONCOLOGY PHARMACEUTICALS IN ENGLAND?

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OBJECTIVES: In April 2016, NICE modified the Cancer Drugs Fund (CDF) appraisal process, to review all new oncology indications and publish final guidance within 90 days of marketing authorisation. Additionally, 11 existing legacy treatments from the previous CDF had not undergone a NICE assessment and required review. This study investigates the efficiency of the new CDF appraisal process for indications without prior NICE evaluations. METHODS: Public data sources were analyzed to determine the outcome of NICE reviews of 42 oncology indications using the modified CDF process. The following information was collected for each indication: Stage of the evaluation process Has it secured interim/baseline funding? Is it approved with the CDF managed access scheme? RESULTS: As of June 2017, NICE have reviewed 31 new indications: 21 positive recommendations (which allows for routine NHS funding), 6 negative recommendations (no NHS funding), whilst 4 indications are recommended for use with CDF managed access schemes. All approved indications entering baseline funding have done so with patient access schemes. Furthermore, NICE has reviewed 2 legacy CDF indications, with 9 still to be evaluated. CONCLUSIONS: NICE appear to have prioritized new oncology indications, reviewing 31 new indications to only two legacy indication. For new indications, it appears the new NICE appraisal process is efficient and enabling faster access to patients. However, this is at the expense of legacy CDF indications, which remain in limbo in the CDF. This may be advantageous to manufacturers as it prolongs the time that their drug will remain a transition drug, preventing engagement in new patient access schemes whilst still allowing new patients to access their drugs. All newly approved indications had a patient access scheme in place to lower the net price to ensure recommendation, highlighting that the NHS list price remains artificial.

PCN287: CHANGES IN TREATMENT PATTERNS OF TYROSINE KINASE INHIBITORS AMONG NON-SMALL CELL LUNG CANCER PATIENTS UNDER THE NATIONAL HEALTH INSURANCE IN TAIWAN

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OBJECTIVES: The reimbursement criteria of tyrosine kinase inhibitors (TKIs) among advanced/metastatic non-small cell lung cancer (NSCLC) patients have gradually been expanded from later-line to the first-line therapy in Taiwan (i.e., gefitinib 2011/06; erlotinib 2013/11; afatinib 2014/05). Little has been documented about the extent to which the treatment sequence regarding TKI therapy had been altered in real-world practice. We aimed to assess the impact of such reimbursement policy change since 2011 under the universal coverage of the National Health Insurance in Taiwan. METHODS: This study was carried out with the 2011-2014 National Health Insurance Research Database in Taiwan. Patients with NSCLC who initiated a TKI after 2012 were included and categorized as receiving TKIs as the first-line or ≥ second-line therapy in our analysis. The trend of receiving TKI as the first-line therapy over time and the treatment status after TKI failure were assessed. RESULTS: A total of 13,341 patients initiated their first TKI therapy during the year 2012-2014 (4,487, 4,429 and 4,425 patients, respectively). The proportion of patients receiving TKI as the first-line therapy in each year elevated from 47.98% to 62.98%. The 30-day survival rate and the percentage of patients receiving salvage chemotherapy after TKI failure were higher in the first-line group (67.5% and 52.5%) compared to the ≥ second-line group (58.8% and 50.2%). Exploratory analysis of the pooled data suggested a median TKI treatment duration of 5.6 months and overall survival of 6.8 months, which appeared to be lower than those derived from trials. CONCLUSIONS: TKI as the first-line therapy has become more prevalent, and thus the rate of receiving salvage therapy after TKI failure has increased. Further studies are warranted to examine whether the sequence change of TKI therapy may cause a difference regarding the overall survival in real-world practice.
**PCN288: NEW INSIGHTS IN METASTATIC COLORECTAL CANCER TREATMENT (MCRC) IN 5 EUROPEAN COUNTRIES**

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**OBJECTIVES:** Targeted therapies for mCRC treatment have been available in Europe for several years now. We used long-term real-world data to study the influence of targeted therapies on the occurrence of side effects and analyzed country specific differences in treatments and influencing factors. **METHODS:** Treatment data of 10,231 mCRC patients collected between 2011 until 2016 in EU5 countries were extracted from the IMS® Oncology Analyzer (OA) database. OA contains anonymous retrospectively collected patient level data on disease and treatment history provided by hospital- and office-based physicians. A count GEE regression model was used to evaluate differences in the number of side effects between treatments with and without targeted therapies. An ordinal GEE regression model was used to examine if the choice of therapy had been affected by factors such as country, year, age, sex or type of insurance. **RESULTS:** In the count GEE regression model patients receiving targeted therapies in combination with chemotherapy had a 0.15 fold increase in the predicted number of side effects compared to patients treated with chemotherapy only. Initially, patients in UK and Spain were less likely to receive targeted therapies than in Germany. Over time, chances to receive targeted therapies increased significantly (P<0.05) in Spain (+25%), France (+13%) and Italy (+13%), but not in Germany (-3%) or UK (-4%). Health insurance type (public versus private) did not affect the likelihood of receiving targeted therapy. **CONCLUSIONS:** Use of targeted therapies increased the number of side effects only to a minor extent in mCRC patients. Over time, the percentage of targeted therapies converged to similar levels in France, Germany, Italy and Spain, but remained lower in UK compared to the other countries. Real world data provide valuable up to date insights into clinically applied therapies, correlating factors of interest and allow further optimization of treatments.

**PCN289: PHYSIOTHERAPEUTIC METHODS AIMED TO IMPROVE THE CARDIORESPIRATORY STATE BEFORE AND AFTER OPERATION IN PATIENTS WITH LUNG CANCER**


**OBJECTIVES:** Our study aims to develop a complex physiotherapy preoperative procedure, which would ensure that lung tumour patients have better physical and mental state to the surgery and have a better general condition after the operation, thus to shorten the period of hospitalization and the chances of complications. **METHODS:** The examination was made between October 2016 and March 2017. 20 patients were involved in the prehabilitated group receiving information and two weeks of exercise program at home before surgery. Further 20 patients were in the group that received only post rehabilitation, after the operation they were only treated according to the protocol used in the hospital ward. Data were collected by questionnaires, tests or exercise program adapted to our patients. We used standardized questionnaires and our own genuine edited questionnaire. In patient education before elective surgery we have described the movement program, taught the breathing exercise and shown the correct usage for respirex then gave them a form to take home on which the patients could mark how many of the options listed are made daily. Stair test and a 2-minute walking test has been carried out with the patients’ arrival and departure, and for prehabilitated immediately before the surgery after the two-week program at home. **RESULTS:** Between the two groups there was a significant difference in depression (p=0.001), chest pain (p=0.007), presence of mucus (p=0.005), subjective dyspnoe (p=0.035), postoperatively measured forced inspiration volume (p=0.002) and measured immediately before surgery forced inspiration volume (p=0.011), heart rate (p=0.020) and oxygen saturation (p=0.045) regard. **CONCLUSIONS:** The two-week exercise program has a significant impact on cardiorespiratory status of the patients. Those receive adequate training before surgery, will be in better physical and mental health when it comes to the operation, and there will be a better general condition after surgery.

**PCN290: ORPHAN DRUG REIMBURSEMENT IN EUROPE: DO LESS STRINGENT REGULATORY REQUIREMENTS TRANSLATE INTO LESS FAVOURABLE REIMBURSEMENT?**


**OBJECTIVES:** The EMA orphan drug legislation incentivises the development of therapies for rare diseases. Medicines approved with orphan designation have become increasingly common; however regulatory approval does not guarantee favourable reimbursement. This research undertakes an analysis of EMA-approved orphan drugs and discusses regulatory versus access requirements. Haematological malignancies have been selected as an area of focus; an indication containing many therapies with orphan designations. **METHODS:** All publically-available EMA and HTA reports from NICE, SMC and HAS of blood cancer drugs that have been EMA-approved with an orphan
designated have been reviewed (from November 2002 to April 2017) and key data extracted. RESULTS: 24/96 currently authorised orphan drugs target haematological malignancies. From those, twelve products were authorised based on single-arm phase II data and twelve based on active-comparator phase III data. 3/24 studies were double-blinded, the rest were open-label. Only 3/24 submissions reported Overall Survival data, while the rest contained surrogate endpoints such as Progression-free Survival and Response rate data. From an HTA perspective, 15/22 products reviewed by HAS have received a favourable ASMR (I-III) for at least one indication and the rest have received an ASMR IV/V. NICE have recommended or restricted 9/10 products reviewed, 8/9 of them with a Patient Access Scheme (PAS). The SMC has recommended or restricted 15/22 of such products assessed, 9/15 with a PAS. CONCLUSIONS: Therapies for haematological malignancies with EMA orphan designations have obtained marketing authorisation on data packages lacking comparative Phase 3 data or any data on any survival endpoints. However, at an HTA-level some have struggled to attain favourable recommendations. As competition within the therapy area is increasing, the hurdles for reimbursement may further increase, widening the evidentiary divergence between regulators and payers, potentially necessitating greater utilisation of RWE studies and/or innovative contracting for optimal reimbursement.

PCN291: REGIONAL DIFFERENCES IN POTENTIAL SAVINGS FOR THE MEDICAL TREATMENT OF ADVANCED PROSTATE CANCER IN THE GERMAN HEALTH CARE SYSTEM

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OBJECTIVES: Gonadotropin-releasing hormone analogues (GnRH-analogues) are well established for treating advanced prostate cancer. In 2015 and 2016, four GnRH-analogues were available in Germany: Buserelin, Goserelin, Leuprorelin and Tripotriol. Only Leuprorelin had generics. Four of 17 regions of physicians’ associations (KV) in the statutory health insurance (SHI) had quotas promoting Leuprorelin in 2015 and 2016 (“Quota-KVs”). Four regions introduced quotas in 2017 (“New-KVs”). This research investigates the regional differences in market penetration and potential savings. METHODS: QuintilesIMS provided monthly SHI prescription data per region, sickness fund and package for 2015 and 2016. Pharmacy sales prices and defined daily doses (DDD) were used for sales respectively volume. RESULTS: Total sales were 207.7m (212.3m) Euro and volume was 37.6m (38.3m) DDD in 2015 (2016). The average quarterly market share (sales) of Leuprorelin differed regionally between 60.5% and 75.7%. Within the Leuprorelin market, the average generics’ share varied between 5.9% and 33.6%. In the “Quota-KVs”, the average share was 23.9% compared to 12.2% in the “New-KVs” and 14.3% in the remaining nine. Leuprorelin generics had a more cost-effective average price level (4.51 Euro/DDD) than other Leuprorelin products (5.38 Euro/DDD) and GnRH-analogues (6.02 Euro/DDD). SHI could have saved 20.6m Euro or 4.9% of sales in 2015 and 2016, when the highest quarterly market shares (DDD) of Leuprorelin in a KV (79.7%) and generics within Leuprorelin (45.8%) would have been achieved over all quarters and KVs. Average potential savings per KV varied between 2.0% and 6.9%. Average potential savings would have been 3.5% in “Quota-KVs” and 5.7% in “New-KVs” as well as the remaining nine. CONCLUSIONS: The analysis shows a low market share for generics and a strong deviation between regions. Quotas push market penetration for generics. Regions with lower shares have recently introduced them. Substantial savings can be achieved without any loss of clinical effectiveness.

PCN292: SYSTEMATIC REVIEW OF PIVOTAL STUDIES OF ONCOLOGY DRUGS AUTHORIZED IN ITALY SINCE 2013: CORRELATION BETWEEN STUDIES’ MAIN CHARACTERISTICS AND TIME TO PATIENT

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OBJECTIVES: in registration of oncology drugs, regulators usually require data from a phase III RCT, exceptionally, data from phase II. RCTs require time to collect data, to enrol patients and resources. The aim of this research is to correlate pivotal clinical trials characteristics and time to patients for oncology drugs negotiated in Italy METHODS: We analysed oncology drugs approved by EMA from Jan2013 to Dec2016. To date, 27 of 45 drugs completed the full Italian P&R process and were included. We classified drugs in three different clusters, on the characteristics of pivotal clinical trials: 1) “A” for phase III with an active comparator; 2) “B” for phase III with placebo 3) “C” for phase II. The oncology drugs considered, are related to various indications (melanoma, multiple myeloma and NSCLC are the most common ones). We evaluated time needed (defined as time from EMA’s CD to price publication on Italian OJ) RESULTS: We observed that the oncology drugs in cluster “A” have a shorter time to patient (mean 410days, median 319days, range164-918); then cluster “B” (mean 470days, median 361days, range316-827) and cluster “C” (mean 498days, median 486days, range157-798). By comparing time for drugs registered with phase III or phase II, the median difference is 125days, around 4months (343 vs 468). Predictably, the patients enrolled in phase III (521, range199-1717) is higher than in phase II trials (158, range79-449). As expected, orphan drugs have been more frequently registered with a Phase II or a Phase III vs placebo (10/13). Afterwards we found the Phase III with an active comparator (3/13: for haematological malignancies) CONCLUSIONS: Our data
show a statistically significant difference among the three clusters identified. In the time to patient, it’s showed a linear correlation between quality of clinical trials and reduction in time to patient for oncology drugs in Italy.

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**PCN293: HEALTH LOSS DUE TO MARKET ACCESS DELAYS AND REIMBURSEMENT RESTRICTIONS IN FIRST-LINE EGFR-POSITIVE NON-SMALL CELL LUNG CANCER IN THE EU5 COUNTRIES**

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**OBJECTIVES:** To maximize health-related quality of life (HRQoL), innovative therapies should be timely accessible to patients. In practice, however, time-consuming reimbursement decision-making processes at health technology assessment (HTA) authorities cause delays between the European Medicines Agency's (EMA) approval and actual market access. This may cause HRQoL losses. Additionally, negative or restricted reimbursement decisions may also result in HRQoL losses. AIM: To quantify potential HRQoL losses due to delayed market access and reimbursement restrictions in first-line EGFR-positive non-small cell lung cancer (NSCLC) treatments in the EU5 countries. **METHODS:** A health impact model employing a 5-year time horizon was developed, comparing actual NSCLC treatment in the EU5 to a scenario assuming direct market access. The model incorporates first-line treatments for EGFR-positive NSCLC, approved by EMA between 2007-2017. Epidemiologic data were used to quantify the number of patients diagnosed with EGFR-positive NSCLC. The model was populated with reimbursement decision data of the EUS HTA agencies and market share estimates for the period 2013-2017, as well as NMA data on clinical effectiveness. Utilities were derived from the literature. **RESULTS:** Eight treatments were included in the model. In the EU5, 56,953 patients were diagnosed with EGFR-positive NSCLC annually. With current treatment algorithms, a total of 69,847 QALYs and 98,592 life years are achieved for these patients over a 5-year period. With direct market access, 3,241 QALYs and 4,622 life years could be gained. Largest HRQoL loss occurred in Italy. **CONCLUSIONS:** This research suggests that delayed market access and reimbursement restrictions result in HRQoL losses in the EU5. One should keep in mind however, that the results presented here may be an overestimation of the actual HRQoL losses due to several factors, such as health care displacements, strategic product launches, and time required for guideline adaptations and clinical implementation.

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**PCN294: THE IMPRESS OF PHARMACOECONOMICS IN PRICING DECISIONS IN IFDA**

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**OBJECTIVES:** The rapidly rising cost of drug therapy is a concern to healthcare providers throughout the world. Based on Iran Food and Drug Administration (IFDA) regulation For the domestic and imported products the routine pricing policy is cost plus and external reference-based pricing. The pharmacoeconomics committee as a main portion of Iran Drug Selection Committee (IDSC) in IFDA evaluate the cost-effectiveness of medicines based upon the comparator price and the differential value. In this way we want to evaluate The impress of pharmacoeconomics in pricing decisions in IFDA. **METHODS:** The role of pharmacoeconomics was assessed with reviewing the economic evaluation studies that was applied and recorded by companies in IFDA. Also the minutes of pharmacoeconomics committees was reviewed in order to assessing the outcomes of pharmacoeconomics committee the in 2 past years. **RESULTS:** The investigation showed that "Cost" components include comparison with other treatments, total cost per year, and cost per patient is the essential part in the evaluation of cost-effectiveness in the committee. All 3 of these approaches have utilized of experts to guide the decision making process in pricing.In the next step Other relevant cost factors include drug administration, monitoring costs and budgetary impact might be used as evidences to decision making. **CONCLUSIONS:** Drug costs are important although drug acquisition costs and total budgetary impact will be important in pricing decision making. The price of a new medicine can be established in this committee that would be important input into strategic pricing decisions. It also introduces a new criterion of evaluation entitled "budget impact" that improve the allocative efficiency of health care financing. Other measurable factors such as cost, and quality-of-life concerns, provides a more balanced approach in the evaluation of specialty medications.

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**PCN295: AN EXPLORATORY COMPARISON OF US AND EU APPROACHES TO ONCOLOGY MANAGEMENT. ARE US PAYERS READY FOR MANAGEMENT TOOLS INCORPORATING HTA METHODOLOGIES?**

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**OBJECTIVES:** US payers are exploring innovative cost containment management tools (value frameworks, pathways, shifting risk, etc.) in oncology today. Compared to their European colleagues, payers in the US face significant barriers to implementing tools designed to drive value based decisions. This research aims to 1) assess
difference in the scope and scale of barriers to implementing such tools in the EU and the US, 2) explain market and legislative conditions that likely create the differences in implementation, and 3) propose the necessary conditions for US payers to implement more value-based decision making in oncology.

**METHODS:** We compared the current price and access of drugs indicated for CLL and NSCLC in the US and 4 EU countries. To assess how price and access decisions are made, we reviewed HTA reports published in Europe and conducted an oncology web-based survey with 20 US payers for an industry assessment of the barriers to implementation and effectiveness of innovative cost containment management tools today.

**RESULTS:** Compared to the US, EU countries have lower list prices and more stringently controlled access. In the US, the use of value frameworks remains limited to date. Pathways of care are largely not designed with value considerations. Where pathways of care do exist, they are weakly enforced or incentivized. Payer management in the US is limited by the lack of comparative data, limited competition in patient sub-populations, rapid evolution of the guidelines, and outside pressure to maintain broad formularies.

**CONCLUSIONS:** Payers are willing to implement innovative management tools, but in absence of a profound public policy change, these tools will be effectively implemented only in oncology indications with mature evidence and robust competition. Value frameworks or other HTA type of value assessment will not significantly influence the evaluation of innovative drugs with high unmet need and low competition.

**PCN296: A COMPARATIVE ANALYSIS OF THE HEALTH CARE UTILIZATION AND COSTS OF PATIENTS DIAGNOSED WITH AND WITHOUT LIVER CANCER IN THE US MEDICARE POPULATION**

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**OBJECTIVES:** To compare the health care utilization (HRU) and costs of patients with and without liver cancer in the US Medicare population.

**METHODS:** A retrospective data analysis was performed using 5% national Medicare data from 01JAN2011-31DEC2015. Adult patients diagnosed with liver cancer were identified using International Classification of Diseases, 9th and 10th Revision, Clinical Modification (ICD-9-CM: ICD-10-CM) diagnosis codes (ICD-9-CM code 155; ICD-10-CM code C22). The diagnosis date was designated as the index date. A comparison cohort of patients without a liver cancer diagnosis was created for patients of the same age, gender, race, baseline individual comorbidities, and Charlson comorbidity index score. A random index date was chosen for the comparison cohort to reduce selection bias. Patients in both cohorts were required to have continuous medical and pharmacy benefits 12 months pre- and post-index date. Propensity score matching (PSM) was performed to compare follow-up HRU and costs between the cohorts, adjusting for demographic and clinical characteristics.

**RESULTS:** After applying PSM, a total of 270 patients were included in each cohort (liver cancer and comparator cohorts), and baseline characteristics were balanced. A higher proportion of patients diagnosed with liver cancer had higher inpatient (40.00% vs 8.15%; p<0.0001) emergency room (ER; 32.6% vs 12.59%; p<0.001), office (96.3% vs 77.41%; p<0.0001), outpatient (85.93% vs 53.33%; p<0.0001), and skilled nursing facility (SNF) (7.41% vs 1.11%; p=0.0003) utilization compared to patients in the comparator cohort. The liver cancer cohort also incurred significantly higher inpatient ($14,298 vs $2,279; p<0.0001), ER ($320 vs $104; p<0.0001), office ($8,585 vs $1,523; p<0.0001), outpatient ($21,039 vs $3,158; p<0.0001), SNF ($1,381 vs $193; p<0.0001), Part D pharmacy ($4,794 vs $9,549; p<0.0001), and total ($53,828 vs $9,549; p<0.0001) costs.

**CONCLUSIONS:** Liver cancer patients incurred higher HRU and costs than those without liver cancer.

**PCN297: A RETROSPECTIVE DATABASE ANALYSIS OF TREATMENT PATHWAYS AND ESTIMATED COSTS OF TREATMENT IN METASTATIC COLORECTAL CARCINOMA (MCRC) IN GERMANY**

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**OBJECTIVES:** Long-term real-world resource utilization and cost data of MCRC patients eligible for targeted therapies are still scarce. Therefore, more information on treatment cost in current treatment pathways is required to allow informed decision making regarding targeted therapies.

**METHODS:** Treatment data for patients with MCRC were extracted from the IMS® Oncology Analyzer (OA) database. Based on this, cost for MCRC therapies of currently treated patients were assessed from the perspective of the German Statutory Health Insurance (SHI), using a micro-costing approach.

**RESULTS:** Treatment pathways from 314 patients who had at least two documented lines of therapy were evaluated. 90% of these patients had been tested for RAS status. RAS testing rates for patients with only one documented line of therapy decreased over time from 71% (2014) to 50% (2016). Data show that RAS wildtype (RAS-WT) patients predominantly received Anti-EGFR treatment whereas RAS mutant (RAS-MT) patients mainly received bevacizumab-based therapy. After 1st line therapy, 82% of RAS-WT patients and 20% of RAS-MT patients switched from one targeted therapy to another in 2nd line therapy. For cost analysis data from 1,343 patients with at least one line of treatment was used. Total mean treatment cost for currently treated patients with RAS-WT (€ 19,733) was 10% higher than for RAS-MT patients (€ 18,003). Compared to a similar analysis in 2014, the difference
in treatment cost between RAS-WT and RAS-MT patients have decreased by more than 5%. CONCLUSIONS: Knowledge of RAS status of mCRC patients affects treatment decisions and allows additional treatment options for RAS-WT patient that are only available for patients who had been tested. Differences in treatment cost for RAS-WT and RAS-MT patients have decreased between 2014 and 2016. The decrease in the RAS testing rate needs to be assessed further to allow best possible treatment for mCRC patients.

PCN298: DISEASE BURDEN DURING THE “WATCHFUL WAITING” PERIOD IN WOMEN WITH RECURRENT OVARIAN CANCER IN GERMANY

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OBJECTIVES: In Europe, use of maintenance therapy is approved to extend the interval between chemotherapy treatments. Still, a substantial number of women with recurrent ovarian cancer are only provided monitoring for signs of recurrence or “watchful waiting”. While studies have shown that patients experience anxiety and fear of recurrence during watchful waiting, use of healthcare services during watchful waiting has not been examined. This study assesses the rate of these events in Germany using sickness fund data. METHODS: This retrospective study identified patients newly diagnosed with ovarian cancer between January 2010 and December 2012 in a German statutory healthcare fund (BKK) that included full billing information for hospitals, ambulatory sector, and pharmaceuticals. Patients with insurance coverage for 12 months before and ≥1 quarter after first diagnosis were included. Recurrence was defined by the presence of 2nd-line platinum-based therapy, and watchful waiting as the period without active treatment following chemotherapy. The rates of inpatient admissions and outpatient visits during watchful waiting were assessed. RESULTS: During the study period, 325 patients were identified as having recurrent OC and were treated with a 2nd-line therapy. There were 147 patients who received platinum-based therapy, and of these, 117 had a watchful waiting period after their 2nd-line platinum treatment. During watchful waiting, 39.3% had an inpatient admission, with 92 inpatient hospitalizations reported (average=0.8 per patient). Furthermore, 93.2% and 24.8% had outpatient visits in either an office-based or hospital outpatient setting, respectively. CONCLUSIONS: A significant proportion of 2nd-line recurrent OC patients were hospitalized during the watchful waiting period post platinum treatment. These findings suggest a substantial ongoing disease burden during watchful waiting.

PCN299: COSTS AND LIFE EXPECTANCY INCREASED AMONG PATIENTS WITH BREAST CANCER ACROSS TWO TIME PERIODS

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OBJECTIVES: The expenditure of National Health Insurance (NHI) on cancer treatment has been growing significantly. However, doubts have been raised about whether the cancer treatments demonstrate ‘value for money’. This study aims to compare life years gained and medical costs between patients diagnosed with breast cancer in different periods, and to estimate the incremental cost per life year gained. METHODS: Patients diagnosed with breast cancer during 2002-2009 and 2010-2013, were identified from Taiwan Cancer Registry, respectively. First, Cox proportional regression adjusted survival curve was assessed with death events identified from the Death Registry. Second, breast cancer related inpatient and outpatient claims for 5 years from initial diagnosis were retrieved from the NHI claims database and expenditures per year survived were calculated using generalized linear models by application of the Kaplan-Meier sample average (KMSA) method. Finally, medical costs and life expectancy for the two patient cohorts were compared. Two-sided 95%-confidence intervals were constructed using 1000 non-parametric bootstrap replications. RESULTS: Cumulative survival for patients with breast cancer in 2002-2009 and 2010-2013 was 4 and 4.144 years as following through 5 years. The medical expenditure per case was NT$409,338 and NT$650,189 for 2002-2009 and 20010-2013 patient cohort, respectively. Average life expectancy rose by 0.144 years, and medical costs increased by NT$74,387-240,851. Overall, costs per life-year gained was estimated to be NT$0.52-1.67 million. CONCLUSIONS: The cost of treating patients with breast cancer has risen considerably, yet the survival has improved simultaneously. Results of this study highlight the importance of considering outcomes and overall costs when assessing the value of new cancer drug treatment.

PCN300: GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF): POTENTIAL FINANCIAL SAVINGS FOR GERMAN HOSPITALS

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OBJECTIVES: Introduction: Granulocyte-colony stimulating factor (G-CSF), is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells. G-CSF accelerates recovery and reduces mortality from neutropenia
after chemotherapy and in patients or Healthy donors for autologous or allogeneic stem cell transplantation. On order to mimic physiological G-CSF release, filgrastim and lenograstim can be applied daily. However, significantly more expensive G-CSF products like pegfilgrastim and lipefilgrastim are used once per cycle of chemotherapy. Guidelines regard all G-CSF products as interchangeable. In Germany G-CSF have got hospital billing codes and fixed reimbursement. These allow insights on inpatient use, including underlying indication. METHODS: Reports from German DRG-Institute (InEK), Statistical Office (DESTATIS) and hospital quality reports for 2008-2015 were analyzed for use of G-CSF. Statistical analysis was performed using Microsoft-Excel and Access version 2016. RESULTS: Documented G-CSF use increased from 22,156 cases in 2008 to 45,942 in 2015 (+107%). Share of daily-G-CSF decreased from 67.6% in 2008 to 33.7% in 2015. Total reimbursement for G-CSF was around €20,724,000 in 2015, share of qd-G-CSF was 12.6%. Reimbursement decreased by 79% for filgrastim to 27% for pegfilgrastim (2008 to 2015). Saving-potential by use of qd-G-CSF is minimum €12m. Low doses of qd-G-CSF are not reimbursed. 1,987 departments in 798 hospitals used G-CSF in 2015. Most hospitals used mainly one G-CSF for all indications. Lenograstim is leading product in stem cell transplantations (46% of use) and most preferred in severe infections. Pegfilgrastim is mainly used in solid tumor chemotherapy (50% of use). CONCLUSIONS: In German hospital the use of G-CSF has more than doubled from 2008 to 2015. Hospitals often use one G-CSF for all indications. Preferred use of filgrastim and lenograstim would result in major savings. Lenograstim is favored in critical situations like stem cell transplant and severe infections. Pegfilgrastim is preferred in solid tumors.

**PCN301: SUBCUTANEOUS DRUGS IN ONCOLOGY: MAKE A DIFFERENCE IN THE TREATMENT? SYSTEMATIC REVIEW FROM DIFFERENT ANALYTICAL PERSPECTIVES**

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**OBJECTIVES:** Compare time and economic benefits of the biotechnological subcutaneous (SC) drugs versus intravenous (IV) drugs in oncology. METHODS: A search of systematic reviews of economic literature, observational and economic studies, official or public policy documents of drug regulatory agencies of reference for Colombia, and INAHTA’s Health Technology Agencies, was carried out. The population was adults who required an IV treatment in room, also available as SC formulation. The databases Medline, Embase, Ecomint and HTA were consulted. The quality of the evidence was evaluated with QHES and AMSTAR. Measures of central tendency and qualitative analysis were used in the final analysis. The third payer, insurer, provider and patient perspectives were considered. RESULTS: 33 articles were included. With SC formulation, the average preparation time in pharmacy was less than with IV (19,1 [12,5] vs. 39,45 [SD 0,845] hours), as well as the median time of administration (3,4 [IQR 3-3,5] vs. 25 [IQR 15,69-60] minutes); the saving time in infusion chair was 55,2 minutes (IQR 46,25-92,9) and the time of visit per session was 55,1 minutes (IQR 40,25-174,75). The time spent by health professionals decreased 18,6 minutes (IQR 8,25-38). The 81,75% of patients preferred SC administration. The estimated median savings in the course of the overall treatment of a patient was €1.121 (IQR €611-€4.605) and payers reported €2.919.796 (IQR €531.781-€14.175.000) in savings in the budget. CONCLUSIONS: The SC administration of biotechnological drugs in Oncology is an efficient choice for the use of resources in health, providing a better quality of life to the patients, without affecting the safety and effectiveness of the treatments. Also is preferred by patients, reduces the direct and indirect costs, optimizes the productivity of professionals in health and allows a greater availability of infusion rooms. A holistic view of the health technologies from different perspectives is important for evidence-based decision-making in health.

**PCN302: DETERMINING THE COMPARATIVE VALUE OF OUTCOME-BASED MONEY-BACK GUARANTEE SCENARIOS IN NON-SMALL CELL LUNG CANCER USING REAL-WORLD DATA**

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**OBJECTIVES:** At the time a reimbursement decision is made, the value of a drug is often uncertain. Several types of policies have been designed to mitigate this uncertainty by sharing the financial risk between payer and sponsor. For instance, a money-back guarantee, where the payer is refunded if patients do not achieve specified clinical targets. This study aimed to evaluate the costs and benefits of alternative money-back guarantee scenarios for various non-small cell lung cancer (NSCLC) therapies based on real-world data. METHODS: Retrospectively collected data of Dutch patients diagnosed with NSCLC was used. Current patterns of drug utilization and clinical outcomes were used to perform “what if” analyses, evaluating the total costs and benefits likely associated with two different money-back guarantee scenarios. The first scenario reduced the payer’s drug costs to zero for patients whose RECIST response was never more favorable than progressive disease. In the second scenario, the real-world median overall survival (OS) was compared to the median OS from a pivotal trial. If the former was lower than the latter, the drug costs were
reduced proportionally. Analyses were done for gemcitabine/cisplatin, pemetrexed/cisplatin, and vinorelbine/cisplatin treatment for non-metastatic (M0) and erlotinib, gemcitabine/cisplatin, and pemetrexed/platinum (carboplatin or cisplatin) for metastatic (M+) NSCLC. RESULTS: Given the proportion of patients with no better response than progressive disease on gemcitabine/cisplatin (M0) (4.3%), pemetrexed/cisplatin (M0) (8.6%), erlotinib (M+) (36.2%), gemcitabine/cisplatin (M+) (14.3%), and pemetrexed/platinum (M+) (18.8), scenario 1 reduced the payer's drug costs by mean €131.40 (17%), €587.82 (9.5%), €2,833.91 (31.9%), €496.18 (12.4%), and €2,699.11 (20%) per patient, respectively. Given that real-world median OS was lower than the trial OS in the case of gemcitabine/cisplatin (M+), proportional cost reduction yielded €184.15 (6.1%) lower drug costs per patient. CONCLUSIONS: Money-back guarantee can mitigate uncertainty around the value of drugs, but the design of such guarantees substantially affects the outcomes.

PCN303: ECONOMIC ANALYSIS AND EVALUATION OF THE VALUE OF THE PARALLEL EXPORT OF MEDICINAL PRODUCTS FOR TREATMENT OF ONCOLOGICAL DISEASES IN BULGARIA, 2016 T. VEKOV 1 AND G. KOLEV2

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OBJECTIVES: The aim of the research is to analyze and assess the parallel export of medicines with annual sales of >3 million BGN for treatment of oncolgical diseases from Bulgaria in the year 2016. Risk assessment for the shortage of life-saving medicinal products. METHODS:A documentary method and analysis was used to compare the quantity and value of oncological medicinal products sold to distributors in Bulgaria in 2016 and paid by the National Health Insurance Fund (NHIF), reported by two independent sources - IMS Health (IMS) and National Health Insurance Fund (NHF). The study included products with annual sales of >3 million BGN. RESULTS: The economic analysis carried out estimated the value of the parallel export of medicinal products for treatment of cancer from Bulgaria in 2016 at 43.2 million BGN. Products of 5 pharmaceutical manufacturers account for 87.2% of the value of the parallel export: Roche (52.8%) - bevacizumab, trastuzumab, rituximab, erlotinib, pertuzumab, vemurafenib; BMS (14.3%) - dasatinib; Bayer (9.2%) - sorafenib, Novartis (6.2%) - everolimus, nilotinib, pazopanib; Astellas (4.7%) - enzalutamide. CONCLUSIONS: Conclusions: This study does not reveal any evidence of either medical product shortage nor limited access to treatment for patients due to lack of access to drug therapy in Bulgaria.

PCN304: DO COUNTRIES WITH SIMILAR GDPS AND HEALTH EXPENDITURES REIMBURSE THE SAME CANCER DRUGS?

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OBJECTIVES: Patients clinically eligible for oncology therapies, as defined by regulatory labels, may be unable to access them because of reimbursement decisions. This study analyzed whether gross domestic product (GDP) per capita (GDPPC) and health expenditure explain the access restrictions imposed in various markets. METHODS: Therapies approved for breast, kidney, lung, and prostate cancer, multiple myeloma, and melanoma in Australia, Belgium, Canada, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, and the UK were identified (2006–2016). For each indication, reimbursement decisions by national agencies were identified and classified according to the level of access restriction on clinically eligible population (none, partial, or full). GDPPC and health expenditure as a proportion of GDP were identified from published sources; mean values over the study period were calculated and related to the restrictions. RESULTS: Reimbursement agencies often do not explain the reasons for restrictions, suggesting a lack of transparency in decision-making. Across 65 cancer drug/indication combinations covering 892 reimbursement decisions by individual agencies, countries with a similar GDPPC such as Australia, Canada, and Germany showed variable rates of full restriction (0–31% of licensed indications). Poland and Portugal, with lower GDPPC, restricted 69% and 60%, respectively; however Spain, with a similarly low GDPPC, applied less restrictions at the national level. Furthermore, Poland, Australia, Italy, and the UK, with <5% mean health expenditure as a proportion of GDP, restricted access in a high percentage of indications while Germany, France, and the Netherlands, with ≥10% mean health expenditure, imposed far fewer restrictions. CONCLUSIONS: Access to cancer therapies varies between countries with similar GDP; healthcare expenditure as a proportion of GDP was moderately predictive of all reimbursement restrictions. The findings suggest unwarranted limitations and inequitable access to cancer treatment among countries with similar living standards, and potential inefficiencies in the organization of healthcare.

PCN305: ACCESS PERCEPTIONS: A KEY DRIVER OF NON-SMALL CELL LUNG CANCER (NSCLC) TARGETED THERAPY PRESCRIPTION IN RUSSIA

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OBJECTIVES: Literature on restrictions on access to innovative oncology treatments in Russia is limited. This research aims to assess the restrictions placed on targeted NSCLC therapies and the related impact on prescribing. METHODS: Data were drawn from the Adelphi Disease Specific Programme (DSP) in NSCLC conducted in Q1 2017. Medical oncologists, actively managing patients with NSCLC, completed a workload questionnaire, survey and patient record forms (PRFs) for up to the next 10 of their consulting NSCLC patients. In addition to clinical considerations, participating oncologists were asked their perceptions of the level of administrative controls for targeted treatments. RESULTS: 53 physicians provided perceptions of access restrictions and completed 329 PRFs. Within the epidermal growth factor receptor (EGFR) class, gefitinib was considered available according to approved indication without further restriction by 59% of physicians, decreasing to 54% for erlotinib and 11% for afatinib. 37% considered gefitinib available, but with restrictions beyond the approved indication, increasing to 39% for erlotinib and 48% for afatinib. Levels of prescribing followed perceived access with 31 of 329 patients currently receiving gefitinib, 9 erlotinib and 2 afatinib. Ease of reimbursed access was considered an important criterion of product choice (mean score of 5.8, on scale of 1-7 with 7 being very important); >50% physicians included this in their top 5 considerations in first-line treatment selection with just under half reporting the same in later-line settings. CONCLUSIONS: A correlation between prescribing levels and perceived access was observed within the EGFR class in Russia; this finding is consistent with the reported importance of reimbursed access in product selection. Reasons for perceived differences in access were not explored; the extent to which they relate to administrative controls, time since launch, familiarity or other factors should be explored to understand factors affecting patients’ access to innovative oncology products.

PCN306: THE IMPACT OF THE STUDY DESIGN SUBMITTED FOR THE EARLY BENEFIT ASSESSMENT ON THE PRICING FOR ONCOLOGIC DRUGS

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OBJECTIVES: Aim of this study was to analyse if the design of the clinical studies influences the price negotiations according to the German AMNOG law between the pharmaceutical companies and the National Association of Statutory Health Insurance Funds. The analysis was conducted for all Oncologic drugs that underwent the early benefit assessment since its introduction in 2011 and had negotiated prices up to September 2016. METHODS: It was differentiated between additive (new therapy in addition to baseline therapy) and substitutive study designs (baseline therapy is replaced through new therapy) with an added or no added benefit. The study design was analysed with the dossiers of the pharmaceutical companies submitted to the Federal Joint Committee. Subgroup specific costs were calculated as annual therapy costs with the German price databank (Lauertaxe) and compared with the costs of the comparative drugs to quantify price premiums (multiplicative and additive premiums). Further price influencing factors were analysed in univariate and multivariate regression analysis and the budget impact for the statutory health insurance was considered. RESULTS: For additive and substitutive study designs with an added benefit a premium was negotiated on the annual therapeutic costs of the comparative drug. The median and the mean of the premium of substitutive designs was higher than for additive designs, if the comparative therapy was different to best supportive care. The multiplicative premium for the substitutive design was 15.07 vs. 2.29 for the additive design. EU-Prices and the population size had a significant effect on the reimbursement price. CONCLUSIONS: The mean reimbursement prices are higher for substitutive designs than for additive designs. Since the number of cases was small for some categories (e.g. additive design and no additional benefit), further analyses should be performed, when more oncologic drugs passed the AMNOG.

PCN307: THE DIFFERENCE BETWEEN REGULATORY AND MARKET ACCESS DECISIONS ON TREATMENT AVAILABILITY FOR NEW DRUGS IN SIX COMMON CANCERS ACROSS AUSTRALIA, CANADA, AND EUROPE

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OBJECTIVES: Patient access to cancer therapies can be limited due to restrictions set by national or regional health technology assessment (HTA) and/or pricing and reimbursement (P&R decision makers). This research explores variation from regulatory to P&R decisions impacting clinically eligible patients’ ability to receive appropriate pharmacotherapies. METHODS: HTA and P&R assessments from Australia, Belgium, Canada, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, and the UK were obtained for oncology drugs approved in six cancers (breast, kidney, lung, multiple myeloma, melanoma, and prostate) by the European Medicines Association, Therapeutic Goods Association and Health Canada during 2006–2016. From published HTA documents, indications were classified according to the level of restriction between the regulatory label population,
and those eligible for reimbursed access. The number of impacted patients was estimated from published epidemiology and budget impact data; potential survival gains from the pharmacotherapy were applied to estimate the impact of (disability) life years lost. RESULTS: Of the 65 drug/indication combinations identified, in 50% no market access restrictions were imposed beyond the regulatory label; 22% of HTA decisions were not yet published, and 13% resulted in restriction to all clinically eligible patients across all countries; Poland, Scotland and Australia had the highest percentage of restrictions to licensed indications. A further 15% of HTA assessments limited access to a subgroup of the licensed population. Reasons for these limitations were infrequently reported across countries but when cited focused on price /budget impact and challenges around efficacy. CONCLUSIONS: Discrepancies between regulatory and reimbursement decisions in Australia, Canada and Europe can impact health outcomes of cancer patients who are clinically eligible for treatment. There is variability in the factors that drive HTA/P&R decision making at the national level, and often the reasons for discrepancies between regulatory and HTA decisions are not transparent.

**PCN308: SYSTEMATIC LITERATURE REVIEW ON MULTI-INDICATION PRICING MODELS IN ONCOLOGICAL DRUGS**

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OBJECTIVES: Drugs approved for multiple indications already represent more than 50% of the major oncological drugs in 2014 and are estimated to become 75% by 2020. A different clinical efficacy could be observed by indication and by patient subpopulation. However, the current pricing systems assign a unique price independent of the indication, therefore price and clinical value do not necessarily align. The objective is to investigate the public information about pricing model agreements, and pros/cons for payors and laboratories. METHODS: A systematic literature review, both in academic and gray sources without country restriction, identifies published models of indication-specific pricing (ISP), their pros/cons for payors and laboratories and their possible implementation in Spain. RESULTS: We found three ways of reflecting indication-specific value in prices: (1) a blended price depending on the value and the number of patients in each indication; (2) a price depending on the indication, through different discount or different price; (3) different brands for the same molecule. These have been used in Italy, Switzerland, Austria and the UK. Italy is the country with the highest number of ISP examples, which could be leveraged for its implementation in other countries. The main obstacle is to monitor that the drug is used in the indication it is paid for. CONCLUSIONS: Indication-specific pricing is a novel tool in many countries, though Italy already implemented it quite widely. More drugs have multiple indications, so aligning price and value will become more compelling in the next future. We show that their implementation is feasible and no major hurdle impedes it in Spain.

**PCN309: MANAGED ENTRY AGREEMENTS (MEA): ANALYSIS OF THE CURRENT SITUATION IN MIDDLE EAST AND NORTH AFRICA**

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OBJECTIVES: Managed Entry Agreements (MEA) are increasingly implemented in European countries and other developed markets. Aim of this study is to understand the types of market access initiatives implemented to ease budgetary hurdles and enable access to patients in Middle East and North Africa. METHODS: Data collected through primary and secondary market research (Sep–Nov/16) from local pharma industry experts in regulatory and market access, clinical pharmacists and physicians involved in formulary enlistment decisions and market access initiatives implemented by pharmaceutical companies. The project scope was limited to identify initiatives implemented for innovative and mostly biologic drugs in oncology, hematology and other specialty care therapy areas. RESULTS: Identified 63 cases in 9 countries and categorized them under two main buckets: 1) enable access initiatives that target registration, pricing and reimbursement barriers, and 2) create demand initiatives that aim to drive uptake of drugs upon launch and address issues around awareness, affordability and adherence. 46 of the 63 cases are under create demand with an emphasis on awareness and accessibility across all countries due to limited diagnosis and treatment capability. Initiatives targeting pricing and affordability are mostly identified in countries which have relatively limited government funding or public healthcare coverage. UAE, Egypt, Saudi Arabia and Algeria, respectively are the most active countries in terms of market access initiatives in the region. CONCLUSIONS: Even though access is the main barrier for innovative products, still very limited number of Managed Entry Agreements have been implemented in the region. Majority of the market access initiatives include projects to increase capacity and infrastructure in health care system or simple price discounts, rather than value based partnerships to improve access to innovative treatments in the region.

**PCN310: BARRIERS TO EFFECTIVE TREATMENT OF PATIENTS WITH CLL IN POLAND IN COMPARISON TO THE UNITED KINGDOM**
**PCN312: VARIATION IN HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT DECISIONS IN ENGLAND, FRANCE, AND GERMANY: SPOTLIGHT ON THE IMPACT OF UNCERTAINTY**


**OBJECTIVES:** European health technology assessment (HTA) bodies vary with regards to methodology, willingness to accept uncertainty, and preferences for different types of evidence. Previous studies have revealed substantial differences in the focus of European HTA processes and final decisions on recommendation. We therefore set out to explore how exactly the variation in decision drivers results in discrepancies in recommendations between the payer archetypes. **METHODS:** A critical review of HTA reports from NICE (England), HAS (France), and IQWiG (Germany) was conducted. These agencies were selected because they represent different payer archetypes, have large associated markets, and are relatively transparent in reporting. Qualitative semi-structured interviews were conducted. Cabazitaxel and pixantrone were selected as case studies due to the mixture of recommendations and rejections received for these products in the target countries. The review investigated the key evidence considered and the agencies’ responses to the evidence, particularly with regards to accounting for uncertainty. **RESULTS:** Cabazitaxel was approved for prostatic neoplasms by HAS and IQWiG, yet rejected by NICE on the grounds of a high ICER (~£90,000/QALY). On the other hand, pixantrone received restricted approval for non-Hodgkin’s lymphoma by NICE and HAS, despite uncertainties created by a small trial population and post hoc sub-group analyses, while IQWiG found no added benefit. The inconsistency in decision-making in European HTA processes is therefore likely to relate, in part, to the relative emphasis placed on different aspects of the clinical and economic evidence, and the willingness of agencies to accept associated uncertainty. **CONCLUSIONS:** While understanding the international HTA processes is important, establishing the key drivers for previous decisions across agencies could be an efficient way to achieve approval and access. This is best achieved through a combination of expert elicitation and a critical review of previous HTA decisions.

**PCN313: CHARACTERISTICS OF THE DIETARY HABITS OF CANCER PATIENTS AND STRUCTURE OF CONSUMPTION OF BASIC FOOD PRODUCTS**


**OBJECTIVES:** study of the feeding habits of cancer patients in comparison with current norms of consumption of products. **METHODS:** We carried out a comparative analysis of actual nutrition of surveyed patients with the recommended norms of food consumption, which were used in Kazakh Research Institute of Oncology and Radiology. Also we calculated the value of nutrients in a variety of diets in percentage of the average recommended by FAO/WHO values and WHO recommended lower limit of value. **RESULTS:** The results of the study showed that the energy value of the ration of actual nutrition of the patients with oncolgical hospitals was below 200 kcal in
comparison with the norms of content of nutrients. The total consumption of proteins, carbohydrates was lower also. Slightly exceeded the fat consumption and percentage of fat calorie of 33.8%. Carbohydrate calories provided to 52.0%, which is also sufficient. The percentage of carbohydrate in the diet was increased in 2 times. From micronutrients in the diet of patients was revealed lack of calcium, phosphorus, and also expressed a lack of iodine, zinc, selenium, folic acid, vitamin A, vitamin E, thiamine, Niacin. Of the required amount of 40.8 g, dietary fiber patients received a total of 8.8 grams. The value of protein in the actual nutrition of patients conforms to the standards but significantly exceeded the recommended value of FAO/WHO.

CONCLUSIONS: Thus, in the actual nutrition of patients in the Oncology hospitals the energy value of the ration of dietary intake, intake of total proteins, fats, carbohydrates was low than the approved standard. Especially pronounced was the lack of dietary fiber, micronutrients. In the hospitals of Kazakhstan it is necessary to apply the methods of correction of the protein component of the diet using a composite of mixtures with a high biological value and a set of essential nutrients.

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**PCN314: BRCA1/2-MUTATED BREAST CANCER IN SELECT EU MARKETS: INCIDENCE, TREATABLE POPULATIONS, AND POTENTIAL MARKET SIZE FOR PARP INHIBITORS**

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**OBJECTIVES:** The germline BRCA1/2-mutation-positive population in breast cancer has long been identified, but is not well characterized in epidemiological research. PARP inhibitors are a class of drugs in development for germline BRCA1/2-mutation-positive breast cancer. This study sought to provide germline BRCA1/2-mutation-positive breast cancer epidemiology to facilitate the generation of a market forecast for PARP inhibitors across 15 European countries. METHODS: Using peer-reviewed sources, we determined the proportion of germline BRCA1/2-mutation-positive breast cancer cases by molecular subtype. We then applied this proportion to the Decision Resources Group (DRG) breast cancer incident cases and metastatic drug-treatable populations by subtype, across the countries under study. We used interviews with breast cancer experts and secondary market research to model patient progression between lines of metastatic treatment. We used database pricing sources to estimate the cost of PARP inhibitor treatment. RESULTS: We estimate that 4% of newly diagnosed breast cancer cases are BRCA-mutation-positive, with the greatest prevalence of this mutation (14%) occurring among triple-negative (HR-\(^{1}/\)HER2-) patients in the 15 European countries under study. The triple-negative subtype accounts for 50% of first-line metastatic patients with BRCA mutations. Our findings indicate that over 3,900 BRCA1/2-mutated breast cancer patients will be diagnosed and eligible for treatment across the 15 markets under study in 2017. If PARP inhibitors effectively penetrate adjuvant and metastatic treatment settings, sales of these agents could exceed US$ 400 million across the 15 countries considered in 2027. CONCLUSIONS: Triple-negative patients account for the majority of diagnosed stage I-III (44%) and metastatic (50%) BRCA1/2-mutation-positive breast cancer cases. Lower numbers of BRCA1/2-mutated breast cancers can be found in the remaining three subtypes, however the total size of this population holds the potential to support healthy market sales.

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**PCN315: IMPACT OF TIME TO REIMBURSEMENT OF DRUG TREATMENTS FOR NON-SMALL CELL LUNG ON PATIENT OUTCOMES IN EUROPE AND LATIN AMERICA**

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**OBJECTIVES:** This study investigated the impact of time to reimbursement of drug treatments for non-small cell lung cancer (NSCLC) on life-years (LYs) and quality-adjusted life-years (QALYs) in patients in Europe and Latin America (LatAm). METHODS: The time delay for marketing authorization and reimbursement was estimated by comparing the time between US FDA approval for a market basket of NSCLC products (nivolumab, pembrolizumab, crizotinib, ceritinib, gefitinib, erlotinib, and afatinib) and the dates of marketing authorization and reimbursement by public payers in five European (EU5: United Kingdom, France, Germany, Spain, Italy) and four LatAm (Mexico, Colombia, Argentina, Brazil) countries. A cost-utility model consisting of three health states (progression-free survival (PFS), progressive disease, death) was used to estimate LYs and QALYs for each product and existing standard of care (SoC). Transition probabilities were estimated from median PFS and overall survival (OS) data from products' respective FDA labels. NSCLC incidence rates and health state utilities were sourced from health technology assessment reports. Population-level LYs and QALYs were calculated by multiplying country-level NSCLC incidence by the estimated per-patient LYs and QALYs lost due to lack of reimbursement of each product in each geography. RESULTS: The median time to access in the EU5 for the NSCLC market basket was 278 days; no product was reimbursed in LatAm according to publicly available sources. The product associated with the largest amount of LYs and QALYs lost was nivolumab (1,806 and 901, respectively), due to lack of reimbursement in the UK and LatAM. Despite LatAm having fewer total NSCLC patients than the EU5 (~25k vs. ~40k), population-level LYs and QALYs lost were greater (LYs: 2,425 vs. 985; QALYs: 1,719 vs. 813). CONCLUSIONS: Slower access to
innovative medicines has a significant impact on population-level patient outcomes across the EU and LatAm, highlighting the need to accelerate access to novel therapies in NSCLC.

PCN316: EMERGING MARKETS TIERED PRICING: A QUANTITATIVE ASSESSMENT OF LOCAL AFFORDABILITY AND EXISTING PRICE TO PATIENT

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OBJECTIVES: Investigate the role of tiered pricing on patient access while considering the factors affecting pharmaceutical pricing in major emerging markets including but not limited to budget constraints, pharmaceutical distribution mark ups, capacity of Govt. to pay for medicines, patient affordability, role of NGOs, lack of trust in generics, wide spread availability of fake medicines, divergence of published list price and net effective selling price. METHODS: A demand model was constructed to evaluate the affordability of price to patient inclusive of mark-ups across 20 UMI & LMI markets by leveraging detailed income distributions across the markets to inform how far down the wealth pyramid recent launch products may be able to reach. A mix of industry stakeholders responded to the model and provided initial reactions to potential policy implications. RESULTS: Our research evaluated the principles of tiered pricing which are based on sound equity principles (Pricing using HDI- and GNI-based indexes). The model outputs determined that a significant proportion of patients cannot access modern innovations in many LMI markets and in payer driven markets negotiated pricing can fall out of equitable bands resulting in UMI markets paying less than LMI markets. CONCLUSIONS: Existing approaches for tiered pricing neglect to incorporate local funding and income distribution dynamics. Although the vaccines industry has been able to leverage NGOs to enhance patient access a gap continues to exist when it comes to pharmaceuticals. There is precedent in many cash pay markets for the role of local access programs to enable patient access to expand down the wealth pyramid. Tiered pricing was once seen as the answer for equitable access but a fresh look is required by manufactures if they are to live up to the ATMI goals and aspirations. On its own tier pricing is not enough to expand access to medicines down the wealth pyramid.

PCN317: ACUTE LYMPHOBLASTIC LEUKAEMIA’S BURDEN OF DISEASE IN PORTUGAL

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OBJECTIVES: Acute lymphoblastic leukaemia (ALL) is a haematological malignancy with a rapid progression, affecting both children and adults. Although rare, it is the most common leukaemia in childhood. The main objective of this study was to estimate the burden of disease impact of ALL measured by Disability Adjusted Life Years (DALY) in Portugal, for 2015. METHODS: DALY combines Years of Life Lost due to Disability (YLD) and Years of Life Lost (YLL) due to premature death. Deaths due to ALL were estimated based on lymphoblastic leukaemia (LL) mortality data from national statistics. The disability weights used to estimate YLD were based on the 2015 Global Burden of Disease (GBD 2015). Four disease states were considered: 1) diagnosis and primary therapy; 2) controlled disease; 3) relapsed/refractory disease; and 4) terminal phase. The incidence of states 1) and 4) was based on national registries and statistics for LL, and on international registries for ALL. The incidence of states 2) and 3) was estimated for children and adults separately through partitioned survival models based on clinical trials in ALL patients. State 1) was assumed to last 2 years (experts’ opinion), and other states durations were based on GBD 2015. RESULTS: In 2015, 130 new ALL cases and 58 ALL deaths were estimated to have occurred in Portugal. The total disease burden attributable to ALL was estimated at 1,039 DALY, with 89% due to YLL and the remaining due to YLD. Per average ALL patient, a burden of 1.78 DALY was estimated. Children and adults share YLD equally, but 69% of YLL took place in adults. CONCLUSIONS: ALL is an important cause of disease burden, both in children and adults, with a higher impact on YLL in Portuguese adults. ALL is therefore an important target for health policy interventions due to its burden by average patient.

PCN318: REVIEW OF REAL-WORLD EVIDENCE TO ASSESS THE BURDEN OF ILLNESS OF MANTLE CELL LYMPHOMA

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OBJECTIVES: Mantle cell lymphoma (MCL), a rare and aggressive disease, accounts for approximately 5% of all B-cell non-Hodgkin’s lymphomas. This review aimed to synthesize the global burden of disease for MCL, which is generally considered to be incurable, by characterizing its epidemiology, natural history, economic, societal, and humanistic burden using real-world evidence (RWE). METHODS: Searches were run in EMBASE, Medline,
RELEVANCE OF REAL WORLD DATA IN GERMAN AMNOG SUBMISSIONS IN ONCOLOGY

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OBJECTIVES: Real World Evidence (RWE) in AMNOG assessments potentially could address various data needs during the process and also thereafter as epidemiology might be limited in oncology. Areas of RWE use are evidence generation for epidemiology (e.g. incidence, prevalence, unmet need) but also the demonstration of effectiveness in daily life settings later on. Aim was to assess how RWE is currently integrated in AMNOG submissions in oncology.

METHODS: German AMNOG dossiers submitted until March 2017 were screened and evaluated if they relate to any oncology field and implemented RWE evidence on incidence or prevalence. Findings were then analyzed and stratified by indication and the applied data sources were described. RESULTS: Out of n=273 submitted AMNOG dossiers until March 2017, n=95 (35%) were submitted in oncology comprising of 168 subpopulations. Per definition, more than one subpopulation is included if the drug is launched in ≥1 target application. The most prevalent indication was NSCLC with n=37 subpopulations, followed by chronic lymphatic leukemia (n=23), and melanoma (n=19). RWE for prevalence/incidence assessments was used in n=161 subpopulations, 3 dossiers were not available, and the remaining 4 subpopulations did not include RWE. Use of claims data was reported in n=12 (7.5%) populations, n=159 (98.8%) used registry data, and n=22 (13.7%) used other data sources such as IMS data, Delphi panels, Kantar Health data, Insight Health data, and Megapharm data. CONCLUSIONS: RWE is commonly used in AMNOG dossiers in oncology forming an integral part of the epidemiology section of the available evidence package. Registry data today is the data source that is applied predominantly. With a rising trend, claims data becomes an important data source adding evidence on epidemiology...
OBJECTIVES: Chronic diseases often require multiple lines of treatment. Inappropriate selection or modelling of subsequent treatments can complicate submissions or result in sub-optimal decisions. Accurate modelling of subsequent treatment is particularly important when a clinical trial used in cost-effectiveness analysis deviates from clinical practice. We investigated the implementation of, and reaction to modelling of, subsequent treatments. We focussed on two particularly crowded disease areas where multiple NICE technology appraisals have been conducted: multiple myeloma (MM) and renal cell carcinoma (RCC). METHODS: The NICE website was searched to identify both manufacturer submissions and the associated evidence review group (ERG)/final appraisal documents published from January 2015 to May 2017 in MM and RCC. If subsequent treatments were included in the model, the following information was extracted: approach, data source (trial versus clinical practice), adjustments made to costs and effects due to subsequent treatments, ERG critique and committee recommendations. RESULTS: Six out of eight submissions reviewed have modelled subsequent treatments. Three submissions each included subsequent therapies using market share data from trials and from clinical practice. In base case analysis, five submissions included impact on costs, and only two included impact on utilities. None of the submissions adjusted the effectiveness observed in the trial (particularly overall survival) for use of subsequent treatments. The ERG and committee regularly criticised the modelling approach for not reflecting clinical practice (three submissions) or biased overall survival estimates (four submissions). CONCLUSIONS: The choice of subsequent treatments should reflect clinical practice. Impact on both costs and effects should also be considered. Where the trial does not reflect clinical practice, methods similar to those used for crossover adjustment could be applied and/or published literature could be used to supplement trial data. The effect of exclusion of subsequent treatments should be explored in scenario analysis to determine model sensitivity.

OBJECTIVES: Since 2013, the CEESP evaluates the efficiency dossier of innovative and high-budget-impact health products and publishes their opinion on the methodological compliance with their guidelines. The objective of this study is to review the published opinions in the indication of advanced melanoma and to synthesize the deviations. METHODS: All publically available CEESP decisions were collected from the HAS website as per June 2017. The deviations were classified in categories and quantified. In-depth qualitative analysis was conducted in order to highlight major causes of deviation. The options to consider for dossier related to the advanced melanoma were also tracked. RESULTS: Three published opinions were identified, for one targeted therapy (trametinib) and two immunotherapies (nivolumab, pembrolizumab). The BRAF mutation and line of treatment are key points to define the population and the relevant comparators. The number of deviations ranged from 11 to 18 (minor: 8 to 15; important: 2 to 4; major: 0 to 1). The highest number of deviations were related for all three opinions to modelling. The weakness of indirect comparison is crucial and is a major influential factor of efficiency results. It is due to short follow-ups of the clinical trials and efficacy of the drugs inducing that the median overall survivals are not always reached. Since the publication of the opinions, clinical data with longer follow-ups were made available and could be used to reduce the uncertainty. Sophisticated statistical methods were implemented in the indirect comparison that are not presented in the related HAS guidelines. CONCLUSIONS: The low number of trials and the short follow-up period of the available clinical trials contributed to a weak clinical evidence and induced important and major deviations. The opinions illustrate the uncertainty induced by a submission of efficiency dossier with early clinical results from a CEESP point of view.

OBJECTIVES: Modern immuno-oncology agents have generated great excitement due to the potential to provide
durable survival for some patients, however there is concern regarding the cost of cancer care, and multiple frameworks have been developed to assess value. The American Society of Clinical Oncology (ASCO) framework awards bonus points if substantial durable survival is demonstrated. The objective of this study was to assess if modern immuno-oncology agents reach defined efficacy thresholds in such value frameworks.

**METHODS:** We reviewed all FDA approvals for immuno-oncology agents between 2011-2017. We collected data required for the ASCO framework, specifically: improvement in proportion of patients alive with the test regimen, and survival rate with standard. We assessed whether bonus points would be awarded for durable survival based on the ASCO criteria. **RESULTS:** 19 metastatic indicators for five immuno-oncology agents were approved by FDA in 2011-2017: ipilimumab, pembrolizumab, nivolumab, atezolizumab, avelumab and durvalumab. 47% of the approvals are based on survival endpoints while 53% are based on response rates. No drug was found to fulfill the threshold defined for the survival rate of standard care. Seven drugs achieved the required level of improvement in proportion of patients alive in the test regimen compared to the standard (above 50%). As there was no overlap between these two groups of drugs, no drug was found to gain the durable survival bonus points defined by the ASCO framework. **CONCLUSIONS:** Durable survival and responses of modern immuno-oncology agents are currently not recognized to be significant by current oncology value frameworks. This may be due to insufficient demonstration of efficacy of such agents, or may be due to inappropriately calibrated value frameworks.

**PCN324: A COMPARISON OF THE APPRAISALS BY THE ENGLISH NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) FOR TWO THERAPIES FOR RELAPSED OR REFRACTORY (RR) CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL): IDELALISIB+RITUXIMAB (IR) AND IBRUTINIB**

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**OBJECTIVES:** In 2014, two new therapies for CLL were launched: IR and ibrutinib. They were appraised by two different NICE committees and two different evidence review groups (ERGs). The objective of this study was to compare the appraisals of IR and ibrutinib in terms of consistency of decision making. **METHODS:** Timings, submissions and meeting papers were sourced from the NICE website. Further information was gathered by attending the Appraisal Committee Meetings. **RESULTS:** The marketing authorisations in CLL were granted by the EMA in September and October 2014 for IR and ibrutinib, respectively. The IR NICE appraisal was conducted from February 2015 to October 2015 from submission to publication; the ibrutinib appraisal was conducted from October 2015 to January 2017 from submission to publication. The appraisals differed widely in duration (253 vs. 455 days for IR vs ibrutinib, respectively), the assumptions made and accepted by the respective Appraisal Committees and ERGs (interchangeability of rituximab and ofatumumab; parametric curve fitting; appropriateness of indirect treatment comparison methodology), the scope and comparators considered relevant, consideration of cross-over in the clinical trials, and applicability of the end-of-life criteria. Moreover, whilst the indirect comparison of ibrutinib versus IR clearly demonstrated the superiority of both efficacy and safety of ibrutinib over IR, the Appraisal Committee questioned this due to the difference in how each evidence base was assessed. **CONCLUSIONS:** There was considerable variation between assumptions made and accepted by the Appraisal Committees and ERGs. Although it is accepted that Committees should have independence of decision making, there should be consistency in assumptions accepted by NICE between appraisals within the same therapeutic area and data for new technologies should be held to the same levels of rigour.

**PCN325: TRENDS IN ONCOLOGY APPRAISAL DECISIONS: A COMPARISON BETWEEN THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) AND THE SCOTTISH MEDICINES CONSORTIUM (SMC)**

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**OBJECTIVES:** NICE of England and SMC of Scotland are responsible for issuing appraisal guidance for reimbursement of new health technologies. While both agencies consider clinical and cost-effectiveness in their decisions, they have unique policies and procedures and may yield different outcomes. We conducted an analysis of past appraisal decisions by NICE and SMC for oncology treatments to compare results and identify trends. **METHODS:** Oncology appraisal decisions from January 2012 to May 2017 were identified on the SMC website and Xcenda’s Health Technology Assessment (HTA) Decision map. Appraisal decisions for both countries were evaluated and categorized as favorable, mixed, or unfavorable. Additionally, reported incremental cost-effectiveness ratio (ICER) and tumor type were compared for each decision. SMC decisions that were classified as withdrawn or superseded were not included. **RESULTS:** A total of 91 decisions were identified for NICE, of which 64.8% (59) were favorable, 3.3% (3) were mixed, and 31.9% (29) were unfavorable. 110 decisions were identified for SMC, of which 40.9% (45) were favorable, 26.4% (29) were mixed, and 32.7% (36) were unfavorable. Between agencies, there were 53 pairs of decisions that were matched across 15 tumor types; of which, 62.3% (33) matched exactly, 24.5% (13) were similar (one agency’s decision was favorable and the other agency’s decision was mixed),
and 13.2% (7) were in disagreement. All 18 NICE decisions with reported ICERs less than £30,000 received favorable guidance; but, the guidance for SMC was more varied. For the 25 SMC decisions with a reported ICER of less than £30,000, 12 were favorable, 10 were mixed, and 3 were unfavorable. 

CONCLUSIONS: The majority (86.8%) of oncology HTA decisions by NICE and SMC were either the same or similar across tumor types. However, compared to NICE, there appears to be less association between the reported ICERs and SMC appraisal decision results.

**PCN326: MARKET ACCESS CHALLENGES TO PD-1 IMMUNOTHERAPIES: LESSONS FROM NICE**

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**OBJECTIVES:** The introduction of PD-1 inhibitors in 2015 for the treatment of multiple cancers has seen beneficial outcomes for patients and healthcare providers. However, there have been setbacks in reimbursement approvals for PD-1 inhibitors in England and Wales in certain indications. The objective of this research was to analyze recent market access challenges faced by PD-1 inhibitors with NICE. 

**METHODS:** Secondary research was conducted to identify NICE technology appraisals (final or draft guidance) that included PD-1 inhibitors (pembrolizumab or nivolumab). 19 appraisals were identified through the NICE website that were published, ongoing or proposed, from March 2015 to June 2017. Each appraisal was reviewed for indication, treatment, NICE recommendation, and reasons for recommendation. 

**RESULTS:** As of June 2017, PD-1 inhibitors have been recommended by NICE in eight appraisals. 82.5% of these recommendations included price discounts. Of note, four of these had previously been initially rejected but approved upon final consultation. Three draft appraisals currently reject a PD-1 inhibitor, citing cost effectiveness, immature data or lack of long-term survival benefit. One appraisal in the first-line treatment of NSCLC recommended one PD-1 inhibitor for inclusion on the Cancer Drugs Fund (CDF), following provision of newer data and a price discount, after initial rejection. Another appraisal recommended a PD-1 inhibitor for the treatment of classical Hodgkin Lymphoma, following initial rejection citing immature clinical data and standard of care outcomes not reflective of UK practice. However, the clinical data was still considered immature, suggesting this is not a significant drawback to positive NICE recommendations provided substantial unmet need is demonstrated and discounts are agreed. 

**CONCLUSIONS:** Numerous strategies exist to achieve positive recommendations for PD-1 inhibitors, even following initial rejection. These include demonstrating substantial unmet need, discounts, and future data collection via the CDF. However, questions remain about feasibility of CDF real-world data collection.

**PCN327: PROS IN ONCOLOGY HTA DECISIONS, DO THEY MATTER?**

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**OBJECTIVES:** Healthcare decision-making is becoming more patient-centric, but it is unclear to what extent European payers are using patient reported outcomes (PRO) and Quality of Life (QoL) data in their assessment of the value of new oncology drugs. The objective was to investigate how inclusion of PRO/QoL evidence in Health Technology Assessments (HTA) has evolved over the past five years and to what extent PRO/QoL data influenced the recommendation by HTA agencies. 

**METHODS:** HTAs for new oncology products by four agencies (G-BA, HAS, NICE and SMC) from 2011-2016 were identified. Original assessments, resubmissions and extensions of indications were included. HTAs were reviewed for inclusion of PRO data. PRO instruments were classified as collected with a general measure, disease-specific measure or utility measure. Both numerical counts of HTA submissions and qualitative evaluation of agency statements were used to understand the attitude of agencies towards PRO data. 

**RESULTS:** A total of 376 HTA reports for 133 drug-indication combinations were identified. 72% of the drug indication combinations included PRO data in one or more submissions. Of the instruments used to capture PRO data, 36% were disease-specific, 38% were generic, 17% were utility-oriented and 9% were unspecified. Submission of PRO data increased over the years, in 2016 50 – 90% submissions per country included PRO data. Demonstrating improvement in QoL led to higher benefit ratings by G-BA and HAS and supported clinical benefit assigned by SMC and NICE. QoL was considered in the recommendation of 89 HTAs (35% of HTA submissions including PRO). In a number of cases, strong PRO data led to a positive recommendation despite lack of overall survival data. 

**CONCLUSIONS:** HTA agencies value the submission of PRO data, however submission is not yet standard practice. Although lack of PRO data does not negatively impact decision-making, PRO data inclusion can have a positive influence on recommendations.

**PCN328: KEY DRIVERS IN HEALTH TECHNOLOGY ASSESSMENT BY ANALYSING THE LEVEL OF IMPROVEMENT IN ACTUAL BENEFIT IN SOLID TUMOR ONCOLOGY DRUGS**

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OBJECTIVES: The price level of drugs in France is based on their medical evaluation by the Transparency Committee. The aim of this study was to understand the rationale behind the evaluation of drugs in solid tumor oncology by determining the key drivers of the Improvement in Actual Benefit (IAB) levels. METHODS: We performed a retrospective analysis between March 2014 and October 2016 of the new products and the new indications in solid oncology. We searched quantitative and qualitative relevant criteria pertaining to the drug evaluation from the opinion of the Transparency Committee and we extracted the data for each product in an Excel® spreadsheet. RESULTS: In total, 28 drugs in 37 indications were evaluated including 1 important IAB (IAB II) (3%), 5 moderate IAB (IAB III) (13%), 14 minor IAB (IAB IV) (38%), 12 no clinical IAB (IAB V) (32%) and 5 (14%) insufficient Actual Benefit (insufficient AB). One quantitative criterion and 9 qualitative criteria were included: effectiveness, tolerance, methodological quality of the studies and type of comparator. The factors related to obtaining a good assessment (II and III) were the following: a statistically significant Overall Survival (OS) (100% of cases), an overall survival increase superior to 3 months (71% of cases) and a relevant active comparator (i.e: gold standard) (33% of cases). Conversely, the criteria that negatively impact the IAB (IV, V and insufficient AB) are: a statistically significant Progression Free Survival (PFS) alone without significant difference in OS (100% of cases), a decrease in tolerance as compared to the comparator (95%), a weak methodology (92%), a poor transposability (46%), an already covered medical need (insufficient AB in 100% of cases). Moreover, there was a linear relationship between the effect size and the IAB level \( R^2 = 0.4628 \). CONCLUSIONS: The drivers influencing the IAB levels are: tolerance, quality of demonstration and data transposability.

PCN329: THE ROLE OF COMPANION DIAGNOSTICS IN HTAS OF DRUGS IN FRANCE, GERMANY AND THE UK

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OBJECTIVES: The number of medicines paired with in vitro diagnostics continues to grow. The role of the diagnostic test in HTAs continues to evolve. Our aim was to examine if payers have used data on subpopulations defined by diagnostics to limit access to innovative oncology medicines and investigate the extent to which the diagnostic is considered during HTAs of the medicine. METHODS: Products were selected based on the FDA’s list of oncology products with CDx. Indications authorized by the European Commission (MA population) for each product were compared with the reimbursed population in France, Germany, and the UK. Commentary on the diagnostic was extracted from documents relating to the HTA of the medicine. RESULTS: Twenty-four medicines were included in the analysis. Thirty-eight indications across twelve tumor types were represented. Thirteen genes/gene products or chromosomal changes were used as the basis for the CDx test. Not all indications for each medicine required biomarker status. NICE has restricted the MA population based on the CDx test twice: trastuzumab for gastric cancer and draft guidance for nivolumab in NSCLC. Other NICE technology appraisals discussed the possibility of different clinical benefit in different molecular subpopulations, among other commentary on testing. The G-BA used CDx tests to define subgroups in assessments of nivolumab, pembrolizumab, and osimertinib; it found additional benefit for afatinib in a subgroup with the Del19 mutation in the EGFR gene, but none for L858R or other EGFR mutations. There were few examples of the TC considering test status, although it recommended limiting BRCA testing for olaparib to INCa laboratories. Additional examples will be presented. CONCLUSIONS: Payers take varying approaches to CDx within HTAs. There have been few examples of payers restricting access to a narrower group than the MA population. However, this practice may increase in future, reducing treatment options for patients and their physicians.

PCN330: THE UNIQUE CHARACTERISTICS OF ADOPTIVE IMMUNOTHERAPIES FOR HEALTH ECONOMIC EVALUATIONS

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OBJECTIVES: Adoptive immunotherapies are an emerging group of health technologies that can be used to target specific diseases, particularly cancers. To produce the technology, immune cells are removed from a patient and modified and multiplied in vitro before being reintroduced to the patient with the aim of eliciting a disease-specific immune response. These adoptive therapies are distinct from other immunotherapies that are currently available, such as therapeutic cancer vaccines, as each therapy is unique to the individual patient. The use of these adoptive immunotherapies is expected to increase over the coming years. Therefore it is important to understand their unique characteristics and how these may impact on future health technology assessments (HTA). METHODS: A pragmatic search of the literature was undertaken to identify published resources relating to the unique characteristics of adoptive immunotherapies and the challenges that these technologies may pose for health economic evaluations. RESULTS: The key challenge identified is the high manufacture cost as the therapy is tailored to each
patient and, therefore, mass production is not possible. Therefore, to be reimbursed within the UK these therapies would have to produce large QALY gains under the current NICE threshold. These therapies do have the potential to generate significant benefits if they prove to be curative. However, this leads to a second challenge as they are often evaluated in small-scale, single-arm clinical trials. Therefore, to estimate long-term benefits, extrapolation would be required leading to potential uncertainty, which will impact on decisions relating to HTAs. If large QALY gains cannot be established with confidence then it may be necessary to explore alternative payment methods (e.g. lifetime leasing). CONCLUSIONS: Adaptive immunotherapies have the potential to generate significant benefits to patients but the high costs of production and uncertainty over long-term outcomes may prove challenging for future HTAs.

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**PCN331: ASSESSMENT OF HEALTH TECHNOLOGY APPRAISALS TO IDENTIFY KEY DRIVERS FOR REIMBURSEMENT OF ONCOLOGY DRUGS WITH ONLY PHASE 2 CLINICAL DATA**

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**OBJECTIVES:** Drugs can obtain marketing authorisation with only Phase 2 data if the data is considered promising, a Phase 3 trial is not considered feasible or there is a high unmet need. Here we identify and review challenges faced by manufacturers of oncology drugs approved with only Phase 2 data in Health Technology Appraisals (HTAs). **METHODS:** Oncology drugs approved on basis of Phase 2 data since 2010 were identified on the European Medicines Agency (EMA) website and were ranked based on inclusion of overall survival data, a control arm, were deemed a targeted therapy, had orphan disease status or conditional marketing authorisation. HTAs from Germany, France, UK, Australia, Canada, Sweden, Italy and Spain for the top-ranked products were then identified using QuintilesIMS proprietary HTA Accelerator and reviewed to identify payer’s rationale for reimbursement decisions. **RESULTS:** Twenty-five oncology drugs were licenced with Phase 2 data alone since 2010. The nine top-ranked products had 51 relevant HTA reports. 47% of the reports recommended unrestricted access, 16% had restrictions, 16% were rejections and 22% provided no reimbursement recommendation. The most frequent positive payer comments related to clinical benefit, good safety/tolerability and innovation. The most frequent negative payer comments related to safety risk, lack of comparator, lack of subgroup data, and limited comparative benefit. Lack of Phase 3 data was not directly cited, but uncertainty and insufficient powering were identified as a payer concern. Many trials were single arm and payers struggled to use these results to assess clinical benefit. In three cases, resubmissions with additional Phase 3 data led to improved reimbursement outcomes. **CONCLUSIONS:** The review found that using Phase 2 alone is not an absolute barrier to reimbursement, but the uncertainty stemming from a less comprehensive evidence base may influence payers’ decisions. Payer comments related mostly to good efficacy and safety data, and robust comparative effectiveness.

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**PCN332: ADC, NOT AS EASY AS 123 - THE UNPRECEDENTED EXAMPLE OF TRASTUZUMAB-EMTANSINE IN THE NICE APPRAISAL PROCESS**


**OBJECTIVES:** On June 15, 2017, NICE announced the third Final Appraisal Determination (FAD) for the antibody-drug conjugate (ADC), trastuzumab-emtansine. This level of reconsideration is unprecedented and can be attributed to the simultaneous reforms of the Cancer Drugs Fund (CDF). This paper highlights the process by which trastuzumab-emtansine was assessed by NICE. **METHODS:** Publically available CDF, EMA, NICE, and SMC data on trastuzumab-emtansine were screened up to June 27, 2017. **RESULTS:** Trastuzumab-emtansine received marketing authorisation in Europe on November 15, 2013 for treating advanced/metastatic pre-treated breast cancer. It was approved for inclusion into the CDF with free-pricing in February 2014, costing £90,381 (€102,118) per patient. The first NICE FAD (August 2014), was not to recommend. The second FAD (November 2015), was again not to recommend. In September 2015, trastuzumab-emtansine was announced as to be axed from the CDF, as part of a cost-containment drive, but in November 2015 after significant discounting, this decision was reversed. Post NAO audit, trastuzumab-emtansine qualified for the CDF rapid reconsideration process in December 2016. As part of this, in its third FAD (June 2017), trastuzumab-emtansine was recommended for routine use on the NHS but with a patient access scheme. In Scotland (where the CDF does not apply), trastuzumab-emtansine was accepted by the SMC in April 2017 after an initial non-recommendation in October 2014. **CONCLUSIONS:** Trastuzumab-emtansine received European market authorisation for over three years prior to it being approved by NICE or the SMC for public reimbursement. Nevertheless, in England, it was available for over two years as part of the CDF, including almost 18 months at list price. Once the CDF was closed, the manufacturer reached an agreement for reimbursement with NICE, suggesting that the existence of the CDF provided an alternative market access route that disincentivised the relevance of seeking a NICE recommendation.
PCN333: GUIDELINE ADHERENCE IN DOCETAXEL TREATMENT OF CASTRATION RESISTANT PROSTATE CANCER (CRPC) PATIENTS IN A REAL-WORLD POPULATION: THE CASTRATION RESISTANT PROSTATE CANCER REGISTRY (CAPRI) IN THE NETHERLANDS

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OBJECTIVES: Docetaxel has been a treatment option for CRPC since 2004. With new treatment options available since, efficacy and guideline adherence are of interest in the Netherlands. The aim of this analysis is to investigate the use of docetaxel in a real-world population, according to guideline adherence based on simplified criteria for docetaxel treatment. METHODS: CAPRI is an observational, retrospective study in 20 hospitals in the Netherlands. All CRPC patients diagnosed between 2010 and 2013 were included. Patients were followed until March 2015. We retrospectively identified patients with an indication for docetaxel based on 3 criteria: 1. metastatic CRPC, 2. WHO performance score 0-2, 3. either symptomatic disease, or asymptomatic with visceral metastases or rapid progression, defined as less than 1 year from start of androgen deprivation therapy to CRPC diagnosis. RESULTS: 1,524 patients were included in the analysis with a median follow-up period of 23 months. During this period, 46% of all patients were treated with docetaxel. 1,083 patients (71%) met the criteria for docetaxel treatment. However, only 646 of these patients (60%) were actually treated with docetaxel. An additional 53 patients not meeting the docetaxel criteria were treated with docetaxel. Of 437 (29%) patients who met the criteria but were not treated with docetaxel, 77% were treated with anti-androgens (285 patients), abiraterone acetate (83 patients) or enzalutamide (12 patients). Patients treated with docetaxel were younger, had less comorbidity and had a more progressive course of disease compared to patients not treated with docetaxel. CONCLUSIONS: Despite having an indication for docetaxel treatment, 40% of patients has not been treated with this life-prolonging drug. Age, comorbidity and less aggressive disease characteristics may be reasons for this observation, as well as alternative life prolonging treatment options, patient preferences or unknown confounders.

PCN334: REAL-WORLD UTILIZATION OF BLINATUMOMAB IN ACUTE LYMPHOBLASTIC LEUKEMIA IN THE US

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OBJECTIVES: Blinatumomab is the first bispecific CD19 directed CD3 T-cell engager immunotherapy to demonstrate overall survival benefit in patients with Philadelphia chromosome-negative (Ph-) relapsed/refractory acute lymphoblastic leukemia (ALL). In December 2014 the FDA granted an accelerated approval to blinatumomab in patients with Ph- relapsed/refractory B-precursor ALL based on findings from a phase II trial in 185 adults followed by the supplemental BLA approval to include new data in pediatric patients. Approved on 12/3/2014, blinatumomab is the first CD19 targeting bi-specific T-cell engagers (Bites) in the immuno-oncology arsenal. As it will likely compete with CD19 targeted CAR-T therapeutics, its uptake since approval may predict CAR-T potential in a similar clinical setting. METHODS: Patients diagnosed with ALL on systemic therapy (ST) between 12/2014 and 12/2016 were identified from the Symphony Health claims database. Market share and time to treatment discontinuation (TTD) were examined. TTD was defined as time from ST initiation to switch or last administration date plus 90 days if no other ST was administered. TTD was described with Kaplan-Meier curves. RESULTS: Of the 18,162 ALL patients on ST since blinatumomab approval, 218 (1.2%) were treated with blinatumomab; of them 29 (13.3%) appeared to be Ph+ (indicated by utilization of nilotinib, ponatinib, dasatinib, imatinib, or bosutinib). The most common regimen was blinatumomab monotherapy followed by combination with methotrexate and/or cytarabine. Of the 218 patients treated with blinatumomab, 123 (56.4%) were male, 83 (38.1%) received blinatumomab in the first-line, and mean (SD) age was 43.9 (18.0) years. The mean (SD) number of prior antineoplastic regimens was 3.2 (3.6). Mean (median) TTD was 122.5 (110.0) days. CONCLUSIONS: This is the first real-world evidence study of blinatumomab and it demonstrates the uniqueness of the patient population for which it is currently indicated. CAR T-cell economic modeling should be informed by this research.

PCN335: REAL-WORLD MULTIPLE MYELOMA TREATMENT PATTERN IN LEBANON: EVIDENCE FROM PATIENT CHART AUDIT

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OBJECTIVES: Understanding symptomatic multiple myeloma (MM) patient management, treatment patterns and
outcomes in real-world practice in Lebanon. METHODS: Data were collected through a cross-sectional phase (X) and retrospective (R) patient chart review (Aug/16–Oct/16) by 20 onco-hematologist managing >10 symptomatic MM patients during the last three months and responsible for treatment initiation. The X-phase collected clinical characteristics and treatment for MM patients seen during a 4 week time-frame, perception on access restriction to MM drugs, and influence of guidelines. The R-phase recorded disease characteristics, including treatment response and duration. Analyses were descriptive. RESULTS: 5 and 9 physicians from public teaching hospitals and public general hospital, respectively; 3 physicians from Cancer Centers and 2 from private hospitals participated in the study. In the X-phase 386 patients were included. Across all lines, bortezomib-based regimens were the most used (57% in 1L, 55% in second-line [2L], 64% from third-line onwards [3L+]). 63% of patients having completed a 1L were SCT eligible and 61% had transplant. Almost one-third of the patients discontinued to their treatment, mainly due to renal issues (29%) and other toxicities (40%). Of those 198 patients recruited in the R phase, 9% had a moderate or severe renal impairment and 24% of them had an ECOG status >2. Physician-assessed depth of response increased in later lines: 49% achieved at least a very good partial response (VGPR) in 1L, while 67% and 71% achieved at least a VGPR in 2L and 3L, respectively. Average length of therapy was 2.5 months in 1L, 2.4 in 2L and 2.3 in 3L. CONCLUSIONS: Although considerable response to therapy in later lines, low treatment duration across lines and discontinuation due to toxicity management suggest a need for alternative treatments in Lebanon.

PCN336: REAL-WORLD MULTIPLE MYELOMA TREATMENT PATTERN IN MOROCCO: EVIDENCE FROM PATIENT CHART AUDIT

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OBJECTIVES: Understanding symptomatic multiple myeloma (MM) patient management, treatment patterns and outcomes in real-world practice in Morocco. METHODS: Data were collected through a cross-sectional phase (X) and retrospective (R) patient chart review (Aug/16–Oct/16) by oncologists, hematologists and internists managing >10 symptomatic MM patients during the last three months and responsible for treatment initiation. The X-phase collected treatment for MM patients seen during a 4 week time-frame, physicians’ perception on MM drugs accessibility and guidelines use. The R-phase recorded disease characteristics, including treatment response and duration. Analyses were descriptive. RESULTS: 4 physicians in public hospital, 2 physicians in Cancer Center and 14 physicians in private hospitals participated in recruiting MM patients in both study phases. All of them, perceive full access to MM therapies and they were mainly using NCCN/ASH and ASCO guidelines for treatment decision-making. In the X-phase, a total of 237 patients were enrolled, 68% were currently undergoing treatment, of which 93% were on 1L treatment. Across all lines, thalidomide-based regimen was mainly used (72% in 1L, 60% in second-line [2L], 100% from third-line onwards [3L+]), while bortezomib-based regimen and lenalidomide-based regimen were used only in 1L (9% and 1% respectively). 95% of patients having completed a 1L were SCT eligible. In the R-Phase, a total of 200 patients were included. Physician-assessed depth of response decreased across lines: 20% patients achieved at least a very good partial response (VGPR) in 1L, while 7% and 17% achieved at least a VGPR in 2L and 3L, respectively. Average length of therapy was 6.2 months in 1L, 5.9 and 6.2 in 2L and 3L, respectively. CONCLUSIONS: Despite the average time of treatment duration, low response rates from 1L onwards suggest a need for more effective therapies in Morocco to support patients in achieving better and sustained responses across all lines.

PCN337: THE IMPLEMENTATION OF ROBOTIC-ASSISTED SURGERY FOR ENDOMETRIAL CANCER IN THE UNITED STATES LEAD TO AN IMPROVEMENT OF OVERALL 30-DAY SURGICAL OUTCOMES WITHOUT INCREASING COSTS: IS TECHNOLOGY FINALLY ALLOWING THE DIFFUSION OF MINIMALLY INVASIVE SURGERY AT A NATIONAL LEVEL?

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OBJECTIVES: To evaluate the role played by the introduction of robotic-assisted surgery for endometrial cancer(EC) treatment in the United States in terms of 30-day morbidity and costs over time. Also, to compare the clinical and economic outcomes that followed the change in surgical treatment. METHODS: The Premier Hospital Perspective Database was reviewed for adult patients who underwent elective total hysterectomy for EC(2008/01-2015/09). Trend analyses for the proportions of surgical approaches, surgical and economics outcomes were performed. Outcomes were compared among surgical approaches after 1:1 Greedy propensity score matching. RESULTS: Overall, 35,224 EC patients were included. An increase in the use of Robotic-assisted hysterectomy(RH)(9.46% in 2008 to 56.82% in 2015) and a concomitant decrease in the use of Open hysterectomy(OH)(70.45% in 2008 to 28.08% in 2015) were observed over time. As a consequence, the rate of minimally invasive surgery increased from 27.59% to 70.65%.
During the study period, the median length of stay (LOS) in US EC patients decreased from 4 to 3 days and 30-day readmission rates from 6.29% to 4.26%. The rate of any major complications decreased from 10.5% to 8.01%, p-for-trend=0.01; any minor complications went from 16.5% to 13.7%, urinary tract infections from 2.21% to 1.40%, and superficial surgical site infections from 2.94% to 1.50% (all P-values-for-trend=0.05). A reduction of overall 30-day complications was registered (from 19.9% to 16.10%, P-value-for-trend=0.05). Perioperative 30-day total cost from US$11048.17 slightly decreased to US$10322.76 (all P-Values-for-trend=0.05). After propensity score matching, RH was associated with shorter hospitalization (Median (Q1, Q3) days: RH=2(2.3) vs. OH=4(3.6), P-Value=0.001) and less 30-day complications (Overall 30-day complications RH=20.3% vs. OH=33.8%, P-value=0.001); Comparable perioperative total costs between approaches (Median (Q1, Q3): RH$22120 (9457, 16371) vs. OH$12017 (8940, 17106), P-value=0.23) was registered.

CONCLUSIONS: The implementation of minimally invasive surgery, thanks to the introduction of RH, led to a reduction of 30-day complications at a national level in the US without increasing treatment-related costs. More investigations are needed to demonstrate the causality.

**PCN338: TRUCS AND CAR-TS - THE EMERGENCE OF IO CELL THERAPIES**


**OBJECTIVES:** A number of promising T cell receptor fusion constructs (TRuC) and chimeric antigen receptor T-cell (CAR-T) therapies are currently in development, showing transformational patient benefits in oncology from single/short treatments. Their potential very high costs in line with their clinical benefits and upfront costs mean that acceptable pricing and reimbursement (P&R) agreements pose a significant challenge for manufacturers and payers. This study aims to investigate any relevant P&R analogues and existing pricing policies which could support their access. **METHODS:** Publically available information on P&R and health technology assessments (HTAs) for cell therapies and other high cost therapies were screened from a targeted literature search. **RESULTS:** CAR-T therapies could be considered cost-effective at $750,000 (£583,000, €662,924) per treatment according to Palmer et al. using a mock NICE HST assessment. The prices of drugs are increasing; Neumann et al. reported an increasing trend for therapies being approved in the US, whose ICERs exceed $100,000 (£77,500, €88,390) per QALY, 6.3% (1990-1999, N=207), 7.8% (2000-2009, N=851), and 16.9% (2010-2012, N=444), respectively, with further growth expected from biologics and specialty medicines. Nevertheless, alipogene-tiparvovec, the first approved gene therapy in Europe (2012), offered potentially curative benefits for an orphan disease (lipoprotein lipase deficiency) and was initially priced at $1.6 million (£1.3 million, €1.4 million) per patient (single treatment), reported only one sale to date in 2016, and in 2017 announced its marketing authorisation would not be renewed for commercial reasons. Strimvelis, another curative gene therapy with single treatment, was EC-approved in 2016, is priced at $665,000 (£520,163, €587,793), but with a full money-back guarantee. **CONCLUSIONS:** The high prices and significant upfront opportunity costs associated with the transformational clinical benefits of cell therapies may pose significant reimbursement challenges for payers. Innovative contracting schemes may have to be explored to ensure that these are priced in an affordable and manageable manner.

**PCN339: IMPACT OF USING OVERALL SURVIVAL OR PROGRESSION-FREE SURVIVAL IN OUTCOMES-BASED PRICING ARRANGEMENTS**

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**OBJECTIVES:** Outcomes-based pricing arrangements (OBPA) can be attractive for payers to address uncertainty. In oncology overall survival (OS) is considered the gold standard outcomes measure. However, implementing OBPA based on OS poses significant practical hurdles. Here we assess the feasibility and impact of using progression-free survival (PFS) as an alternative measure to enable OBPA. **METHODS:** A three-part, mixed-methods study was performed to assess the use of OBPA in oncology. A scoping review was conducted to identify current and past OBPA. Further, the impact of OBPA - using either OS or PFS - on savings and health improvements in the population the payer is paying for was modelled for four metastatic cancer compounds. (Ex-) payers’ perceptions and attitudes where also explored through semi-structured qualitative interviews. **RESULTS:** In the metastatic setting OBPA based on OS or PFS can both address uncertainty around health outcomes and costs. In the four compounds, OBPA based on OS had a greater impact on payers’ outcomes in the population the payer is paying for (increase in median OS of 6.9 months compared to 2.8 months in median PFS) and potential savings (15% compared to 10%). Although PFS has a smaller impact, the time to trigger a payback was reduced between 18.9 and 4.9 months in the 4 compounds. **CONCLUSIONS:** The definition of a relevant and measurable endpoint is necessary to increase the use of OBPA. OS is seen as the ultimate outcome by the interviewees and is beneficial to payers in terms of health outcomes in the population they pay for and savings. However, it is often not feasible to implement because of the long follow-up time required. Using PFS might be a good alternative to OS in the metastatic setting. More research is needed to further explore alternative outcome measures to successfully support OBPA.
**PCN340: REAL-WORLD PATIENT CHARACTERISTICS AND PATTERNS OF CARE AMONG METASTATIC UROTHELIAL, HEAD AND NECK, NON-SMALL CELL LUNG CANCER PATIENTS USING A GERMAN SICKNESS FUND CLAIMS DATABASE**

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**OBJECTIVES:** Recent major advances in cancer treatment have been driven by availability of new immuno-oncology therapies. The aim of this study was to describe patient characteristics and current treatment patterns among adults in Germany with either metastatic urothelial cancer (mUC), head and neck squamous cell cancer (mHNSCC), or non-small cell lung cancer (mNSCLC).

**METHODS:** This retrospective observational study reported demographics, comorbidities (Charlson Comorbidity Index; CCI), and treatment using the Betriebskrankenassenn German Sickness Fund claims database. Patients included in this study were identified by ≥1 inpatient admission or ≥2 outpatient visits for diagnosed UC, HNSCC, or NSCLC with their first qualifying claim (index date) between Q1-2011 to Q4-2014. These patients were aged ≥18, and with continuous insurance coverage ≥12 months and no cancer therapy claims prior to their first qualifying diagnosis. Patient follow-up was defined as the index date until the earliest of continuous enrollment, or survival to end of study period (Q4-2015), or death.

**RESULTS:** Patients with mUC (n=750), mHNSCC (n=458), and mNSCLC (n=2,745) were predominately male (68.6%) with a mean age of 65.3 (SD=10.2) years and a mean follow-up of 583.5 (SD=392.7) days. Those with mUC had a mean CCl of 2.0 (SD=2.0), most frequently reporting diabetes without chronic complication. Patients with mHNSCC and mNSCLC had a mean CCI of 1.7 (SD=2.0) and 1.9 (SD=2.0), respectively, with chronic pulmonary disease most common for each. Pyrimidine analogs (36.1%) followed by platinum therapy (26.4%) were the preferred therapies among mUC patients treated with antineoplastic agents. Platinum compounds were most frequently prescribed for mHNSCC (68.8%) and mNSCLC (56.6%), respectively.

**CONCLUSIONS:** While treatment patterns reported for this study were similar to German guidelines, the disease burden coupled with the seriousness of each of these tumor types suggests an ongoing need for more effective therapies.

**PCN341: REAL WORLD TREATMENT PATTERNS OF PATIENTS WITH OVARIAN CANCER RECEIVING FIRST LINE CHEMOTHERAPY IN THE UNITED STATES**

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**OBJECTIVES:** Information on the treatment of epithelial ovarian cancer (EOC) in real-world settings is limited. This study examines first-line treatment patterns among advanced ovarian cancer (OC) patients from two large US healthcare claims databases. **METHODS:** The MarketScan Commercial Claims & Medicare (CCMC) and Surveillance, Epidemiology, and End Results-Medicare (SEER-M) databases were used to identify females aged ≥18 years diagnosed with advanced OC (including EOC, fallopian tube [FTC] and primary peritoneal cancer [PPC]) and receiving first-line treatment (i.e. the first claim for any chemotherapy within 90 days post-OC diagnosis) between 1/1/2010 and 12/31/2015. Patients were followed from their initial diagnosis of OC (i.e. index date) until death, loss-to-follow-up or end-of-study period to assess and compare their clinical characteristics and treatment patterns. **RESULTS:** A total of 7,825 advanced OC patients were identified (N= 6,170 in CCMC, N= 1,655 in SEER-M). Majority of patients were diagnosed with EOC (CCMC: 89%, SEER-M: 80%), and the mean age (SD) at diagnosis was 59 (11) and 75 (6) years, respectively. The median follow-up time was 1.4 and 2.3 years, respectively. Staging information was only available for the SEER-M cohort; 65% of patients were diagnosed with stage III or IV disease. The mean (SD) time from index to initiation of first-line treatment was 35 (20) days in the CCMC cohort and 51 (19) days in the SEER-M cohort. Advanced OC patients most frequently received platinum/taxane-based regimens, with carboplatin/paclitaxel used in 63% and 67% of patients, respectively. Bevacizumab-containing regimens were utilized in 7% of CCMC OC patients and 5% of SEER-M OC patients, with bevacizumab/carboplatin/paclitaxel combination being the most common. **CONCLUSIONS:** Results suggest that platinum-containing chemotherapy remains the standard-of-care for advanced OC patients in the US. Despite differences in age between the two OC cohorts, similar treatment patterns were observed.

**PCN342: TREATMENT PATTERNS OF SECOND-LINE (2L) METASTATIC UROTHELIAL CANCER (MUC) IN SPAIN**

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**OBJECTIVES:** The primary objective was to understand the treatment patterns of patients receiving 2L therapy for
mUC in Spain. METHODS: This study was a retrospective, non-interventional study conducted using a panel of 50 Spanish physicians. Patient characteristics, treatment patterns, and outcomes data were collected from medical charts of the five most recent patients who began and stopped 2L mUC treatment. 2L was defined as treatment after progression/recurrence after 1L treatment, or recurrence with ≤12 months of neoadjuvant/adjuvant treatment. Analyses were conducted using descriptive statistics. RESULTS: Data were collected from 241 patients. Mean age at 2L treatment initiation was 63.5 (±9.04) years, and 81% were male. Initial urothelial cancer diagnosis was metastatic for 88% of patients, with the primary tumor site being urinary bladder (76%) and histology being transitional cell (80%). Most patients received platinum-based combination 1L treatment: gemcitabine + cisplatin (50%) and gemcitabine + carboplatin (24%). 60% of patients had complete or partial response to 1L treatment. At initiation of 2L treatment, 54% of patients had ECOG Grade 0 or 1. The most common 2L treatment was non-platinum-based monotherapy: vinflunine (41%) and paclitaxel (20%). At the end of 2L treatment, 29% of patients achieved a complete or partial response, 25% stable disease and 46% disease progression. Platinum-based treatments compared with non-platinum-based treatments were associated with significantly more hospital days for chemotherapy administration (p<.001) and more hospital days for monitoring/recovery (p=.002). Non-platinum-based treatments compared with platinum-based treatments were associated with significantly shorter duration of time from end of 1L to start of 2L (p<.001), from the end of 2L to start of 3L (p=.005), and time on 2L treatment (p=.005). 10% of patients received third line treatment. CONCLUSIONS: In Spain, the most common 2L mUC treatment is non-platinum-based monotherapy. Poor 2L treatment outcomes indicate a high unmet need for these patients.

PCN343: REAL WORLD TREATMENT PATTERNS AND RESOURCE USE FOR ADVANCED NON-SMALL CELL LUNG CANCER IN BRAZILIAN PRIVATE INSTITUTIONS

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OBJECTIVES: In Brazil, data on clinical and economic burden of non-small cell lung cancer (NSCLC) are scarce. This study presents real-world data on patient characteristics, treatment patterns and resource use for advanced NSCLC (aNSCLC) patients in Brazilian private institutions. METHODS: Data from medical charts were collected from six private institutions in Brazil. Eligible patients were ≤18 years old at diagnosis, diagnosed with advanced or recurrent (stages IIIb and IV) NSCLC between January 2011 and July 2014, and had received at least two chemotherapy treatment lines. Data were summarized using descriptive statistics. RESULTS: Out of 430 charts screened, 152 (non-squamous=121, squamous=26, unknown=5) were eligible. Patients’ median age was 62 years, 55.9% were male, 43.4% were former smokers and 16.4% were smokers. All patients had received two treatment lines, and 57.2% and 31.6% had received three and four treatment lines, respectively. EGFR mutation testing was performed in 116 patients (76.3%), of which 41 (35.5%) were EGFR+. Among the EGFR+ patients, 87.8% received a tyrosine kinase inhibitor (46.3% first-line, 41.5% in other lines). Sixteen and 21 different regimens were used as first- and second-line treatments, respectively. Bevacizumab + carboplatin + paclitaxel (32; 21.1%), carboplatin + pemetrexed (31; 20.4%) and cisplatin + pemetrexed (26; 17.1%) were the most frequent first-line regimens, while docetaxel (36; 23.7%), pemetrexed (26; 17.1%) and carboplatin + pemetrexed (20; 13.2%) were the most common second-line regimens. Regarding resource use, 52%25% of the patients had hospitalizations/ER visits, 95.4% used supplemental medication (median number of medications 13 [1-85]), and 50% had supplemental procedures (median number of procedures 1 [1-16]). CONCLUSIONS: Treatment patterns for patients with aNSCLC in this study were highly heterogeneous, suggesting lack of a clear standard-of-care in the pre-immunooncology era. The observed high resource use suggests an important economic burden to the private healthcare system and need for therapies that can reduce resource use.

DIABETES/ENDOCRINE DISORDERS - Clinical Outcomes Studies

PDB1: INCIDENCE AND COSTS OF HYPOGLYCEMIA IN DIABETES PATIENTS INITIATED ON BASAL INSULIN: A POPULATION-BASED STUDY

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OBJECTIVES: For diabetes mellitus (DM) patients who received anti-diabetes therapy, hypoglycemia is a common and serious adverse event which is associated with higher incidence of cardiovascular events and mortality. The aim of this study is to estimate the incidence of hypoglycemia event of DM patients using basal insulin and its related medical utilization. METHODS: Data came from the Longitudinal Cohort of Diabetes Patient in Taiwan from 2006 to 2013. A total of 1,060,845 DM patients were included in the cohort. After excluding patients who never use basal insulin (n=1,012,980) and used only 1 time basal insulin during follow-up period (n=14,374), a total of 33,491 patients were included in the analysis. The duration of basal insulin treatment was defined as the first prescription date of basal insulin and followed to the last prescription date. If the duration of two prescription dates were apart over 30 days, it was identified as a different treatment episode. Hypoglycemia event was defined by the diagnosis. RESULTS: During 2006-2013, there were 1,571 hypoglycemia events and 91.4% went to emergency visit. Total follow-up duration was 40,113.28 person-years and the incidence rate per 100 person-year was 3.91 and the mortality was 0.51%. The incidence rate of hypoglycemia was 7.32 and 3.29 per 100 person-year for type I and type II DM, respectively. Furthermore, the combination of basal insulin and other insulin therapy had the highest incidence rate compared to basal insulin plus oral anti-diabetes agent and basal insulin monotherapy group. The mortality of hypoglycemia event were 0.44% and 0.54% for type I and type II DM patients, respectively. The average medical cost per hospitalization due to hypoglycemia was €1,898 and €109 per ER visit. CONCLUSIONS: More aggressive anti-diabetes therapy may increase the risk of occurring hypoglycemia. More attention should by paid to prevent hypoglycemia events.

PDB2: GLYCEMIC CONTROL OF ADULT TYPE 2 DIABETES MELLITUS PATIENTS IN THE NETHERLANDS: A CROSS-SECTIONAL REAL WORLD DATABASE STUDY

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OBJECTIVES: The objective of this study was to determine proportions of T2DM patients in the Netherlands reaching individualized glycemic targets (53, 58 or 64 mmol/mol, depending on age, treatment intensity and diabetes duration), stratified by treatment regimen. METHODS: In this retrospective cross-sectional database study, treatment and patient characteristics of adult T2DM patients were obtained from electronic healthcare records within the PHARMO Database Network at September 30th, 2015. Treatment was categorized by lifestyle management, metformin monotherapy, other “classic” oral antidiabetic drugs (OADs), “modern” OADs (DPP-4 and SGLT-2 inhibitors), GLP-1RA and various insulin regimens. Patients with HbA1c levels assessed ≥6 months after treatment initiation were included. Individualized HbA1c targets were applied; for elderly with unknown T2DM duration and treatment other than metformin monotherapy, the target was 64 mmol/mol. Per treatment category proportions at target, above target but ≤64 mmol/mol, and >64 mmol/mol were determined. RESULTS: 53,045 patients met the inclusion criteria, 31% of whom were managed with lifestyle modification. Overall, 76% achieved their HbA1c target. Goal attainment was 75% for those with a target of 53 mmol/mol, 75% for those with a target of 58 mmol/mol and 85% for those with a target of 64 mmol/mol. Goal attainment decreased with increasing treatment intensity: 86% with lifestyle modification, 70-77% with OAD (all categories), 54% with basal insulin or GLP-1RA, and 46-62% for multiple daily insulin regimens. In patients with HbA1c target of 53 or 58 mmol/mol and who had not achieved these target levels, 7% had an HbA1c >64 mmol/mol (ranging from 3% in the lifestyle modification group to 31% in the basal-bolus insulin group). CONCLUSIONS: Although most patients achieve glycemic control after individualization of glycemic targets in Dutch guidelines, a quarter of adult T2DM patients do not reach their targets, with fewer patients achieving targets as treatment intensifies and the disease progresses.

PDB3: A MODEL-BASED META-ANALYSIS FOR THE EFFECT OF METFORMIN ON HBA1C LEVELS IN PATIENTS WITH TYPE-2 DIABETES MELLITUS

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OBJECTIVES: Describe the time course of glycated hemoglobin (HbA1c%) response to metformin therapy in type-2 diabetes mellitus (T2DM) patients using model-based meta-analysis. METHODS: A systematic literature review was performed identifying studies reporting longitudinal aggregate HbA1c% data in T2DM patients treated with metformin. Various databases were considered from date of inception through January 2016. A non-linear mixed effects model was developed to pool the evidence of the studies and describe mean change from baseline HbA1c% as a function of time and selected average study-level covariates (e.g.: demographics, T2DM duration, extended/immediate release formulation). The model combined a first-order exponential model for initial response with a linear model for progression. Standard model diagnostics, including visual predictive checks, were applied to ensure model convergence and fit. RESULTS: A total of 56 full-text studies were reviewed, 14 of which were included in the evidence synthesis (16 metformin study-arms, 100 data-points and 4696 patients). The final model described...
**PDB4: SYSTEMATIC LITERATURE REVIEW AND INDIRECT TREATMENT COMPARISON OF THE EFFICACY OF SEMAGLUTIDE VERSUS EMPAGLIFLOZIN AS ADD-ON TO BASAL INSULIN**

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**OBJECTIVES:** To conduct a systematic literature review (SLR) and network meta-analysis (NMA) to determine the comparative efficacy and safety of semaglutide relative to all SGLT-2 inhibitors among adults with type 2 diabetes with inadequate glycaemic control on basal insulin. **METHODS:** Systematic searches were conducted, up to April 2016, in: EMBASE, MEDLINE, and CENTRAL; and in major conferences up to September 2016. Eligible studies were randomized trials with ≥20 weeks of treatment, evaluating the efficacy and/or safety of semaglutide once-weekly or SGLT-2 inhibitors. The sparse evidence base, only allowing for fixed-effects Bayesian indirect treatment comparisons (ITC), a form of NMA, to be used for change in HbA1c, weight and fasting plasma glucose (FPG) at 30 weeks. Safety outcomes were only reported at 30 weeks in SUSTAIN 5 and 78 weeks in EMPA-REG BASALT. Therefore, ITCs were not feasible for safety outcomes. **RESULTS:** From the 32,869 references identified through the systematic searches, two trials, SUSTAIN 5 and EMPA-REG BASALT, were included in the evidence base. Four trials of SGLT-2is as add-on to mixed insulin regimens were excluded. The evidence base was composed of two doses of each semaglutide and empagliflozin, and placebo. For change from baseline in HbA1c, semaglutide 1.0mg once-weekly was more efficacious than empagliflozin. The mean differences (MDs) relative to empagliflozin 10mg weekly was more efficacious than both doses of empagliflozin, with equivalent MDs of -2.23 kg and 95% Crls within -3.72 and -0.74. Although semaglutide led to larger decreases in FPG, differences were not statistically significant. **CONCLUSIONS:** Semaglutide showed larger reductions in HbA1c and body weight than empagliflozin when used as an add-on to basal insulin; however, the evidence base was too sparse to conduct safety analyses.

**PDB5: SAFETY AND EFFECTIVENESS OF INSULIN ANALOGUES VERSUS HUMAN INSULIN IN TYPE 2 DIABETES; A SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** Most of Type 2 diabetes mellitus(T2DM) receive insulin therapy(analogue or human insulin). The aim of this study was to evaluate safety and effectiveness of Insulin analogues versus human insulin in T2DM. **METHODS:** A systematic review of the literature (The Cochrane Library, Scopus, Web of Science, Pubmed, Embase) and a meta-analysis were performed. We evaluated randomized clinical trials published until 2016. Studies of different insulin types including short-actings (Lispro, Aspart), long-actings (glargine, detemir) and intermediate-acting(neutral protamine Hagedorn (NPH)) for adults T2DM were encompassed into the study. Two reviewers screened the selected studies independently and differences were resolved by discussion. Quality and risk of bias was appraised by using Jadad scale. Level of HbA1C, episodes of hypoglycemia and nocturnal hypoglycemia were considered as safety and effectiveness criteria. **RESULTS:** Ten randomized clinical trials were included after screening of 2712 titles/abstracts and 36 full text articles. Pooled data regarding effectiveness indicated no significant differences in HbA1C values between glargine, detemir, aspart and NPH insulin. However, Lispro produced differences in HbA1C values that favored lispro (-0.14%[95% CI: 0.18 to 0.7];p<0.0001;I²=0%). Also in almost all studies, just one, the episodes of hypoglycemia of human insulin were lower than analogues one; though not significant. **CONCLUSIONS:** The most of analogues insulin appears to have no advantages over human insulin in reducing HbA1C in T2DM population. Only Lispro provided better results for lowering the level of HbA1C for diabetes patients. Nonetheless insulin analogues cause slightly fewer episodes of hypoglycemia in T2DM patients comparing to human insulin.
OBJECTIVES: Sodium-glucose co-transporter type 2 (SGLT-2) inhibitors have been associated with an increased risk of fractures of the upper or lower limbs (FUL) in patients with type 2 diabetes (T2DM). We aimed to compare the risk of FUL in users of SGLT-2-inhibitors and other non-insulin antidiabetic drugs in Germany. METHODS: We used the InGef database to conduct a cohort study with nested-case control analysis in new users of non-insulin antidiabetic drugs between 12 November 2011 and 31 December 2016. Cases were defined as hospitalization for FUL. For each case, up to 40 controls were randomly selected using risk-set sampling. We applied conditional logistic regression to estimate confounder adjusted odds ratios (OR) with 95%-confidence intervals (CI) of FUL comparing current use of SGLT-2 inhibitors to current use of two or more non-insulin antidiabetic drugs. In a subgroup analysis, we compared the risk of FUL in current users of metformin+SGLT-2 inhibitor to metformin+dipeptidyl-peptidase-4 (DPP-4) inhibitor. RESULTS: The cohort comprised 216,255 new users of non-insulin antidiabetic drugs with a crude incidence rate of 8.3 FULs per 1,000 person years. For the nested case-control analysis, 4,719 FUL cases were matched to 186,018 controls. No increased risk of FUL was observed comparing current use of SGLT-2 inhibitors to two or more non-insulin antidiabetic drugs (OR: 0.99; 95%-CI: 0.82-1.20). In contrast, we found an elevated risk for current users of metformin+SGLT-2 inhibitor compared to metformin+DPP-4 inhibitor without reaching statistical significance (OR: 1.48; 0.99-2.20). In a post-hoc analysis, we observed an increased risk of FUL for the latter comparison in patients aged 65 years and older (OR: 1.94; 1.13-3.30). CONCLUSIONS: Our study suggests that SGLT-2 inhibitors are associated with an increased risk of FUL in older patients and highlights the importance of a precise comparator group for safety studies in T2DM to avoid attenuation of risk estimates.

OBJECTIVES: To assess the relationship between type of employment and serum glycosylated hemoglobin A1c level in type 2 diabetes patients. METHODS: A retrospective observational study, carried out in a tertiary care teaching hospital. As per the study criteria, the data for patients diagnosed with Type 2 Diabetes Mellitus for the year 2015 were collected from the Medical Records Department using the following ICD codes: E.11.0 for Type 2 Diabetes Mellitus. The logistic regression was applied to look at the association between the occupation with the glycemic control obtain the adjusted odds ratio and 95% CI were calculated. RESULTS: A total of n=653 cases were reviewed in the study. The patients mean age was 59.36±10.438 years of which 487 (74.5%) were male. The total number of microvascular complications and macrovascular complications were found to be 151 (23.04%), 130 (19.91%). Among microvascular and macrovascular complications, patients with peripheral vascular disease exhibited in the form of foot ulcer was the highest with 76 (11.6%) followed by neuropathy 68 (10.4%), retinopathy 47 (7.4%), CAD 44 (6.7%), nephropathy 36 (5.5%), stroke (CVA) with 10 (1.5%) of patients. Among the different occupational groups Agriculturist & Businessman have a higher risk for the fluctuation in the glycemic control (OR greater than 1). CONCLUSIONS: Serum HbA1c may be a potential biomarker used to investigate the effects of occupational stress outcome. Patients with occupational groups of Agriculturist & Businessman had HbA1c levels overestimate the mean glucose concentration compared with patients of in-service, Retired and House Wife, possibly owing to increased stress in this patient population group.

OBJECTIVES: Different West-European countries have observed a rise in the prevalence of type 2 diabetes during the last decade. As the Dutch population is aging, the prevalence of obesity, a major risk factor for diabetes, is increasing, survival is improving and multiple screening initiatives are implemented, this trend probably also exists in the Netherlands. Unfortunately, recent and reliable data is lacking. The aim was to study the trend in the prevalence of diabetes in the Netherlands for the period 1999-2014 and to investigate the influence of changes in population demographics on this trend. METHODS: The prevalence of diabetes during the period 1999-2014 was studied using data from the PHARMO Database Network, a network of electronic databases that includes data from public pharmacies for 3.8 million residents of the Netherlands. A person with diabetes was defined as someone with at least two dispensings of a glucose lowering-drug within six months. Age-adjusted prevalences were calculated per sex to
investigate the influence of changes in these population demographics. RESULTS: The prevalence increased from 1.8% in 1999 to 4.9% in 2014. The increase was more pronounced among men and among persons older than 74 years. Among men, 75-84 years of age the prevalence increased from 7.6% in 1999 to 16.5% in 2014. Among women 75-84 years of age this increase was from 8.7% to 16.8%. Only half of the increase was explained by changes in population demographics (i.e. age and sex). CONCLUSIONS: This study showed that the prevalence of diabetes in the Netherlands more than doubled during 1999-2014. The absolute change in prevalence increased with age and was larger among men. The increase was only partly explained by changes in age and sex over time. To temper the increasing prevalence of diabetes, it is essential to gain more insight into the other factors responsible for the increase.

PDB9: PREVALENCE OF CARDIOVASCULAR DISEASE IN TYPE 2 DIABETES: A GLOBAL SYSTEMATIC REVIEW

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OBJECTIVES: To summarize prevalence rates globally for cardiovascular disease (CVD) in persons with type 2 diabetes (T2DM) published within the last 10 years (2007-2017). METHODS: We searched Medline, Embase, and proceedings of scientific meetings to identify published studies documenting the prevalence of CVD among people with T2DM. Search terms included stroke, myocardial infarction, angina, heart failure, ischemic heart disease, cardiovascular disease, coronary heart/artery disease (CAD), atherosclerosis, and cardiovascular death. No restrictions were placed on country of origin or publication language. Two reviewers independently searched for articles and abstracted data, with results adjudicated through consensus. Data were summarized descriptively. Risk of bias was explored by applying the checklist from the STROBE Initiative. RESULTS: We analyzed data from 57 articles with 4,549,481 persons having T2DM. Overall, 51.8% were male, 47.0% obese, 63.6±6.9 years old, with T2DM duration of 10.4±3.7 years. CVD affected 32.2% overall (53 studies, N=4,289,140); 29.1% had atherosclerosis in four studies (N=1,153), 21.2% had CAD (42 articles, N=3,833,200), 14.9% heart failure (14 studies, N=601,154), 14.6% angina (4 studies, N=354,743), 10.0% myocardial infarction (13 studies, N=3,518,833), and 7.6% stroke (40 studies, N=3,901,505). Males had higher rates than females for stroke (6.7% vs. 5.9%), myocardial infarction (11.9% vs. 9.8%), angina (21.1% vs. 17.4%), and CAD (18.7% vs. 14.3%). CVD was cause of death in 9.9% of all T2DM patients (representing 50.3% of all deaths), with CAD responsible for 6.3% (29.7% of all deaths) and cerebrovascular disease for 1.5% (11.0% of all deaths). Risk of death in T2DM doubled with CVD (OR=2.09; CI95%:1.56-2.80) and nearly tripled with concomitant CAD (OR=2.97; CI95%:2.18-4.06). Europe produced the most articles (49%), followed by the Western Pacific/China (19%), and North America (14%). Risk of bias was low, as 80%±12% of the Strobe checklist items were adequately addressed. CONCLUSIONS: Globally, CVD affects approximately 32.2% of all persons with T2DM.

PDB10: REAL-WORLD PREVALENCE OF MILD TO MODERATE HYPOGLYCEMIC EVENTS IN PORTUGAL - RESULTS FROM THE HIPOS-PHARMA STUDY

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OBJECTIVES: We aim to characterize and measure the prevalence of ambulatory Type 2 Diabetes Mellitus (T2DM) patients with mild to moderate hypoglycemic events and to explore potential factors associated with these episodes. METHODS: HIPOS-PHARMA was a nationwide observational, cross-sectional, multicenter study performed in community pharmacies of Portugal, which surveyed T2DM patients under treatment for at least 3 months (4April-20May2016). A structured questionnaire was administered by the pharmacist (socio-demographic and anthropometric data, T2DM related data, antihyperglycemic agents [AHA], other clinical information and previous experience with hypoglycemic episodes). Multivariate logistic regression was used to explore factors that may contribute to mild to moderate hypoglycemic episodes. RESULTS: A total of 233 pharmacies recruited 1890 patients (males: 50.6%) with a mean age of 67.1 (SD=10.0) years. On average, participants reported to have diabetes for 11.8 (SD=9.3) years. 86.9% had at least one chronic illness or complication of diabetes and 76.8% were usually followed-up in the primary care setting. 58% were on monotherapy or combination of AHA excluding a secretagogue or insulin. The overall prevalence of mild to moderate hypoglycemic episodes in the 3 months prior to recruitment was 17.8% (95%CI:16.1%-19.6%). Results suggested that men and patients having any AHA therapy except secretagogue or insulin were less likely to have mild to moderate hypoglycemic episodes (p<0.05). Patients with BMI≥30kg/m2, practicing regular physical exercise, employed, with diabetes for ≥10 years, with eye diseases (cataract), disorders of the kidney (nephropathy/kidney failure) and hepatic failure were more likely to suffer these episodes (p<0.05). CONCLUSIONS: Mild to moderate hypoglycemic episodes were commonly reported in this first Portuguese nationwide study. Findings suggested that several factors may contribute to the occurrence of these
events, namely the type of AHA therapy, duration of the disease and due complications. In clinical practice, T2DM management should take in consideration such factors potentially associated with hypoglycemic episodes

**PDB11: FACTORS ASSOCIATED WITH SUSTAINED SMOKING AFTER TYPE 2 DIABETES DIAGNOSIS IN KOREAN MEN**

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**OBJECTIVES:** Patients diagnosed with type 2 diabetes (T2DM) are strongly recommended to stop smoking to improve health outcomes. The goal of this study was to analyze factors associated with continual smoking behavior among the newly diagnosed T2DM in Korean men. **METHODS:** The study population consisted of smokers who were newly diagnosed with T2DM between 1 January 2004 and 31 December 2011 from the Korean National Health Insurance Service (NHIS) national health screening cohort database. Participants at the baseline were categorized into heavy, moderate and light smokers based on the questionnaire regarding smoking status. We analyzed factors associated with continual smoking behavior after diagnosis of T2DM using multivariate logistic regression adjusted for age, socioeconomic status, disability, smoking status, Charlson Comorbidity Index (CCI), hypertension. **RESULTS:** Age, socioeconomic status, smoking amount, Charlson Comorbidity Index (CCI) and hypertension were identified as Factors associated with sustained smoking even after diagnosis of T2DM. Older men (65 to 80 years old) were more likely to quit after diagnosis of T2DM compared to younger men (40 to 64 years old) (adjusted odds ratio, aOR 0.71, 95% confidence interval, CI 0.64-0.79). Smokers with a higher CCI score (1 or more) were more likely to quit compared to those with a low CCI score (0) (aOR 0.87, 95% CI 0.79-0.95). In contrast, smokers in the lower half of socioeconomic status (aOR 1.30, 95% CI 1.18-1.42), those who smoked greater amounts, (moderate smoking: OR 1.52, 95% CI =1.35-1.72; heavy smoking: OR 1.90, 95% CI 1.67-2.17), those with hypertension (OR 1.26, 95% CI 1.12-1.42) were more likely to continue to smoke after diagnosis of diabetes. **CONCLUSIONS:** Customized education and more clinical attention for smoking cessation maybe required for newly diagnosed T2DM patients.

**PDB12: RISK OF Dipeptidyl-peptidase-4 (DPP-4) INHIBITORS ON SITE-SPECIFIC CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** The long-term impact of DPP-4 inhibition is unknown and there are concerns about the influence of DPP-4 inhibition on carcinogenesis of the pancreas and thyroid. The aim was to identify and summarise all publications on the risk of DPP-4 inhibitor use on specific cancer types. **METHODS:** The databases PubMed and EMBASE were searched between January 2005 and April 2017 to identify studies comparing DPP-4 inhibitors with either placebo or anti-diabetic drugs on cancer risk. Studies were included if they reported on at least 1 specific cancer outcome and had a follow-up of at least one year after start drug use. Methodological quality of the studies was assessed by the Cochrane Collaboration’s tool and the Newcastle-Ottawa Scale. Screening of full-text and data-extraction was performed independently by two reviewers. Random effects model meta-analysis was used for quantitative data synthesis. Sensitivity analyses were performed including studies with high quality. **RESULTS:** Twenty-five studies met the inclusion criteria. Sample sizes of the DPP-4 inhibitor groups ranged from 29 to 8,212 patients for RCTs and from 2,422 to 71,137 patients for observational studies, mean age at the start of the study ranged from 51 to 76 years; median follow-up was 1.0 year for RCTs and 2.0 years for cohort studies. None of the pooled (sensitivity) analyses, except the observational studies regarding breast cancer (pooled HR (95% CI) = 0.76 (0.60-0.96), showed evidence for an association between DPP-4 inhibitors and cancer. Also for pancreatic and thyroid cancer no statistically significant risk was found. Most of the included studies suffered from serious biases. **CONCLUSIONS:** Our meta-analysis does not support the hypothesis that DPP-4 inhibitor use is associated with an increased risk of site-specific cancer. Future studies should address the methodological limitations and follow patients for a longer period in order to determine the long-term cancer risk of DPP-4 inhibitors.

**DIABETES/ENDOCRINE DISORDERS - Cost Studies**

**PDB13: BUDGET IMPACT ANALYSIS OF EMPIAGLIFLOZIN FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT INCREASED CARDIOVASCULAR RISK IN GREECE**
OBJECTIVES: To investigate the budgetary impact of adding empagliflozin to standard of care (SoC) for the treatment of adult patients with Type 2 diabetes mellitus (T2DM) and high cardiovascular risk (CV) in Greece. METHODS: A budget impact model was adapted from a third-party payer perspective (National Organization for Healthcare Services Provision [EOPYY]) to delineate the financial implications of introducing empagliflozin as add-on to SoC over 3 years. The model assumed Greek epidemiological data and local reimbursement requirements. Drug use and diabetes-related complication events were estimated based on the drug use and event rates seen in EMPA-REG OUTCOME 3-year trial, respectively. Directly reimbursed costs associated with drug acquisition and clinical events management were included in the analysis and corresponded to 2016 costing year. Officially published sources were used to derive unit costs and resource consumption was based on experts’ advice. The model measured outcomes were incremental budget impact and potential number of events saved for empagliflozin versus SoC for treatment of T2DM patients with high CV risk. RESULTS: The total number of eligible Greek patients receiving empagliflozin as add-on treatment was estimated at 2.475, 4.400, and 5.500 in the years 1 to 3, respectively. Patients on empagliflozin experienced lower rates of diabetes-related clinical events resulting in 40 hospitalizations for heart failure avoided and 71 lives saved. Over 3 years, cost-savings of €1,058,670 were generated due to less management costs compared to SoC. The total annual incremental cost associated with the introduction of empagliflozin as add-on therapy to SoC was €802,267, €1,386,996, and €2,265,217, for years 1 to 3, respectively, resulting in a total 3-year budget impact of €4,454,480. CONCLUSIONS: The analysis suggests that, the clinical benefits of empagliflozin as add-on to SoC for adult Greek patients with increased CV risk come at a reasonable and bearable cost for payers in Greece.

PDB14: VARIOUS STRATEGIES OF MANAGEMENT OF PATIENTS WITH DIABETIC POLYNEUROPATHY: MODELING OF CLINICAL OUTCOMES AND PHARMACOECONOMIC ANALYSIS

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OBJECTIVES: To analyze strategies of management of patients with diabetic polyneuropathy (DPN) considering the prevalence of DPN and diabetic foot (DF) in Russia. METHODS: The analysis was based on epidemiologic data on DPN and DF, and placebo controlled trials (ALADIN III for alpha-lipoic acid, and D. Ziegler study for Actovegin). Strategies with alpha-lipoic acid (1st group) and with Actovegin (2st group) were compared. In both cases, a 160-day course consisted of 20 days of parenteral injection in hospital, and 140 days of outpatient oral administration. Clinical outcomes and health care system costs were analyzed; cost-effectiveness ratio (CER) was calculated. The share of patients without DF was the main measure of effectiveness. Costs of the drugs, and hospital and outpatient treatment for budget holder were evaluated in two equal-sized groups. During the sensitivity analysis, clinical outcomes (risk of DF) were modeled with increment of 100 persons from 100 to 1000 patients. RESULTS: The cohort of 10 000 patients with type 2 diabetes mellitus contained 6100 patients with DPN including 3700 patients with medium or severe stages. 2100 persons were in risk group for DF, including 1100 patients with high risk. 6100 patients with DPN including 3700 patients with medium or DF) were modeled with increment of 100 persons from 100 to 1000 patients. The cost of the treatment in patients without DF was 70.02% and 62.7%. CER were 103,556.19 in alpha-lipoic acid group and Actovegin group, respectively. The number of amputations in these groups was 70 and 56. The costs of 160-day treatment was 64,929.73 RUB in the 1st group, and 64,355.73 RUB in the 2nd group. The share of patients without DF was 70.02% and 62.7%. CER were 103,556.19 in alpha-lipoic acid group, and 91,910.50 in Actovegin group. The sensitivity analysis confirmed the advantage of Actovegin administration. CONCLUSIONS: The study showed clinical and pharmacoeconomic advantages of Actovegin administration in patients with DPN and DF. This strategy has more preferable CER and lower costs for public health care system.

PDB15: ESTIMATING THE COST OF DIABETES-RELATED CARDIOVASCULAR COMPLICATIONS IN SELECTED CENTRAL AND EASTERN EUROPEAN COUNTRIES

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OBJECTIVES: Cardiovascular complications (CVCs) in diabetes mellitus (DM) are important from clinical and economic perspective. Pragmatic search of literature demonstrated lack of cost data for Central and Eastern Europe (CEE), while the rapid health technology assessment (HTA) advancement requires substantiated information to guide decisions. We aimed to estimate the direct public payer medical costs of CVCs in Bulgaria, Lithuania, Poland, Republic of Srpska, Bosnia and Herzegovina (RSBH), Romania, and Slovenia. METHODS: The considered CVCs included: myocardial infarction (MI), unstable (UA)/stable angina pectoris, peripheral vascular disease (PVD), heart failure (HF), stroke, transient ischemic attack, painful neuropathy, retinopathy, end-stage renal disease (ESRD), and diabetic foot. Local clinical and HTA experts provided data (based on experience, literature, databases, etc.) on epidemiology, rate/prevalence of CVCs, mortality (at the event and during follow-up), and cost (event, 1st year, subsequent years; split into hospitalizations, other procedures, and drugs) by filling a unified questionnaire. All doubts and inconsistencies were discussed. RESULTS: The total cost (all costs expressed in Euros per annum) amounted to 1,231 million in Poland, 581 million in Romania, 103 million in Bulgaria, 76 million in Slovenia, 47 million in RSBH, and 26 million in Lithuania (hospitalizations only, resulting in possible underestimation). The cost per single DM patient was similar for Romania, Slovenia, Poland, and RSBH (range 586–759) and lower in Lithuania (267.6) and Bulgaria (218.5). The average (for all countries, except Lithuania) share of individual CVCs in total cost is largest for HF (20.9%), followed by around 13% for MI, UA, stroke, and ESRD. CONCLUSIONS: Our study is the first attempt to assess the cost of DM-related CVCs in CEE and can be used in economic modelling. CVCs form an important financial burden for public payers. Collecting data for several countries is challenging as available information differs, but it allows quality checks by juxtaposing the input parameters.

PDB16: ECONOMIC BURDEN OF CARDIOVASCULAR DISEASE IN TYPE 2 DIABETES: A SYSTEMATIC REVIEW

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OBJECTIVES: Cardiovascular diseases (CVD) constitute major comorbidities in type 2 diabetes (T2DM), contributing to substantial additional treatment costs. An updated overview of its cost impact has not been presented. Our objective was to systematically review published articles describing the costs associated with treating CVD in people with T2DM. METHODS: Two reviewers independently searched Medline, Embase, and abstracts from scientific meetings for original research published between (2007–2017), with no restrictions placed on publication language. Studies reporting direct and/or indirect costs of T2DM at either a macro level (e.g., burden of illness for a country) or micro level (e.g., cost incurred by one patient) were included. Extracted costs were inflated to 2016 values and converted to USD. RESULTS: Out of 81 articles identified, 24 were accepted for analysis, of which 14 were full articles and 10 abstracts. Studies from 13 countries were included: Brazil, Croatia, Estonia, India, Italy, Japan, Mexico, Scotland, South Korea, Spain, Sweden, United States, and the United Kingdom. CVD comorbidities in patients with T2DM incurred a significant burden both at a population and patient level. Two studies reported results from a population level. CVD costs contributed from 32%–49% of the total direct costs of treating T2DM (weighted average=42%). From a patient level, compared to patients with T2DM without CVD the median annual cost per patient for cardiovascular disease, coronary artery disease, heart failure and stroke were 112%, 107%, 59%, 322% higher, respectively (average=91%). Two studies reported indirect costs of 37% (Brazil) and 60% (UK) of total costs. Discount rates were not reported in any of the studies. A description of the model/type of economic evaluation undertaken was described in 75% of the studies. CONCLUSIONS: Globally, CVD exerts a substantial additional costs to the treatment of diabetes for both healthcare systems (+42% to total cost) and per patient (+91% annually).

PDB17: COST OF TYPE 2 DIABETES MANAGEMENT AND ASSOCIATED COMPLICATIONS IN THE UNITED KINGDOM

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OBJECTIVES: The objective of this study was two-fold. Firstly, to systematically collect up-to-date published cost data for management (pharmacotherapy) and associated complications (cardiovascular, renal, eye disease and
OBJECTIVES: The objective of this study was two-fold. Firstly, to collect up-to-date published cost data for management (pharmacotherapy) and associated complications (cardiovascular, renal, eye disease, diabetic foot and acute events) of type 2 diabetes mellitus in Spain for use in the CORE Diabetes Model (CDM). Secondly, where data was scarce, calculations were carried out to estimate the cost inputs for the CDM. METHODS: A pragmatic literature review for published direct medical costs in English and local languages was performed in four European markets (France, Germany, Italy and Spain) in years 2011-2017. The search was conducted in Embase, MEDLINE, EconLit and NHS EED. Spanish costs were collected from a national or regional public healthcare payer or third party insurer perspective in peer-reviewed journals and on government websites. High impact sources were prioritised such as government tariffs and publications, registry data, physicians’ consortium publications or health technology appraisals. Hospital diagnosis-related group (DRG) and ambulatory tariffs were used to update procedures costs, event costs and costs of contacts with healthcare professionals. Where possible, complications costs were taken from the Ministry of Health website (DRG costs) and via eSalud platform. Pharmacotherapy costs were estimated using published prices from the Official College of Pharmacists in Spain. All costs were inflated to 2017 prices, using the Spanish consumer price index. RESULTS: After duplicates were removed there were 1,489 records from four European markets that included 302 abstracts from Spain. 27 articles met the eligibility criteria. The highest cost was for end-stage renal disease ranging between €6,830 and €41,646 followed by diabetic foot (€9,509), myocardial infarction (€6,586) and non-fatal stroke (€6,544). Other cardiovascular, renal and eye disease cost are also identified. Costs are annual. CONCLUSIONS: This study provides the most up-to-date direct medical costs for type 2 diabetes complications and management for use in the Spanish setting.

PDB18: COST OF TYPE 2 DIABETES MANAGEMENT AND ASSOCIATED COMPLICATIONS IN SPAIN

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OBJECTIVES: The objective of this study was to generate a set of updated costs for diabetes complications and care systems and constitute a major part of the cost of diabetes. Studies have shown that health care utilisation and costs of diabetes complications are higher among older patient groups. The study aims to systematically collate the available information on costs of major complications of type 2 diabetes mellitus in the United Kingdom (UK) for use in the CORE Diabetes Model (CDM). Secondly, where data was scarce, calculations were carried out to estimate the cost inputs for CDM. METHODS: A systematic literature review (SLR) for published direct medical costs from the UK’s National Health Service and societal perspective was performed in peer-reviewed journals and on government websites in years 2011-2017 in English. The SLR was conducted according to the general principles for undertaking systematic reviews in health care. These methods adhere to the UK’s National Institute for Health and Care Excellence standards for evidence generation. Where the papers did not present primary data the references were explored. A quality assessment of included studies was performed using either the checklist for assessing costing studies or the checklist for assessing cost-effectiveness studies. When conducting calculations, pack sizes, dosages, treatment duration and number of hospital visits were taken into account. All parameters were converted to British Pound and updated to 2016 prices by an inflation factor. RESULTS: The SLR identified 2,472 records of which 52 met the final eligibility criteria. Non-fatal stroke cost was the highest among cardiovascular complications (£7,154), followed by myocardial infarction (£6,706) and congestive heart failure (£3,355). Overall, renal complications were the most costly with renal transplant being the highest (£42,060). Eye disease costs spanned between £109 and £2,557 for retinopathy laser treatment and cataract operation respectively. Diabetic foot amputation cost was £13,926 followed by gangrene treatment at £3,583. Costs are annual. CONCLUSIONS: This study presents an updated set of costs for diabetes complications and management for use in the UK setting.

PDB19: COSTS OF MAJOR COMPLICATIONS OF TYPE 2 DIABETES: A SYSTEMATIC REVIEW

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OBJECTIVES: Diabetes complications such as coronary heart disease pose a significant economic burden to health care systems and constitute a major part of the cost of diabetes. Studies have shown that health care utilisation and costs of diabetes complications are higher among older patient groups. The study aims to systematically collate the available information on costs of major complications of type 2 diabetes mellitus in Australia, Canada, UK and USA. METHODS: Published literature is searched in Medline, Embase, Cochrane, Scopus and EconLit to identify relevant English-language articles for the period 2005 to 2017. The review included studies that present monetary estimates on costs of one or more type 2 diabetes mellitus complications among adults 18 years and above. All costs are inflated to 2016 values using the health care component of consumer price indices in the respective countries and converted into 2016 international dollars (Int$) to facilitate comparability across countries, with information to enable translation into local currencies. RESULTS: Studies on direct costs of type 2 diabetes complications, most of which were conducted from a health care payer perspective using cost data from administrative databases, were included. The annual direct medical cost of myocardial infarction associated with diabetes is Int$13,833, Int$9,875 and Int$17,193 per patient in Australia, UK and US, respectively. Stroke and amputation costs are Int$ 16,623 and 19,405
in Australia and Int$10,535 and 14,778 in UK, respectively. Australia and US spend Int$18,424 and Int$13,030 as direct medical cost of heart failure. Diabetic foot ulcer costs were Int$18,285, Int$17,145, Int$12,241 in Australia, Canada and US. Costs of nephropathy varied considerably ranging from Int$8,590 in US to Int$34,002 in Australia. CONCLUSIONS: Despite variation in methodology and findings on estimated costs, all of the reviewed studies agree that costs of complications constitute a major part of the economic burden of diabetes.

PDB20: THE FINANCIAL BURDEN OF DIABETES MELLITUS TYPE 1 AND TYPE 2 IN EGYPT

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OBJECTIVES: Diabetes Mellitus (DM) imposes a huge economic burden on individuals, families, health care systems and countries. This cost of illness study aims to calculate the direct and indirect costs incurred by both governmental and private sectors in Egypt during 2016. METHODS: Both, top-down and bottom-up approaches were used. Data was collected from: the governmental sectors for spending on diabetes management, retail audit data for medication costs spent on both diabetes and its complications by private sector, interviews with five thousand DM subjects conducted nationwide stating direct medical costs and productivity loss as indirect cost. Premature mortality cost was calculated from cause of mortality reports and the average daily wage from Egyptian reports. RESULTS: Total cost of Diabetes was calculated to be (EGP 25.2 billion) equivalent to (USD 3.5 billion), using the exchange rate of EGP 1 = USD 0.13976. The direct medical cost was calculated to be (EGP 22.3 billion), where DM complications management cost recorded the highest share (65%) representing (EGP 14.4 billion). The cost of DM medications was (EGP 2.5 billion), cost of hospitalization and amputation was (EGP 1.6 billion), and cost of investigations and monitoring was (EGP 3.7 billion). Indirect cost was calculated to be (EGP 2.9 billion), with highest share caused by absenteeism (EGP 2.1 billion) and premature mortality (EGP 740 million). CONCLUSIONS: The highest burden on both governmental and private sectors was attributed to the management of complications cost. More effort should be exerted to decrease the cost of complications in order to lower the diabetes burden in Egypt. This can be achieved by reaching higher level of glycemic control of subjects with DM, through more awareness, adherence and monitoring programs at the primary care units, increasing the number of diabetic educators, and focusing on DM treatment protocols that provide more glycemic control.

PDB21: ONE-CENTER ANALYSIS OF COST ASSOCIATED WITH ACROMEGALY MANAGEMENT IN POLAND.

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OBJECTIVES: Acromegaly is a rare disease caused by growth hormone (GH) hypersecretion from pituitary adenoma. Peripheral action of GH is mediated by insulin-like growth factor-1 (IGF-1), and results in acral overgrowth and metabolic complications. Acromegaly and its treatment is associated with high direct and indirect costs, caused by the necessity of life-long treatment of hormonal normalisation and systemic disturbances management. The aim of our study was to assess the costs of medical care of patients with acromegaly in real life setting in one academic centre in Wroclaw. METHODS: Data was collected from medical charts of patients diagnosed, treated and followed-up in Department of Endocrinology, Diabetes and Isotope Therapy in years 2011-2016. RESULTS: The retrospective analysis was performed on 20 consecutive patients (12 males, 8 females), aged 53.4 ± 8.4 years, with mean disease duration of 11.1 ± 7.8 years. In this group 6 patients were successfully operated, other 14 are still on long-term somatostatin receptor ligands (SRL) therapy. In the analysis, the costs of surgeries (pituitary adenoma neurosurgery, cholecystectomy, thyroidectomy), medical therapy (SRL, dopamine agonists, replacement therapy, complications' therapy) and radiotherapy were calculated. Costs of therapy using long-term SRL amount to circa 15.844 Euro annually, what constitutes 72% of all costs. Second largest expense group consists of costs of neurosurgery which are valued at 3.807 Euro, what is 17% of total annual costs. Next significant expense group are costs of hospitalisation which add up to 1001 Euro constituting 5% of total annual costs. Other costs had a marginal share in the total expenditure therefore being insignificant. CONCLUSIONS: Life-long acromegaly management is highly expensive. The major costs represent SRL therapy. Early diagnosis at the initial stage of the disease increases opportunity of successful surgery and reduce the costs of medical therapy.

PDB22: AVAILABILITY OF HEALTH ECONOMIC MODEL INPUTS IN JAPAN: A Targeted Literature Review

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OBJECTIVES: Cost-effectiveness analyses are playing an increasingly important role in Japan, as an integral part of the upcoming introduction to health technology assessment (HTA). However, current data availability to conduct such analyses may be limited. We conducted a targeted literature review to assess the availability of health economic (HE) model inputs for use in type 2 diabetes mellitus (T2DM) patients in Japan. METHODS: A comprehensive literature review was performed to identify studies published between 2010 and 2016 that reported costs and utility values associated with the management and complications of T2DM in Japan. PubMed, EMBASE and Ichushi Web databases were searched using medical headings and key terms in English and Japanese for macro – and microvascular complication costs and associated utility values. A manual search of Japanese sources related to medical societies, conferences, and diabetes networks was also conducted to enhance the search results. Articles that met the inclusion and exclusion criteria were screened at the title and abstract level followed by full-text screening by two reviewers. RESULTS: A total of 35 articles met the inclusion and exclusion criteria. Cost data were extracted from 27 articles while utility data were extracted from 17 articles. The identified articles included direct cost data pertaining to cardiovascular, eye, renal and acute diabetes-related complications as well as foot ulcer, neuropathy and amputation. Most health state utility values reported for T2DM and commonly occurring complications were based on the EQ-5D questionnaire. CONCLUSIONS: While substantial HE model input cost data for T2DM patients in Japan was identified, data on utility values remains limited for some common T2DM complications. In addition, identified utility studies were often limited in terms of patient numbers or were outdated. Further research in this area is needed to establish standardized and strengthened HE modelling inputs for the rising HTA needs in Japan.

PDB23: GROWTH OF NATIONAL HEALTH INSURANCE EXPENDITURE RELATED TO ANTIDIABETICS AND THEIR PROJECTIONS UNTIL 2020

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OBJECTIVES: National health insurance expenditure related to diabetes represents €10 billion, i.e. 8% of all expenditure. Mean expenditure per diabetic patient has stabilized since 2012, but the use of expensive new drugs could modify this curve. METHODS: This study was based on the population covered by the national health insurance general scheme that had received ≥1 reimbursement for antidiabetic drugs in 2012 and ≥1 reimbursement 3 years later. Treatment regimens were defined in the French health insurance system database (SNIIRAM) by reimbursements over a 4-month period to minimize the risk of wrongly attributing a modification of monotherapy to dual therapy. Projections were performed until 2020. RESULTS: Between 2012 and 2015, monotherapy and triple therapy rates remained stable (39% and 13% of patients), while the use of dual therapy decreased from 25% to 23% and the use of insulin therapy increased from 23% to 25%. Use of an insulin + other antidiabetic combination increased from 53% to 56%. The use of metformin, gliptins and GLP-1 agonists increased, while the use of sulphonylureas and other antidiabetics decreased. Expenditure related to antidiabetics increased from €1.09 billion to €1.2 billion. Half of the increased expenditure related to insulin therapy (€514 to €614 million) was due to the increased use of insulin + GLP-1 agonist combinations (€62 to €115 million, +€53M). Simple projection of the number of diabetic patients would result in an increase in the expenditure attributable to antidiabetics of +€178M between 2015 and 2020. According to various assumptions (treatment intensification, increasing use of certain molecules), this increase would be situated between +€208M and +€626M. CONCLUSIONS: The financial impact related to modifications of the treatment modalities of diabetes constitutes a major challenge to a health system subject to budgetary constraints and in the presence of innovative treatments in fields such as oncology or hepatitis C.

PDB24: COSTS OF ADDING SITAGLIPTIN OR SULPHONYLUREA TO METFORMIN: AN OBSERVATIONAL STUDY USING ADMINISTRATIVE DATABASE OF ITALY

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OBJECTIVES: To compare health-care costs of diabetic patients who start treatment with Sitagliptin (SITA) or Sulphonylurea (SUL), using Health Information Systems (HIS) of the Marche region. METHODS: From HIS, which collects information related to hospitalizations, drugs prescriptions and outpatient visits, we identified all diabetic patients who started treatment with SITA or SUL in addition to MET, during the period 2009-2011. To identify the cohort of interest, we applied the following inclusion criteria: first prescription (index-prescription) of SITA (ATC A10BH01, A10BD07) or SUL (ATC A10BB, A10BD02); adherence to SITA or SUL treatment, measured by Medication Possession Ratio (MPR), ≥80%; adherence to MET (ATC A10BA02) treatment, MPR≥80%, during the year before the index-prescription. Selected patients were stratified in SITA or SUL users, according to the index-
empagliflozin was estimated to have a 100% probability of being cost-effective from the payer perspective and PLN21198 (€4,907) per QALY from the payer plus patient perspective, which is well below the effectiveness threshold in Poland (PLN130002(€30093)/QALY). Irrespective of the cost perspective chosen, empagliflozin was estimated to have a 100% probability of being cost-effective as an add-on to standard care (SoC) in Polish patients with Type 2 Diabetes (T2D) at high risk for cardiovascular events (CV). Method: An existing health economic, stochastic model was used to simulate individual profiles of patients treated with empagliflozin 10mg added to SoC versus patients treated with SoC only, over a lifetime horizon. Modelling of diabetes-related events was implemented using a risk equations derived from the EMPA-REG OUTCOME™ study patient-level data for 10 cardiovascular and renal events by fitting parametric survival functions. Model outcomes included annual and cumulative event rates, life years (LY) and quality-adjusted life-years (QALYs). Two perspectives were adopted using cost data from Polish sources: the public healthcare payer (PP) and the public payer plus patient (PP+P) perspective. Simulated costs and outcomes were discounted at a 5.0% and 3.5% annual rate, respectively. Probabilistic (PSA) and deterministic (DSA) sensitivity analyses were conducted to address uncertainty and test the robustness of the model results. Results: Adding empagliflozin 10mg to SoC resulted in longer survival (9.8 LY vs 8.7 LY with SoC) and a QALY gain of 0.81 at an additional cost of PLN10895 (€2,522) (PP) and PLN17184 (€3,978) (PP+P) versus SoC only. The base-case incremental cost-utility ratio (ICUR) was PLN13440 (€3,111) per QALY from the healthcare payer perspective and PLN21198 (€4,907) per QALY from the payer plus patient perspective, which is well below the cost-effectiveness threshold in Poland (PLN130002(€30093)/QALY). Irrespective of the cost perspective chosen, empagliflozin was estimated to have a 100% probability of being cost-effective. Base-case results were shown to be robust across a range of model parameters, with empagliflozin remaining cost-effective in all DSA scenarios.
investigated. CONCLUSIONS: Empagliflozin 10mg represents a highly cost effective option for the treatment of T2D patients with high risk of CV events in Poland.

PDB27: COST-EFFECTIVENESS OF SWITCHING TO INSULIN DEGLUDEC (IDEG) IN REAL-WORLD CLINICAL PRACTICE IN ITALY

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OBJECTIVES: To evaluate the cost-effectiveness of switching to IDEg from another basal insulin in type 1 (T1D) or type 2 (T2D) diabetes in routine care. METHODS: Data were drawn from an Italian subpopulation of EU-TREAT, a multicentre, retrospective chart review study, which investigated switching from any basal insulin (± prandial insulin [± oral antidiabetic drugs in T2D]) to IDEg. Parameters in the base-case model were change in hypoglycaemia rates, basal and prandial insulin dose and body weight at 6 months post-switch and cost of treatment and complications. A 1-year, cost-effectiveness model evaluated the Incremental Cost-Effectiveness Ratio (ICER) in terms of cost per Quality-Adjusted Life Year (QALY). The robustness of the results were tested with sensitivity analyses by varying input parameters. To validate the base-case results, a lifetime horizon analysis was conducted using the IMS CORE Diabetes Model. RESULTS: Patients with T1D (n=397) were mean (SD) age 47.3 (14.5) years; previous insulin regimens were NPH 1.8%, insulin glargine U100 73.8%, insulin detemir 23.9%. Patients with T2D (n=155), were age 65.6 (9.2) years; previous insulin regimens were NPH 2.6%, insulin glargine U100 42.5%, insulin detemir 54.2%. Short-term cost per QALY gained for IDEg versus original basal insulin was estimated at €2897 for T1D (below the Italian ICER threshold of €20,000) and was dominant (lower cost and improved QALYs) in T2D. IDEg remained either highly cost-effective or dominant after elimination of any benefit in severe/non-severe hypoglycaemia, basal insulin dose and resource utilisation, in T1D and T2D. IDEg was dominant in the lifetime model for T1D and T2D and cost-savings were even greater compared with the short-term model. CONCLUSIONS: In an Italian population, switching to IDEg in routine care is highly cost-effective or dominant versus not switching basal insulin, for patients with T1D or T2D who are considered appropriate for treatment with IDEg.

PDB28: COST-EFFECTIVENESS OF EMPAGLIFLOZIN FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT INCREASED CARDIOVASCULAR RISK IN GREECE

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OBJECTIVES: To evaluate the cost-effectiveness of empagliflozin, in addition to standard of care (SoC), for the treatment of adult patients with Type 2 diabetes mellitus (T2DM) and high cardiovascular risk (CV) in Greece. METHODS: A health economic model was used to project clinical and economic outcomes of patients receiving empagliflozin plus SoC compared with those receiving SoC alone over a lifetime horizon. Long-term CV and renal event rates were derived from patient level data from EMPA-REG-OUTCOME trial by fitting time-dependent parametric survival functions. 5,000 individual patient profiles randomly sampled from the trial were simulated using a time to event approach. Model extrapolated outcomes included life years (LYs), quality-adjusted life years (QALYs), costs as well as incremental cost-effectiveness ratios (ICERs). Following a Greek third-party payer perspective, only direct medical costs related to drug acquisition as well as fatal and non-fatal developed diabetes-related complications were considered (€ 2016). Resource consumption associated with each treatment was based on experts’ advice. Cost units and utility data were extracted from literature and publicly available official sources. Sensitivity analyses explored the impact of changes in input data. RESULTS: Over a patient’s lifetime, empagliflozin was predicted to result in longer mean survival (14.01 LY versus 11.87 LY with SoC) and reduced rate of clinical events accumulating 7.75 QALYs versus 6.83 QALYs on SoC alone at additional costs of €4,235. The generated ICER of empagliflozin was €4,633 per QALY gained. One-way sensitivity analysis confirmed empagliflozin cost-effective profile. At the defined willingness-to-pay threshold of €34,000 per QALY gained, probabilistic sensitivity analysis showed that empagliflozin was estimated to have a 100% probability of being cost-effective relative to SoC. CONCLUSIONS: Empagliflozin added to SoC was estimated to be a highly cost-effective treatment option for the treatment of T2DM in adults with increased CV disease risk in Greece.

PDB29: METFORMIN EXTENDED VERSUS IMMEDIATE RELEASE IN SAUDI ARABIA: A COST-EFFECTIVENESS ANALYSIS

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**OBJECTIVES:** Metformin extended release (XR) has higher treatment adherence than immediate release (IR) formulation, due to lower pill burden and better gastrointestinal tolerability, leading to better glycated hemoglobin (HbA1c) levels control. This study aimed to compare metformin XR versus metformin IR monotherapy for type 2 diabetes mellitus (T2DM) considering the long-term cost-effectiveness outcomes. **METHODS:** A discrete event simulation model based on a comprehensive literature review was used to estimate costs and effectiveness of a therapeutic sequence started with metformin XR versus metformin IR in T2DM patients. This model was based on UKPDS modelling framework. HbA1c profile progression was modelled monthly, the impact of adherence on effectiveness was considered and Saudi Arabia specific data was included whenever available. This study assessed quality adjusted life years (QALY), time to insulin therapy, time spent with diabetes complications and lifetime costs. **RESULTS:** Metformin XR represents lifetime savings of 3,028 SAR per patient comparing with IR formulation (total lifetime costs with metformin XR: 420,356 SAR vs IR: 423,384 SAR). The delay in more expensive advanced lines of therapy in patients with metformin XR as first-line therapy (time to insulin initiation with metformin XR: 12.31 years vs IR: 12.05 years) leads to lower lifetime drug costs (drug costs with metformin XR: 234,420 SAR vs IR: 236,826 SAR). QALY are estimated to be higher with XR formulation compared to IR (12.46 QALY vs 12.42 QALY, respectively). Diabetes complications as renal failure were slightly less prolonged (time spent with renal failure with metformin XR: 0.236 years vs IR: 0.240 years). Diabetes complications also had lower costs in patients with metformin XR (diabetes complications’ costs with metformin XR: 185,936 SAR vs IR: 186,558 SAR). **CONCLUSIONS:** Treating Saudi Arabia patients with metformin XR as first-line therapy, instead of IR formulation, is cost saving and improves health outcomes.

**PDB30: COST-EFFECTIVENESS OF EMPAGLIFLOZIN (JARDIANCE®) IN THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN TURKEY BASED EMPA-REG OUTCOME DATA**

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**OBJECTIVES:** The aim of this study is to compare empagliflozin and standard of care (SoC) for Diabetes mellitus type 2 (T2DM) treatment with a cost-effectiveness analyses in Turkey. In this study, a simulation model designed for time to first cardiovascular (CV) event in T2DM patients was used in the EMPA-REG OUTCOME study population based on health care payer perspective. **METHODS:** A cost-effectiveness model was created to stimulate profiles of patients treated with empagliflozin versus patients treated with placebo, both as an adjunct to standard of care (SoC) over a life time horizon. Time dependent survival regression analysis was performed on the EMPA REG OUTCOMES trial data to model event rates over time and the interaction between events. Model outcomes included costs incurred, life years (LY) and quality adjusted life years (QALYs). Future costs and QALYs were discounted at a 3.5% annual rate according to health care payer’s opinion. **RESULTS:** According to effectiveness results, empagliflozin plus SoC was associated with longer survival (20.06 LY vs 16.72 LY with placebo plus SoC) with an incremental LY 3.34. Moreover, it was designated that the QALYs gained by empagliflozin was 10.13 and the QALYs gain by SoC was 8.90. The incremental QALYs was 1.23. Comparing placebo with empagliflozin’s incremental cost and effectiveness values in the analysis of empagliflozin and cost per patient, the ICER was found as $2183.8 per the QALY and it was $804.6 per LY gain. According to time the first CV event and survival outcomes of T2DM, empagliflozin is a cost-effective treatment. Probabilistic sensitivity analyses showed with 100% accuracy that empagliflozin is more cost-effective as compared to SoC. **CONCLUSIONS:** Empagliflozin is a cost effective additive treatment over SoC for T2DM patients. The cost-effectiveness results was further confirmed with sensitivity analysis.

**PDB31: COMPARISON OF THE LONG-TERM COST-EFFECTIVENESS OF IDEGLIRA VERSUS MULTIPLE DAILY INSULIN INJECTIONS IN THE SPANISH SETTING USING REAL-WORLD CLINICAL DATA**

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**OBJECTIVES:** IDegLira (fixed-ratio combination insulin degludec/liraglutide) represents an alternative treatment option for people with type 2 diabetes (T2DM) not optimally treated with multiple daily insulin injections (MDII). The present analysis compared the long-term cost-effectiveness of IDegLira with remaining on MDII for people with T2DM in the Spanish setting using real-world data. **METHODS:** Clinical data were taken from the sub-group of people with T2DM in the single-arm, 12-month, European Xultophy Treatment Retrospective Audit (EXTRA) real-world evidence study, who were receiving MDII at enrolment and switched to IDegLira (N=153, 73.9% basal insulin, 84.3% bolus
insulin, 17.6% premix insulin). The QuintilesIMS CORE Diabetes Model was used to project health-economic outcomes over patient lifetimes. The IDegLira arm was modelled by applying the treatment effects seen on initiation of IDegLira, with the MDII arm modelled based on baseline characteristics before initiation of IDegLira. Costs were accounted from a Spanish National Health System perspective. Long-term outcomes were discounted at 3% annually and sensitivity analyses were performed. **RESULTS:** Compared with remaining on MDII treatment, IDegLira was associated with reduced cumulative incidence and delayed onset of diabetes-related complications, driven by reductions in glycated hemoglobin, systolic blood pressure, and body mass index on switching from MDII to IDegLira. Improved clinical outcomes resulted in improved discounted life expectancy (by 0.14 years) and quality-adjusted life expectancy (by 0.14 quality-adjusted life years [QALYs]) with IDegLira. IDegLira was associated with increased diabetes medication costs, but this was partially offset by cost savings due to diabetes-related complications avoided. Overall, IDegLira was associated with a mean increase in lifetime costs of EUR 415 per patient. IDegLira was associated with an incremental cost-effectiveness ratio of EUR 3,013 per QALY gained versus MDII. **CONCLUSIONS:** IDegLira was projected to be a cost-effective treatment for people with T2DM not optimally treated with MDII in the Spanish setting.

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**PDB32: COST-EFFECTIVENESS OF COMMUNITY PHARMACISTS’ INTERVENTION FOR PATIENTS WITH TYPE 2 DIABETES IN PREVENTION OF DIABETIC RETINOPATHY**

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**OBJECTIVES:** This analysis assesses the cost-effectiveness of interventions conducted by community pharmacists in Japan that modify the lifestyle of patients with type 2 diabetes mellitus (T2DM). **METHODS:** We conducted the Community Pharmacists Assists (COMPASS) Project, a cluster randomized controlled trial in Japan. In the project, community pharmacists support these patients’ lifestyle modification within three minutes. The result indicated that brief intervention conducted by community pharmacists could significantly decrease HbA1c in patients with T2DM. Using the Markov model, we estimated the effect of the intervention conducted in the COMPASS Project on the medical cost of diabetic retinopathy in the future. We conducted the analysis from payer’s perspective. A 10-year model with annual cycle duration was developed. Progression of diabetic retinopathy was characterized into three degrees. Incremental cost effectiveness ratios (ICER) were expressed in JPY per quality-adjusted life year (QALY) gained with costs discounted at 3% over 10 years. We conducted deterministic sensitivity analysis to assess the effect of uncertainly on the model. **RESULTS:** In the survey periods, medical cost was calculated at 2,227,817 JPY for the intervention group, while it was 2,251,375 JPY for the control group. These interventions conducted in the COMPASS Project were shown to be cost-effective with an ICER of -2,441,196.11 JPY/QALY gained. Sensitivity analysis did not change the results. **CONCLUSIONS:** This analysis suggests that the intervention conducted in the COMPASS Project was cost-effective for diabetic retinopathy. Hence, community pharmacists should actively support patients with diabetes.

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**PDB33: DELAYING SECOND LINE DIABETES TREATMENT ONSET IN PATIENTS UNCONTROLLED WITH METFORMIN XR IN SAUDI ARABIA: COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** Type 2 diabetes mellitus (T2DM) treatment guidelines recommend therapy intensification with a second oral agent if glycated hemoglobin (HbA1c) target is not achieved over three to six months. However, in clinical practice, therapy intensification occurs as soon as one month. The objective of this study was to compare the cost-effectiveness of treatment intensification with metformin/ DPP4i inhibitor fixed-dose combination in uncontrolled patients (HbA1c > 7.5%) at three versus one month(s) after metformin XR monotherapy initiation. **METHODS:** A discrete event simulation model was created based on UKPDS and a comprehensive literature review was performed in order to model lifetime therapeutic sequence in T2DM. This model was adapted to include a monthly HbA1c profile progression, an adherence impairment on effectiveness and to consider Saudi Arabian specific data. This model allowed the lifetime assessment of quality adjusted life years (QALY), persistence in metformin, time to insulin therapy, percentage of patients with diabetes complications and costs. **RESULTS:** Postponing therapy intensification will lead to more patients achieving HbA1c target, augmenting metformin monotherapy (3 months group: 3.58 years vs 1 month group: 3.28 years) and delaying insulin therapy initiation by 6.8 months (3 months group: 12.31 years vs 1 month group: 11.75 years). As a consequence, cost savings of 7,591 SAR (3 months group: 420,356 SAR vs 1 month group: 427,948 SAR) and QALY gains (3 months group: 12.46 QALY vs 1 month group: 12.39 QALY) are estimated. The percentage of patients with long-term diabetes complications as congestive heart failure decreases with postponing therapy intensification (3 months group: 12.02% vs 1 month group: 12.17%), as well as diabetes
complications costs (3 months group: 185,936 SAR vs 1 month group: 186,310 SAR). **CONCLUSIONS:** Saudi Arabian guidelines recommendation is not only cost saving but also increases metformin persistence and time to insulin therapy initiation.

**PDB34: LONG-TERM COST-EFFECTIVENESS OF IDEGLIRA VERSUS BASAL-BOLUS INSULIN AS INTENSIFICATION THERAPIES FOR PEOPLE WITH TYPE 2 DIABETES INADEQUATELY CONTROLLED ON BASAL INSULIN IN SPAIN: PROJECTIONS BASED ON THE DUAL VII TRIAL**

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**OBJECTIVES:** The analysis compared the long-term cost-effectiveness of IDegLira (fixed-ratio combination insulin degludec/liraglutide) and basal-bolus insulin as intensification therapies for people with type 2 diabetes mellitus (T2DM) inadequately controlled on basal insulin from the perspective of the Spanish National Health System (NHS). **METHODS:** Cost (accounted from a Spanish NHS perspective) and clinical outcomes were projected over patient lifetimes using the QuintilesIMS CORE Diabetes Model. Clinical inputs (baseline cohort characteristics and treatment effects) were taken from the DUAL VII study, a 26-week, open-label trial, enrolling 506 people with T2DM with glycated hemoglobin 7-10% on previous insulin glargine U100 (20-50 units/day) plus metformin. Subjects were randomly allocated to once-daily IDegLira or insulin glargine U100 plus insulin aspart (≤4 times/day). Utilities and costs associated with diabetes-related complications were taken from published sources. The costs of insulin Abasaglar and insulin aspart were applied in the basal-bolus insulin arm. Outcomes were discounted at 3% annually. **RESULTS:** IDegLira was associated with increased decreased life expectancy (14.90 versus 14.85 years) and discounted quality-adjusted life expectancy (9.79 versus 9.55 quality-adjusted life years [QALYs]) versus basal-bolus insulin. Improvements resulted from reduced incidence and delayed time to onset of diabetes-related complications, and significantly lower rates of hypoglycemia with IDegLira. IDegLira was associated with higher treatment costs, but this was partially offset by cost savings as a result of avoided diabetes-related complications. Of particular note were the cost savings as a result of avoided cardiovascular complications. An incremental cost-effectiveness ratio of €6,868 per QALY gained was calculated. Univariate and probabilistic sensitivity analyses confirmed that IDegLira was projected to be a cost-effective treatment compared with basal-bolus insulin in the Spanish NHS. **CONCLUSIONS:** IDegLira was projected to be a cost-effective treatment for people with T2DM inadequately controlled on basal insulin, compared with basal-bolus insulin from the Spanish NHS perspective.

**PDB35: COST-EFFECTIVENESS STUDY TO EVALUATE INSULIN GLARGINE COMPARED WITH NPH INSULIN IN PATIENTS WITH TYPE 2 DIABETES UNCONTROLLED WITH ORAL ANTI-DIABETIC AGENTS IN HONG KONG**

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**OBJECTIVES:** Insulin glargine is superior to neutral protamine Hagedorn (NPH) insulin in reducing blood glucose and has lower risk of hypoglycaemia. Due to higher acquisition costs, use of insulin glargine remains second-line in Hong Kong. We conducted a cost-effectiveness analysis of insulin glargine compared with NPH insulin by applying local patient and cost data to a published diabetes outcome model. **METHODS:** The IMS CORE Diabetes Model Version 9.0 was used for projection of complication and economic outcomes. The model was populated with clinical data from the Hong Kong Diabetes Registry. We selected patients with type 2 diabetes, on non-insulin anti-diabetic drugs and were uncontrolled with HbA1c ≥7.5%. Efficacy of intervention with respect to reduction of HbA1c and rates of hypoglycaemia were based on results of Lantus Evaluation in Asian Diabetics study, which compared insulin glargine and NPH insulin in an Asian population. Costs of insulins and diabetes complications were assembled using cost data listed in Hospital Authority Gazette. Costs and outcomes were discounted at 3%/year. A simulation period of 50 years was applied. **RESULTS:** The simulation cohort had mean age 57.3±13.1 years and HbA1c 8.9±1.5%, between 2-8% had established cardiovascular disease, and 23-29% had microvascular complications. Over 50-year simulation, total costs of treating diabetes which included costs related to diabetes complications were modestly higher with insulin glargine (HKD 708,250 [US$ 91,142]) than NPH insulin (HKD 707,289 [US$ 91,018]). Treatment with insulin glargine led to a gain in life year of 0.017 years/patient and in quality-adjusted life year (QALY) of 0.025 years/patient compared with treatment with NPH insulin. The incremental cost-effectiveness ratio of insulin glargine over NPH insulin was HKD 38,788 (US$ 4,991)/QALY, which was below the current gross domestic product per capita in Hong Kong. **CONCLUSIONS:** Applying WHO threshold of cost-effectiveness, insulin glargine was highly cost-effective relative to NPH insulin.

**PDB37: COST-EFFECTIVENESS ANALYSIS OF EMPAGLIFLOZIN IN THE TREATMENT OF T2D WITH PREVIOUS CARDIOVASCULAR DISEASE IN ITALY**
**PDB38: COST-EFFECTIVENESS ANALYSIS OF INSULIN DEGLUDEC VERSUS INSULIN GLARGINE U100 IN TYPE 1 AND TYPE 2 DIABETES PATIENTS FROM THE PORTUGUESE NATIONAL HEALTHCARE SYSTEM PERSPECTIVE: EVIDENCE FROM THE SWITCH 1&2 TRIALS**

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**OBJECTIVES:** SWITCH 1&2 randomised, double-blind, two-period, crossover trials in patients with Type 1 and Type 2 diabetes showed fewer hypoglycaemic events with insulin degludec (IDeg) vs insulin glargine U100 (IGlar U100). The current study assessed the cost-effectiveness of IDeg vs IGlar U100 from a Portuguese healthcare perspective, using data from the SWITCH 1&2 trials. **METHODS:** A short-term cost-effectiveness model was elaborated to calculate effectiveness results for IDeg vs IGlar U100. Hypoglycaemia and insulin dose data from SWITCH 1&2, the costs of insulin, needles, blood glucose tests and hypoglycaemic events in Portugal, and disutilities for different types of hypoglycaemic events have been used to populate the model. Benefits were measured in QALYs. **RESULTS:** In both trials non-severe nocturnal and severe hypoglycaemic events were significantly lower in favour of IDeg. Non-severe daytime hypoglycaemic events did not show any difference in SWITCH 1 trial while in SWITCH 2 trial there were a significant lower number of events in favour of IDeg. End-of-trial basal insulin dose was significantly lower with IDeg vs IGlar U100 while bolus doses in T1DM were similar. IDeg proved to be a cost-effective therapy for T1DM and T2DM showing an incremental cost-effectiveness ratio (ICER) of 7,349.19€/QALY and 21,930.20€/QALY, respectively. Both ICERs were lower than the willingness to pay threshold of 30,000€/QALY. Sensitivity analyses confirmed the robustness of results. **CONCLUSIONS:** This cost-effectiveness study demonstrates that IDeg is a cost-effective therapy over IGlar U100 for T1DM and T2DM patients from the perspective of the Portuguese healthcare system.

**PDB39: COST-UTILITY EVALUATION OF INSULIN GLARGINE (300 U/ML) VERSUS INSULIN GLARGINE (100 U/ML) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN SLOVENIA**

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**OBJECTIVES:** The study aims to assess the cost-utility of insulin glargine 300U/ml (GLA-300) compared to a biosimilar of insulin glargine 100U/ml (GLA-100) and insulin degludec 100U/ml (DEG-100) in patients with type 2 diabetes mellitus in Slovenia. **METHODS:** A cost-utility model was developed to estimate differences in costs and clinical outcomes. The perspective of the analysis was that of a healthcare payer in Slovenia within one year time horizon. Main outcome was incremental cost-effectiveness ratio (ICER) expressed in Euros (EUR) per quality adjusted life years (QALYs). Costs considered were drug costs, resource consumption costs and costs of treating hypoglycaemia. Insulin dosages used per each of the comparators relied on pooled analysis of EDITION 1-2-3 clinical trials. Efficacy in the model was analysed based on comparators’ impact on: incidence of hypoglycaemic events, body mass index and dosage flexibility. Changes of these parameters were cited from EDITION 1-2-3 for
1.3), and other aftercare (1.6, 0.1). Predictors of increased costs were (% change in cost, SD): south region (1.2, [76,751], p<0.001) compared to non hospitalizations (mean [SD]: 1.5 [2.0] vs 1.1 [1.6], p<0.001) and higher costs ($70,808 [$102,568] vs $43,319 [$76,751], p<0.001) associated with incremental health gains with associated cost savings. At the $25,000 cost-effectiveness threshold, PSA estimated a probability of 54% and 99% for GLA-300 being cost-effective in comparison with GLA-100 and DEG-100, respectively. CONCLUSIONS: Based on a reduced incidence of hypoglycaemia and possibility for dose flexibility, GLA-300 is likely to be cost effective in economic and clinical conditions of Slovenia in comparison to GLA-100 and pharmaceoeconomically dominant in comparison to DEG-100.

**PDB40: COST-UTILITY EVALUATION OF INSULIN GLARGINE (300 U/ML) VERSUS INSULIN GLARGINE (100 U/ML) AND INSULIN DEGLUDEC (100 U/ML) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN SERBIA**

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**OBJECTIVES:** The study aims to assess the cost-utility of insulin glargine 300 units/ml (GLA-300) compared to insulin glargine 100 units/ml (GLA-100) and insulin degludec 100 units/ml (DEG-100) in patients with type 2 diabetes mellitus in Serbia. **METHODS:** A cost-utility model was developed to estimate differences in costs and clinical outcomes. The perspective of the analysis was that of a healthcare payer in Serbia within one year time horizon. Main outcome was incremental cost-effectiveness ratio (ICER) expressed in dinars (RSD) per quality adjusted life years (QALYs). Costs considered were drug costs and costs of treating hypoglycaemia. Insulin dosages used per each of the comparators relied on pooled analysis of EDITION 1-2-3 clinical trials. Efficacy in the model was analysed on the comparators’ impact on: incidence of hypoglycaemic events, body mass index and dosage flexibility. Changes of these parameters were cited from EDITION 1-2-3 for comparison with GLA-100, and from network meta-analysis for comparison with DEG-100. Probabilistic sensitivity analysis (PSA) was conducted to test the model robustness. **RESULTS:** In the base case analysis, GLA-300 was associated with incremental QALYs compared to GLA-100 and DEG-100 estimated at 0.0082 and 0.0112, respectively. Total costs associated with GLA-300 were higher than those of GLA-100 (+RSD3,714.9) and lower than those of DEG-100 (-RSD35,560.7). In comparison with GLA-100, the estimated ICER was RSD 452,536/QALY, while in comparison with DEG-100, GLA-300 was pharmacoeconomically dominant as it obtains additional health gains with associated cost savings. At the 3xGDP/capita cost-effectiveness threshold, PSA estimated a probability of 66% and 93% for GLA-300 being cost-effective in comparison with GLA-100 and DEG-100, respectively. **CONCLUSIONS:** Based on a reduced incidence of hypoglycaemia and possibility for dose flexibility, GLA-300 is likely to be highly cost effective in economic and clinical conditions of Serbia in comparison to GLA-100 and pharmaceoeconomically dominant in comparison to DEG-100.

**PDB41: IMPACT OF COMORBID CRITICAL LIMB ISCHEMIA AND DIABETES ON HEALTHCARE RESOURCE USE AND COSTS**

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**OBJECTIVES:** Prevalence of diabetes in peripheral artery disease patients is high and these patients are at increased risk for major cardiovascular events. This study’s aim was to use a retrospective cohort to assess healthcare resource use (HRU) and costs among critical limb ischemia (CLI) patients with diabetes. **METHODS:** Using a major US database comprised of integrated administrative claims and electronic health records (2007-15), we estimated annual all-cause HRU and total healthcare costs for a sample of 3,189 CLI adults ≥50 years. CLI was characterized by rest pain, ulceration or gangrene. HRU and costs were calculated from medical and pharmacy claims for 1 year following first diagnosis of CLI (index date). Patients who died in the post-index period were included. We stratified patients into 2 cohorts: with and without pre-index diabetes diagnosis. Reverse Engineering and Forward Simulation (REFSTM), a hypothesis free machine learning platform that uses Bayesian network inference, was used to build an ensemble of prediction models for hospitalization and annual total healthcare costs of CLI patients. **RESULTS:** Nearly 50% of CLI patients had comorbid diabetes. Diabetics had more hospitalizations (mean [SD]: 1.5 [2.0] vs 1.1 [1.6], p<0.001) and higher costs ($70,808 [$102,568] vs $43,319 [$76,751], p<0.001) compared to non-diabetics. REFSTM selected factors with the highest frequency in both models. Those predictive of hospitalization were (OR, SD): cellulitis and abscess (2.1, 0.04), beta blockers non-selective (2.1, 1.3), and other aftercare (1.6, 0.1). Predictors of increased costs were (% change in cost, SD): south region (1.2,
0.03), chronic skin ulcers (2.0, 0.1), and chronic kidney disease (1.9, 0.2). **CONCLUSIONS:** HRU and costs were higher for CLI patients with comorbid diabetes. Factors driving these increases in the overall CLI population may be related to the increased complexity of comorbid diabetes and may provide an opportunity for cost savings via timely care decisions in diabetes and CLI.

**PDB42: THE REAL-WORLD IMPACT OF MILD TO MODERATE HYPOGLYCEMIC EVENTS IN PORTUGAL – RESULTS FROM THE HIPOS-PHARMA STUDY**

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**OBJECTIVES:** We measured the impact of mild to moderate hypoglycemic events occurring in ambulatory Type 2 Diabetes Mellitus (T2DM) patients, including healthcare consumption, productivity losses and disease management. **METHODS:** HIPOS-PHARMA was a nationwide observational, cross-sectional, multicenter study performed from 4 April until 20 May 2016 in community pharmacies of Portugal, which surveyed T2DM patients under treatment for at least 3 months. A structured questionnaire was managed by pharmacists, including questions about awareness, prevalence and the impact of hypoglycemic episodes. **RESULTS:** Among those T2DM patients experiencing a mild to moderate hypoglycemic episode in the previous 3 months (17.8% out of 1890 surveyed T2DM patients) 9.1% required non-scheduled medical/nursing consultations and 9.4% reported absenteeism from work (mean loss of 1.5 working days) as a consequence of such events. In addition, almost a fifth (18.3%) not only required therapeutic modification, mainly dosage modification (66.9%), but also drug switch (18.0%) and temporary treatment interruption (8.2%). The recorded hypoglycemic events also led to a modification of self-monitoring of blood glucose levels in over a third of patients (38.3%; with a mean additional consumption of 2.7 blood glucose test strips). Furthermore, in our study, T2DM patients didn’t fully acknowledge when they were having a hypoglycemic episode (Always: 53.0%; Almost always: 27.1%; Sometimes: 11.1%; Rarely: 5.0%; Never: 3.8%) and that underreporting of these relevant events occurred with only 46.4% of patients reporting it to a healthcare professional (Physician: 80.7%; Pharmacist: 18.7%; Nurse: 17.4%; Other 1.9%). **CONCLUSIONS:** In this nationwide study we observed that mild to moderate hypoglycemic episodes are associated with healthcare consumption, productivity losses and changes in management of Diabetes. Furthermore, we also confirmed that there is a need for improvement in the communication between patients and healthcare professionals in order to increase patient awareness and reporting of diabetes-related hypoglycemic events.

**PDB43: PUMP-DOWNLOADED INSULIN USAGE FOR THE FIRST 12 MONTHS IN A COHORT 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 risks of developing long term microvascular and macrovascular complications in type 1 diabetes (T1D). As part of a randomised clinical trial (SCIPI, ISRCTN29255275), we compared insulin usage downloaded from CSII pumps with General Practitioner (GP)-recorded insulin prescriptions given to a newly-diagnosed paediatric cohort. **METHODS:** Patients between 7 months and 15 years of age, newly diagnosed with T1D participated in this pragmatic, open, multicentre, parallel group, randomised, controlled trial. Total daily insulin usage (basal and bolus) recorded in the pumps from day 0 to day 365 was downloaded for patients initially randomised to CSII and analysed and compared to insulin usage recorded from their GP prescriptions. **RESULTS:** Pump data was available for 94/144 patients randomised to CSII (<5y: 21; 5 to <12y: 54; 12 to 15y: 19). Among these patients, data were available for a median of 198 days (range 28 to 343; mean 194). Mean prescribed insulin usage for these 94 patients was 70 U/day (95%CI: 58, 81) and compared well with the prescribed mean of 72 U/day (95%CI: 63, 82) for the whole 144-patient cohort. Mean recorded daily usage (min, max; 95%CI) for the three age groups was: (i) <5y: 12 U/day (2, 21; 9 to 14); (ii) 5 to <12y: 20 U/day (4, 36; 17 to 23); (iii) 12 to 15y: 37 U/day (9, 65; 32 to 42). **CONCLUSIONS:** Pump downloads provide an accurate record of insulin usage in paediatric populations with T1D. However, this study shows a large disparity between the quantities of insulin prescribed and insulin used. Reasons for this disparity might include: over-prescription, prescriptions not being collected and physical losses (e.g. spillage and priming of pumps). This may have implications when estimating drug utilisation costs.

**PDB44: ASSESSMENT OF ANTIDIABETIC DRUGS IN FRANCE: WHAT IS THE BASIS FOR A REIMBURSEMENT RECOMMENDATION?**

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**OBJECTIVES:** The French National Authority for Health (HAS) is responsible for health technology assessment, providing opinions for reimbursement purposes on drugs. Recommendations for reimbursement are based on the Clinical Benefit (CB) score with a 4-point scale from insufficient (no reimbursement) to important (highest level of reimbursement). According to the French legislation, the CB takes into account 5 criteria: disease severity, treatment aim, efficacy/side effects ratio (ranked on a 4-point scale), the drug’s place in the therapeutic strategy and public health impact. We observed that antidiabetic drugs frequently have several CB scores as they’re assessed by (sub)indication and therefore aimed to identify criteria driving the CB appraisals for antidiabetic indications. **METHODS:** A retrospective and descriptive study analysing of HAS appraisals for all new antidiabetic (sub)indications assessed between 2010 and 2015 was conducted. For each appraisal, information regarding CB criteria was collected. **RESULTS:** 89 antidiabetic indications (25 drugs) have been assessed with the following CB results: 37% important, 25% moderate, 6% low, 31% insufficient. For all assessments, the CB conclusions were: 80% important, 10% moderate, 3% low and 7% insufficient. The efficacy/side effects ranking was correlated to the CB score in 80% of the indications. When HAS concluded that the drug had no place in the therapeutic strategy, the CB was systematically insufficient. Other CB criteria were less decisive: severity of the disease was always important, treatment aims were always symptomatic and only one indication obtained a positive impact on public health. **CONCLUSIONS:** The percentage of insufficient CB in antidiabetic drugs appears to be higher than for all drugs assessment. However, all of these drugs are available as they obtained a favorable opinion for reimbursement in other (sub)indications, questioning the rationale for such a precise assessment. CB appraisal appears to be mostly driven by the efficacy/side effects ratio and the drug’s place in therapeutic strategy.

**DIABETES/ENDOCRINE DISORDERS - Patient-Reported Outcomes & Patient Preference Studies**

**PDB45: ADHERENCE ISSUES IN DIABETES TREATMENT: HOW CAN ACCEPTANCE MEASUREMENT HELP UNDERSTANDING PATIENTS’ CONCERNS AND WORKING ON SOLUTIONS?**

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**OBJECTIVES:** Patients with diabetes 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 type 1 and type 2 diabetic patients (T1D/T2D) 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 diabetic 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: Oral Anti-Diabetic (OAD) versus Insulin. **RESULTS:** 267 T1D and 946 T2D were included. T1D patients showed a significantly higher mean Acceptance/General score compared to T2D patients (67.04 ± 29.50 vs 51.21 ± 32.24, p < 0.0001); T2D patients showed significantly higher scores than T1D patients for Acceptance/Treatment Inconvenience, Long Term and Regimen Constraints. Patients taking OAD had a significantly lower mean General/Acceptance score compared to those taking insulin, but higher Acceptance/Medication Inconvenience, Long Term, Regimen Constraints and Side Effects mean scores. Acceptance/General was highly correlated with Acceptance/ Effectiveness (R = 0.61, p < 0.001). Having difficulty accepting treatment for the future was the main reported issue. **CONCLUSIONS:** Treatment acceptance is not satisfactory in diabetes. Diabetic patients treatment acceptance is primarily driven by perceived effectiveness. Long-term treatment is their major concern. These findings give indications about T1D and T2D patients’ priorities and unmet needs.

**PDB46: ADHERENCE TO ORAL ANTIDIABETIC MEDICATION IN TYPE 2 DIABETES MELLITUS CLIENTS IN THE VOLTA REGION OF GHANA**

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**OBJECTIVES:** This study sought to assess adherence to oral anti-diabetes mellitus medications and associated factors among clients reporting to four randomly selected Hospitals in the Volta region of Ghana. **METHODS:** A cross-sectional study was conducted among type 2 diabetes mellitus clients who attended the Diabetes Clinic of four randomly selected Hospitals in the Volta region of Ghana between the months of January 2015 to March 2015.
Adherence prevalence was assessed using the eight (8)-item Morisky Medication Adherence scale. Study participants were interviewed using a structured questionnaire to, among other things, determine the commonest self-reported reason (s) of non-adherence. Data generated were analyzed using SPSS version 21. Cross-tabulation analysis was performed between the adherence levels and the indicators generated from the questionnaire. Multiple logistic regression was further performed between adherence level and the statistically significant variables. RESULTS: Adherence prevalence rate to oral anti-diabetes in Type 2 Diabetes Mellitus was found to be 47.75%. The odds of adherence was about twice more likely in respondents with fasting blood glucose of 1 – 6 mmol/L (OR = 1.9, 95% CI 1.128 – 3.232, p-value 0.002) compared to those having fasting blood glucose of above 10 mmol/L while the odds of adherence among respondents with tertiary education was about 3-fold (OR = 2.888, 95% CI 1.394 – 5.982, p-value 0.004) compared to those with no formal education. The commonest self-reported reason for non-adherence was forgetfulness. CONCLUSIONS: Adherence to oral anti-diabetes in type 2 diabetes mellitus was found to be suboptimal and was independently predicted by the levels of hyperglycaemia and education of respondents. Management of type 2 diabetes mellitus with oral anti-diabetes must include strategies to identify non-adherent clients for adherence counseling before modification of therapy in ensuring good glycaemic control and prevention of the more costly management of its complications.

PDB47: PREVALENCE OF AND BARRIERS TO MEDICATION ADHERENCE AMONG PATIENTS WITH UNCONTROLLED DIABETES MELLITUS IN PRIMARY HEALTHCARE CENTERS IN QATAR: A QUANTITATIVE ANALYSIS

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OBJECTIVES: The prevalence of microvascular and macrovascular complications among patients with diabetes is high. These complications are often associated with poor medication adherence and poorly controlled diabetes. The objective of this study was to determine the rate of and barriers to medication adherence among patients with uncontrolled diabetes in Qatar. METHODS: A cross-sectional study was conducted among patients with uncontrolled diabetes attending two primary healthcare clinics in Qatar from October 2016 to January 2017. An interviewer-administered questionnaire comprising three sections was utilized in the study: patients’ characteristics, Adherence to Refill and Medications Scale in Diabetes (ARMS-D), and barriers to medication adherence. ARMS-D is a validated instrument that is used to determine the level of medication adherence in patients with diabetes. Descriptive and inferential statistics were used for data analysis. RESULTS: Of 260 patients included in the analysis, 191 (74%) were nonadherent to their diabetes medications (ARMS-D score greater than 11). The majority of barriers to medication adherence were reported by nonadherent patients and forgetfulness was the most commonly reported barrier. Furthermore, higher levels of nonadherence were reported among patients who were younger than 65 years old and those who were illiterate. CONCLUSIONS: The high rate of medication non-adherence observed among patients with uncontrolled diabetes in primary healthcare setting calls for urgent interventions. However, in-depth understanding of barriers to medication adherence often requires qualitative research approach as these barriers are very complex and multifactorial in nature.

PDB48: USING DIABETES SELF-MANAGEMENT QUESTIONNAIRE (DSMQ) TO ASSESS DIABETES SELF-CARE ACTIVITIES FOR DIABETES PATIENTS IN KING FAHAD UNIVERSITY HOSPITAL - SAUDI ARABIA

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OBJECTIVES: The study main objectives was to assess the diabetes self-care associated with glycemic control METHODS: we used a 16 item questionnaire that has been developed by Schmitt et al to assess self-care activities associated with glycemic control in King Fahad University hospital in Dammam. This instrument contains four subscales, ‘Glucose Management’ (GM), ‘Dietary Control’ (DC), ‘Physical Activity’ (PA), and ‘Health-Care Use’ (HU), as well as a ‘Sum Scale’ (SS). We assessed socio-demographic and medical characteristics using survey and medical record data, including age, sex, self-reported race/ethnicity, educational attainment. The statistical analyses were performed using SPSS RESULTS: Among 30 eligible respondents, 56% were aged above 60, 32% were aged between 41 and 60 years. 60% were women and 40% were men. 28% with intermediate education, 20 % graduated from universities. Age, education, and working status showed statistical significance in dietary control at 0.01, 0.03, 0.012 respectively. Obesity statistically correlated with using health care use and the insulin therapy show significant relationship with glucose management. CONCLUSIONS: Age had an positive influence on patients’ dietary control which may present that older patients showed higher rates of dietary control than younger patients. Another factor affecting dietary control is level of education which indicates more educated patients were associated with increased dietary control. In this research, it was found out that there was a relationship between insulin therapy and glucose management. Thus, patients who took insulin alone or insulin combined with oral medications had more glucose management than patients who took only oral medications. Only obesity was affecting health care use, it indicates
that obese patients were less likely to use health care services. Patients who exercise 3 times or more a week associated with more physical activity than those who exercise once or less a week.

PDB49: IMPACT OF A COMMUNITY PHARMACY-BASED INFORMATION PROGRAM ON TYPE 2 DIABETIC PATIENTS’ ADHERENCE: IPHODIA, A CLUSTER RANDOMIZED STUDY VS USUAL PRACTICE - 12 MONTH FINAL RESULTS

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OBJECTIVES: Despite significant improvements in the follow up of type 2 diabetes patients, Entred’s latest results showed an insufficient level-of-control with 41% of patients with HbA1c over 7%. Pharmacists could play a beneficial role in patient adherence given their expertise and accessibility. The IPHODia study aims to assess the impact on adherence when community pharmacists provide specific information to patients. METHODS: The intervention consists in three different 30-minute-long interviews over a period of 6 months. Two groups of pharmacists have been randomized; one group providing patient interviews in addition to the usual drug delivery, the other group delivering drugs in the usual setting. Criteria of evaluation are the Medication Possession Ratio (MPR) and HbA1c level. RESULTS: In total, 182 pharmacists (91+91) recruited 553 patients (296+257). Patients’ main characteristics are similar in both groups (mean age 66.58±male; 45% obese and about 10 years mean diabetes duration). Primary analysis was performed on 377 patients. MPR at baseline was very high and does not change at 6 or 12 months. Mean HbA1c levels significantly decreased after 6 months in the group of patients interviewed by pharmacists (n=160, Baseline 7.9% – 6 months 7.4%) versus the group that didn’t have a pharmacy interview (n=162, Baseline 7.7% – 6 months 7.5%). (-0.5% – -0.2 %,p=0.0035)). At 12 month, HbA1c levels continue to decrease in the group of patients interviewed by pharmacists (n=123, Baseline 7.9% - 12 months 7.3%) versus the group without pharmacy interview (n=151, Baseline 7.8% - 12 months 7.5%). (-0.6% - -0.2% ,p=0.0057). These results highlight the permanence of the intervention 6 months after it stops. CONCLUSIONS: 12 months results show the persistence of the intervention as HbA1c levels continue to decrease significantly in the group with pharmacist interviews. In total, after a period of one year, 0.6% of HbA1c reduction from baseline has been achieved in the intervention group.

PDB50: DOES THE DISTANCE TO THE NEAREST PHARMACY AFFECT MEDICATION ADHERENCE RATES AMONG ELDERLY PATIENTS WITH DIABETES?

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OBJECTIVES: The purpose of this study was to examine whether a relationship exists between adherence to oral anti-diabetic medications and distance to nearest community pharmacy among elderly patients with diabetes mellitus in Pennsylvania. METHODS: This cross-sectional study used data obtained from Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE) programs’ database to identify enrollees and community (independent or chain) pharmacies operating in PA. The addresses of the enrollees’ residences and community pharmacies were geocoded as longitude and latitude coordinates. The straight-line distances using haversine formula were calculated (in miles) to determine the distance between the enrollee and each pharmacy in PA. The shortest distance was considered as the distance required for an elderly to visit the nearest pharmacy. Medication adherence was calculated as proportion of days covered (PDC) using prescription claims data for oral anti-diabetic medications. Enrollees receiving prescriptions via mail order were excluded from this study. Generalized linear model (GLM) using a gamma distribution and log link was applied to evaluate the relationship between medication adherence and distance to a nearest pharmacy, including other variables such as sex, age, annual household income, marital status, race and ethnicity. RESULTS: The study included 11,848 elderly patients with diabetes mellitus enrolled in the PACE program in 2015. The median distance to nearest community pharmacy was 0.59 miles (IQR: 0.29 – 1.55). Of the study population, 62.8% and 37.2% lived less than a mile and more than a mile from the nearest community pharmacy, respectively. Females (PDC=0.83), divorced enrollees (PDC=0.84), White (PDC=0.84) and Hispanic (PDC=0.83) enrollees were more adherent to medications. GLM showed that there is no significant relationship between medication adherence and distance to a nearest community pharmacy (p-value = 0.112). CONCLUSIONS: Adherence to oral anti-diabetic medications is not associated with the distance to nearest community pharmacy among elderly with diabetes mellitus in Pennsylvania.
**PDB51: EVALUATION OF PHARMACIST’S EDUCATIONAL AND COUNSELING IMPACT ON PATIENTS CLINICAL OUTCOMES IN A DIABETIC SETTING**

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**OBJECTIVES:** The study aimed to evaluate pharmacist’s educational and counseling impact including adherence to instructions of diabetic patients’ outcomes in the endocrinology clinic of Olabisi Onabanjo University Teaching Hospital, Sagamu, Ogun State, Nigeria.

**METHODS:** This was a 6 Month randomized controlled study involving 150 consented elderly type 2 diabetic patients. Patients who met the inclusion criteria were randomly assigned into both control and intervention groups (75 patients each). The 75 patients on our intervention group were educated by the Pharmacist on diabetes and hypertension, their complications, risks, preventive measures and management. This was done at least six times during the study period unlike the control group who received no such education. In particular, they were counselled on the need for medication and treatment adherence such as clinic visits, and lifestyle modifications including diet and exercise. Outcome measure included changes in fasting blood sugar (FBS), blood pressure (BP), body mass index (BMI) and adherence to instructions.

**RESULTS:** There were no statistical differences between the baseline and 6 months data of the control group as mean fasting blood sugar were 162.2 ± 69.1 and 159.9 ± 57.2 (P = 0.825) and mean systolic blood pressure of 144.7 ± 23.8 and 145.5 ± 18.6 (P = 0.819) respectively. The intervention group had mean fasting blood sugar of 156.7 ± 30.5 and 131.8 ± 40.4 (P < 0.001) and mean systolic blood pressure of 146.4 ± 13.9 and 133.8 ± 18.5 (P < 0.001) respectively. Adherence levels to medication taking in the groups were 42.7% : 94.7% respectively (P = 0.001).

**CONCLUSIONS:** In diabetes management, patient education and counseling have become key tools in achieving both glycaemic and blood pressure control. Key words: Diabetes, education, counseling, elderly, patients.

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**PDB52: HEALTH STATE UTILITIES IN INDIVIDUALS WITH GOITER, HYPOTHYROIDISM, HYPERTHYROIDISM AND GRAVES’ DISEASE AS AN EXAMPLE FOR THYROID DISORDERS – A SYSTEMATIC REVIEW**

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**OBJECTIVES:** A wide spectrum of illnesses due to iodine deficiency is termed as iodine deficiency disorders (IDD). IDD include thyroid diseases, such as goiter, hypothyroidism and hyperthyroidism. However, iodine excess can also provoke thyroid diseases, such as Graves’ disease. IDD and related consequences negatively affect quality of life. Our aim was to identify utilities, reflecting health-related quality of life, for health states associated with thyroid disorders.

**METHODS:** We conducted a comprehensive systematic literature search in Medline and Tuft’s CEA Registry to identify relevant published literature. Studies were required to report on health-related utilities in individuals with hypothyroidism, hyperthyroidism, goiter or Graves’ disease. Results were summarized in evidence tables including information about population, original source, and methods for utility estimation.

**RESULTS:** Overall, we found 944 studies. After title/abstract and full-text screening, eleven studies were included. We found utilities for different ages, treatments, treatment sequelae. Utilities for hypothyroidism were dependent on population and therapeutic options. The range was 0.469 (unscreened newborns) to 1 (treated subclinical hypothyroidism in adults).

Utilities for hyperthyroidism depend on treatment. The range was 0.467 (without treatment) to 0.98 (euthyroid with anti-thyroid drugs). For goiter, we found utilities for the condition after thyroidectomy (0.81). Utilities for Graves’ disease ranged from 0.85 (screened pregnant woman) to 0.88 (Graves’ ophthalmopathy). Health utilities were collected using different outcome measurements including time-trade-off, standard gamble, Health Utilities Index Mark.2, and expert opinion. In several studies, utilities were derived from literature and data were originally collected for medical conditions unrelated to thyroid diseases.

**CONCLUSIONS:** We identified studies reporting on utilities for different health states related to thyroid diseases. However, there is a lack of robust estimates on utility decrements. Future studies should incorporate the collection of utilities for application in decision-analytic models for the evaluation of the benefit-harm ratio of IDD prevention strategies.

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**PDB53: QUALITY OF LIFE AMONG PATIENTS WITH DIABETES MELLITUS AT KING ABDULAZIZ UNIVERSITY HOSPITAL IN SAUDI ARABIA**

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OBJECTIVES: The purpose of this study was to assess the health-related quality of life among a group of people with diabetes at King Abdulaziz University Hospital in Jeddah, Saudi Arabia in 2017. METHODS: A quantitative, observational, cross-sectional study was conducted on patients with type 2 Diabetes, aged 18 years and older selected conveniently from outpatient clinic visitors at King Abdulaziz University Hospital, Jeddah, Saudi Arabia from February to March 2017. HRQoL was assessed using EQ-5D Arabic version, which includes patient’s perception of their health status in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Background information such as socioeconomic status, demographics and concurrent medical conditions were also assessed. A series of descriptive and inferential statistics were carried on using SPSS version 14. RESULTS: 190 participants were included in this study, of which seventy-one (55%) respondent were female. A hundred participant (77%) were married and forty-six (35%) were suffering from hypertension. The majority of the studied population reported having diabetes for more than 5 years (65%), in regards to the health status dimensions, forty seven (36%) of participants reported no problem with mobility. A hundred and five (81%) reported no problem with self care, seventy four (57%) reported no problem with usual activities, fifty one (39%) reported mild problem with pain/discomfort, and sixty nine (53%) reported no problem with Anxiety/depression. A moderate level of HRQoL (0.69 ± 0.20) was recorded in the study cohort. HRQoL mean scores were statistically significant between gender (P=0.030), exercise habit (P=0.035) and education level (P=0.001), but the difference was not statistically significant in smoking (P=0.315). CONCLUSIONS: HRQoL scores were moderate in type 2 diabetic patients in, Jeddah, Saudi Arabia. It is likely that a high quality self-management education and physical activities programs will provide benefits and affect significantly on type 2 diabetes patients in Saudi Arabia.

PDB54: EFFECT OF GASTROINTESTINAL ADVERSE EVENTS ON TREATMENT SATISFACTION IN SEMAGLUTIDE TREATMENT OF TYPE 2 DIABETES

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OBJECTIVES: Semaglutide, a GLP-1 analogue in development for type 2 diabetes (T2D), demonstrated superior glycaemic control and weight loss across the phase 3a SUSTAIN 2–5 trials vs placebo (on a background of insulin) and active comparators, but higher rates of gastrointestinal adverse events (GI AEs). Treatment satisfaction (TS), the subjective appraisal of an individual’s treatment experience, is an important outcome measure associated with improved adherence. In SUSTAIN 2–5, TS improvement had been consistently significantly higher for semaglutide 0.5 mg (2.7–5.3 points) and 1.0 mg (3.5–5.9) vs comparators (1.3–4.5) in all trials, based on the Diabetes Treatment Satisfaction Questionnaire (DTSQ). This post hoc analysis of SUSTAIN 2–5 reviewed the impact of GI AEs on TS changes. METHODS: In SUSTAIN 2–5, subjects with inadequately controlled T2D were randomised to subcutaneous semaglutide 0.5 mg or 1.0 mg once weekly, or to a comparator (sitagliptin, exenatide extended release, insulin glargine or placebo). TS was assessed with the DTSQ at baseline and end of treatment, using the overall satisfaction component (36-point scale). Subjects were grouped by whether or not they reported any GI AE. RESULTS: A total of 3530 subjects were randomised (semaglutide, n=2214; comparators, n=1316). Among 1774 semaglutide-treated subjects who completed treatment and had available data on TS changes from baseline, 659 (37.1%) experienced GI AEs. TS improvements in subjects who did not experience GI AEs (2.7–5.5 and 3.7–5.9 with semaglutide 0.5 mg and 1.0 mg, respectively) were higher than in those who experienced GI AEs (2.8–4.7 and 3.1–5.7, respectively), although the difference was not significant (p=0.08). CONCLUSIONS: Treatment satisfaction was significantly greater with semaglutide vs comparators and was not significantly affected by the presence of GI AEs. Thus, the patient-perceived beneficial effects of semaglutide appear to outweigh the negative impact of GI AEs.

PDB55: SPANISH PATIENT’S PERSPECTIVE AND PREFERENCES FOR TELEMEDICINE RESOURCES IN TYPE 2 DIABETES MANAGEMENT

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OBJECTIVES: To describe type 2 diabetes mellitus (T2DM) patients’ perceptions about telemedicine (TM), and to identify preferences of use. METHODS: An observational, cross-sectional study was conducted in Spanish T2DM patients. A questionnaire containing 30 questions (dichotomous, multi-choice and 5-likert scale) was specifically designed. RESULTS: From 1,036 respondents (mean age: 60.3 years; 50.5% men), 9.8% had used TM resources. Of them, 70.5% were satisfied with TM. Patients with experience in TM had better perception than naïve patients about how TM reduces the use of healthcare resources: visits to the physician (61.8% vs. 46.1%; p=0.005), to the nurse (59.8% vs. 42.2%; p=0.003), to the emergency room (59.8% vs. 37.7%; p<0.001), and time required per
physician’s visits (63.7% vs. 41.0%; p<0.001). Similarly, patients with experience in TM perceived greater benefits in the improvement of knowledge about the disease (78.4% vs. 60.9%; p=0.001) and consequences of not adhering to treatment (77.5% vs. 54.7%; p<0.001), adherence to treatment (74.5% vs. 54.6%; p=0.001), observance of dietary recommendations (67.6% vs. 55.6%; p=0.006) and physical exercise recommendations (76.5% vs. 53.1%; p<0.001), glycemic control (73.5% vs. 58.7%; p<0.001), prevention of hypoglycemic episodes (77.5% vs. 56.9%; p<0.001), HRQoL (78.4% vs. 61.3%; p=0.003) and the reduction of absenteeism (65.7% vs. 33.4%; p<0.001). Experienced patients preferred the following TM resources: web pages supervised by professionals (70.6%), platforms to communicate with the medical team (70.6%), Apps (70.6%) and SMS/WhatsApp reminders (66.7%). The participants considered that the most important App contents were: information about medication (54.4%), dose reminders (47.4%), diet plans (41.0%), calorie calculators (35.4%) and physical activity meters (34.8%). CONCLUSIONS: TM is well accepted by patients, and it is perceived as a useful tool to improve T2DM management reducing healthcare resources use. TM resources that allow information exchange within the medical team regarding treatment and lifestyle habits, are the most preferred.

PDB56: EVALUATING PATIENTS’ PREFERENCES FOR DULAGLUTIDE VERSUS INSULIN GLARGINE PROFILES IN THE UNITED KINGDOM: A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: To use a discrete choice experiment (DCE) to determine patient preferences for the treatment features of dulaglutide 1.5 mg vs insulin glargine (Lantus SoloStar®) among people with type 2 diabetes mellitus (T2DM) in the United Kingdom (UK). METHODS: In-person interviews were conducted among people in the UK with self-reported T2DM, naïve to treatment with injectable diabetes medications. The DCE examined 7 treatment attributes each described by 2 levels: frequency of gastrointestinal side effects, frequency of hypoglycaemia, frequency of pancreatitis, dosing frequency, HbA1c change, weight change and type of delivery system (deidentified dulaglutide and Lantus SoloStar® devices). Attribute selection was informed by qualitative interviews with people with T2DM treated with oral and/or injectable medications. Part-worth utilities were estimated using random effects logit models and used to calculate relative importance (RI) values for each attribute. Chi-square test was used to determine differences in preferences for dulaglutide vs insulin glargine profiles. RESULTS: 232 participants completed the study [mean±SD: age 61.8±10.8 years; BMI 29.8±6.1 kg/m2; 74.1% male], RI of attributes in rank order were: type of delivery system (19.8%), frequency of gastrointestinal side effects (18.2%), dosing frequency (17.7%), weight change (15.6%), HbA1c change (14.2%), frequency of pancreatitis (12.3%) and frequency of hypoglycaemia (2.2%). The majority of participants preferred the dulaglutide profile (75.0%) compared to the insulin glargine profile (25.0%) (p<.01). CONCLUSIONS: This study elicited UK patients’ preferences for attributes and levels representing the actual characteristics of dulaglutide and insulin glargine (Lantus SoloStar®). Of the attributes tested, no one attribute highly drove patients’ preferences. The majority of participants preferred the dulaglutide profile over the insulin glargine profile. The results will help treatment providers understand the clinical and non-clinical factors influencing preferences of people with T2DM, naïve to injectable diabetes medications, when considering next treatment options.

PDB57: MAPPING ACROQOL SCORES TO EQ-5D TO OBTAIN UTILITY VALUES FOR PATIENTS WITH ACROMEGALY

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OBJECTIVES: Estimate a preference-based single index for disease specific instrument (AcroQOL) by mapping it onto the EQ-5D for future economic evaluations. METHODS: 245 acromegaly patients with AcroQol and EQ-5D scores was obtained from three previously published European studies. Across these studies, mean age was 50-60 years, proportion male was 36%-59%. At overall level the percentage of patients with controlled disease was 37.4%. Patient level data were obtained and the overall sample was divided into two sub-samples, with one sub-sample being used to construct the model (n=184) and the other used as confirmation (n=61). Various multiple regression models including two-part model, tobit model and generalized additive model were tested and/or evaluated for predictive ability, consistency of estimated coefficients, normality of prediction errors, and simplicity. RESULTS: Mean(SD) scores for AcroQol Global Score and EQ-5D utility were 62.3(18.5) and 0.71(0.28), respectively. The best model for predicting EQ-5D was a generalized regression model that included the Physical Dimension summary score and categories from questions 9 and 14 as independent variables (Adj. R2=0.56, with
mean absolute error of 0.0128 in confirmatory sample): Utility = 0.30778 + 0.00734 x Physical score - 0.23227 x Acroqol item 9 - 0.07128 x Acroqol item 14 (categories 1 or 2). Observed and predicted utilities were strongly correlated (Spearman r = 0.73, p < 0.001) and paired t-tests revealed non-significant differences between means (p = 0.05).

Estimated utility scores showed minimum error of ±10% in 45% of patients; however, error increased in patients with observed utility score under 0.2. The model’s predictive ability was confirmed in the second sub-sample. **CONCLUSIONS:** A mapping algorithm was developed for mapping of AcroQoL to EQ-5D, using patient level data from 3 previously published studies, and including validation in confirmatory sub-sample. Mean(SD) utilities index in this study population was estimated as 0.71(0.28). Additional research may be needed to test this mapping algorithm in other acromegaly populations.

**PDB59: CHARACTERISING THE RELATIVE IMPACT OF ESTABLISHED CARDIOVASCULAR DISEASE AND CHRONIC KIDNEY DISEASE ON QUALITY OF LIFE IN DIABETES PATIENTS**


**OBJECTIVES:** Common complications for patients with type 2 diabetes mellitus (T2DM) include cardiovascular disease (CVD) and chronic kidney disease (CKD) both which often compromise QoL. This research explores the impact of these conditions on the QoL of T2DM patients. **METHODS:** Data was drawn from 2016 US/EU Diabetes Adelphi Disease Specific Programme. Diabetes specialists and primary care physicians completed physician-reported forms for the next 10 consulting patients. Established CVD (EstCVD) was defined as patients who suffer with myocardial infarction, coronary artery disease, peripheral vascular disease or stroke. Renal impairment was defined as CKD stages 3-5 (eGFR: ≤45 ml/min/1.73m²). Patients were classified into 4 groups defining CKD or CVD presence: [1] Neither; [2] CKD-only; [3] EstCVD-only; [4] EstCVD/CKD. **RESULTS:** 853 physicians included 8,523 patients as follows: 73% Neither; 16% CKD-only; 8% EstCVD-only; 4% EstCVD/CKD. Differences were observed between patients with neither, either CKD or EstCVD or both. Comparing to patient with neither condition, patients with one or both conditions were older (70.2 Both vs 64.6 Either CVD/CKD vs 59.5 Neither), more likely to have a caregiver (23.2% vs 11.4% vs 4.4%), less likely to work full-time (13.7% vs 24.1% vs 37.3%), suffer more comorbidities (7.0 vs 3.9 vs 2.2), receive insulin-only regimens (19.4% vs 9.6% vs 3.9%), more total prescribed products (8.3 vs 6.2 vs 4.4), experience more hypoglycaemic episodes (23.7% vs 13.5% vs 8.6%). Similarly, their diabetes ‘sometimes/greatly’ affects family/social life (37.2% vs 24.1% vs 22.6%), sleep (32.6% vs 24.3% vs 18.2%), leisure activities (38.4% vs 30.4% 27.7%). All results p < 0.05. **CONCLUSIONS:** Compared to patients with neither CKD/CVM, patients suffering one or both conditions have a higher resource burden and experience a greater impact on their lifestyle. It is important to be aware of these comorbid conditions when managing T2DM patients.

**PDB60: ECONOMIC AND HUMANISTIC BURDEN OF ILLNESS AMONGST DIABETES PATIENTS EXPERIENCING TREATMENT INERTIA**


**OBJECTIVES:** A recent publication exploring real-world treatment patterns between 2000-2015 found HbA1c control in type 2 diabetes has not improved post-2008, one reason being attributable to treatment inertia. This analysis aims to identify the humanistic and economic burden amongst this patient type compared to patients receiving more active management. **METHODS:** Data were drawn from the 2016 US/EU Adelphi Diabetes Disease Specific Programme. Diabetes specialists and primary care physicians completed physician-reported forms for the next 10 consulting patients including demographics, clinical measures, prescribed drugs, healthcare practitioner (HCP) visits. Patients provided information about the impact of diabetes. Current therapy duration and current HbA1c classified 3 groups: 1) actively managed (dynamic): treatment change within previous 6 months; any HbA1c; 2) non-dynamic/controlled: last treatment change >6 months; HbA1c <7.5%; 3) non-dynamic/uncontrolled (treatment inertia): last treatment change >6 months; HbA1c >7.5%. **RESULTS:** 853 physicians included 7,487 patients; 32% dynamic, 52% non-dynamic/controlled, 16% clinically inert. Compared to dynamic patients, clinically inert patients visit the HCP more often per annum (3.4 vs. 2.9), are co-managed with a cardiologist (22.9% vs. 19.6%), a nephrologist (7.9% vs. 5.9%) or a community specialist diabetes nurse practitioner (20.2% vs. 16.6%), take more products for all conditions (7.6 vs. 6.4). Clinically inert patients report their diabetes ‘sometimes’ or ‘greatly’ affects family/social life (30.6% vs 25.2%), leisure (37.0% vs 28.6%), long distance journeys (36.4% vs 30.9%) and sleep (36.4% vs 21.2%). All results p < 0.05. **CONCLUSIONS:** Clinically inert patients represent a group with higher economic burden and suffer a greater impact on lifestyle. Identification and understanding of these patients could help personalise treatment to achieve optimal diabetes control and thus reduce burden of illness.
PDB61: DIABETES MELLITUS SELF-MANAGEMENT INTERVENTIONS IN LATINO ADULTS IN THE UNITED STATES - THE ROLE OF PHARMACISTS

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OBJECTIVES: To conduct a systematic review of the diabetes mellitus (DM) self-management interventions conducted by non-pharmacy personnel in Latinos with DM and by pharmacists in patients with DM (all races) at the individual, interpersonal and community levels respectively. METHODS: A systematic review was conducted using different computerized databases like Pubmed, Google scholar. Embase and the Cochrane database from inception to March, 2017. Out of the 145 studies whose abstracts or titles were skimmed for this systematic review, 80 studies had theory or non-theory driven DM self-management interventions. Out of those 80 studies, 22 theory based intervention studies were conducted by non-pharmacy personnel (physicians, nurses, diabetes educators, community health workers/promotoras, social workers) in Latinos with DM and 6 theory based intervention studies were conducted by pharmacists in patients (Latinos, non-Latino African Americans, non-Latino Caucasians, non-Latino Native Indians, other races) with DM. RESULTS: Among the DM intervention studies, the constructs there were targeted at the individual level were self-efficacy, motivation, positive reinforcement, knowledge, vicarious experiences and performance mastery, at the interpersonal level were social support, social networks, coping, empowerment and social persuasion and at the community level were community engagement, community integration and social cohesion respectively. The studies conducted in Latinos with DM by the pharmacists were mostly targeted at the individual level whereas the studies conducted by non-pharmacy personnel were mostly targeted at the interpersonal and the community levels respectively. The studies reported improvements in clinical parameters, dietary habits, physical activity, medication management, social support and other social factors. CONCLUSIONS: Overall, studies that were culturally targeted towards Latinos with DM showed an improvement in DM self-management. Robust interventions backed by theory for chronic disease management salient to non-Latino racial/ethnic minorities like African Americans and Native Americans should be translated in practice to improve the overall quality of healthcare delivered to the minorities.

PDB62: BURDEN OF DIABETIC FOOT ULCERS IN INDIA: EVIDENCE LANDSCAPE FROM PUBLISHED LITERATURE

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OBJECTIVES: The objective of the current review was to summarize burden of diabetic foot ulcers (DFUs) in Indian patients based on findings reported in published literature. METHODS: MEDLINE was queried using key words: foot ulcer; diabetes mellitus; infection; diabetic foot ulcer. Evidence was synthesized from shortlisted articles, presenting epidemiology, microbiology and economic burden of DFUs in Indian patients. RESULTS: In India, DFUs affect 15% of diabetics during their lifetime. Mono/polymicrobial etiology of diabetic foot infections was widely reported including high prevalence of Pseudomonas, E. coli, and S. aureus infections. Evidence from published literature showed 100,000 leg amputations/year due to diabetes-related problems and an expense of approximately $1,960 for complete treatment of DFUs. Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected, requiring hospitalization while 20% need amputation. DFUs contribute to approximately 80% of all non-traumatic amputations in India, annually. Patients with a history of DFU have 40% higher 10-year death-rate, than those without. Average time required for healing of DFUs is 28 weeks (range 12-62 weeks). Two studies indicated that patients with DFUs spent four times more than those without (Satyavani, 2013: Rs.19,020 (~$295.95) vs. Rs. 4,493(~$69.91)) and (Shobhana, 2001: Rs. 15,450(~$240.40) vs. Rs. 4,373(~$68.04)). Also, India is the most expensive country for DFU care, as 5.7 years (68.8 months) of an average patient’s income is required to pay for complete DFU therapy. Amongst Indian diabetics, treatment cost of neuropathic ulcers (ambulatory care), infected neuropathic foot (ambulatory care), advanced diabetic foot (salvage, limb amputation, salvage followed by amputation), and neuroischemic foot (bypass) was reported as $56, $165, $1080, $960, $2650 and $1960, respectively. Moreover, 50% of DFU patients who get amputated once, suffer another amputation within next 2 years. CONCLUSIONS: DFU specific clinical guidelines and cost-effective therapies need to be developed urgently to halt this catastrophic pandemic.

PDB63: TREATMENT PATTERNS AMONG NEWLY DIAGNOSED DIABETES PATIENTS IN DUBAI

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OBJECTIVES: American Diabetes Association’s recommendations related to pharmacologic therapy in type II diabetes mellitus advises metformin monotherapy as the preferred initial therapy, while use of dual and triple therapy is suggested to more expeditiously achieve the target A1C level. The objective of the study is to understand the treatment patterns among newly diagnosed T2DM patients in Dubai and make broad-level comparisons against the ADA’s recommendations. METHODS: A retrospective database analysis was conducted using Dubai Claims Database. All patients with a T2DM diagnosis were identified during July 2014 to March 2016, and their first diagnosis was assigned as the index diagnosis. Patients with a diabetes diagnosis or use of anti-diabetic therapy (ADT) during prior six months were excluded. Patients were continuously enrolled during 6 months before and 12 months after the index diagnosis. RESULTS: The final study cohort included 25,320 patients, of which 63.1% did not receive any ADT during 12 months follow-up from the index diagnosis. For the remaining 9,349 patients, 54.6% patients received the first ADT on index diagnosis date, while the mean time to ADT for the remaining 45.4% patients was 68.6 days. The most common first ADT was metformin received by 88.9% patients, of which 42.9% received it as a monotherapy while remaining 57.1% received it in combination with another drug. The proportion of patients having their first ADT as combination therapy or insulin was 50.3% and 4.3%, respectively. Mean number of oral prescriptions during follow-up was 2.9. The average most recent HbA1c value before initiating monotherapy, combination therapy and insulin-based therapy was 7.0, 8.4 and 9.1, respectively. CONCLUSIONS: While most patients received metformin as their first ADT, majority received it in combination with another drug. Also, a large proportion of patients did not receive any ADT during follow-up, which needs to be further studied.

PDB64: ADEQUACY OF GLYCEMIC CONTROL IN GREEK PATIENTS WITH TYPE 2 DIABETES MELLITUS TREATED WITH METFORMIN MONOTHERAPY AT THE MAXIMUM TOLERATED DOSE: THE RELOAD STUDY

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OBJECTIVES: To assess adequacy of glycaemic control in Greek patients with type 2 diabetes mellitus (T2DM) treated with maximum tolerated doses of metformin. METHODS: RELOAD was a multi-centre, retrospective study in patients with T2DM treated with metformin only. Data were collected from the medical files of patients with T2DM diagnosed at an age ≥40 years who received metformin monotherapy at maximum tolerated doses for ≥24 months during the 5 years prior to enrolment. Demographic and clinical data were collected at metformin initiation, 9, 17-20 and 24 months. Primary endpoints were the percentage of patients achieving metabolic compensation (MC, reduction of HbA1c values from ≥6.5% at baseline to <6.5%) and the mean HbA1c reduction rate after 9 months of metformin treatment. Secondary endpoints included the average time spent with HbA1c ≥6.5% while on metformin monotherapy and the mean time to treatment intensification. In pre-specified analysis the relationship of comorbidity to MC was explored. RESULTS: 316 patients with T2DM were enrolled in the study. Baseline (mean±SD) demographic and clinical characteristics were: age 65.8±10.4 years, T2DM duration 5.8±4.2 years, weight 84.4±15.9kg and HbA1c 7.2%±1.1%. 78% (247/316) of patients had HbA1c ≥6.5%. Following 9 months of metformin treatment, 36.4% (90/247) of patients achieved MC, with a mean HbA1c reduction of 1.3% [95% confidence interval [CI]=(-1.57,-0.95)]; mean metformin daily dose was 1,561±532 mg. Mean time of exposure to HbA1c ≥6.5% for the overall population was 24.3±15.0 months and time to treatment intensification was 30.6±9.5 months. The percentage of hypertensive patients achieving HbA1c <6.5% was numerically higher as compared to normotensive patients (40.9% vs 28.4%, respectively; p=0.051). CONCLUSIONS: In this real-world study, approximately half of Greek T2DM patients treated with maximum tolerated metformin doses had an HbA1c >6.5% for a substantial period of time, indicating clinical inertia and an increased risk for diabetic complications.

PDB65: COSTS OF CLINICAL EVENTS IN DIABETES TYPE 2 PATIENTS IN THE NETHERLANDS: A SYSTEMATIC REVIEW

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OBJECTIVES: Diabetes mellitus type 2 (T2DM) is an established risk factor for vascular complications, cardiovascular events, and kidney failure. Prevalence of T2DM is expected to be as high as 8% in the year 2025. This will result in significant clinical impact and increases in healthcare expenditures, highlighting the need for well-informed reimbursement decisions. However, availability and consistent use of costs is limited. Here, we aim to systematically review available costing data for T2DM-related major cardiovascular and nephropathic events in the
consumption of OHDs, which indicates an insufficient level of OHDs consumption.

The indicator of the consumption of OHDs in Ukraine is 2.6 to 6.9 times lower than necessary for the treatment of patients (7.6% of the population), their consumption was 6.9 times less than the required amount. Thus, the calculated population, but real consumption of OHDs 2.6 times less than is necessary for all officially registered patients. When the population of Ukraine from the total number of residents received 1 DDD of oral hypoglycemic drugs daily. Taking methodology.

In Ukraine in 2015.

Patients with type 2 diabetes is the use of oral hypoglycemic drugs (OHDs). Most OHDs have high clinical efficacy, these data, we can assume that in Ukraine there are about 3.6 million patients with diabetes (8.45% of population), of which 90% (3.24 million) are patients with type 2 diabetes (7.6% of population). The main method of treatment of patients with type 2 diabetes is the use of oral hypoglycemic drugs (OHDs). Most OHDs have high clinical efficacy, their use increases the duration and quality of patients life. The objective - determining the consumption of the OHDs in Ukraine in 2015. METHODS: Calculation of OHDs consumption was carried out on the basis of the ATC/DDD-methodology. RESULTS: In Ukraine in 2015 total consumption of OHDs was 11.14 DIDs. This means that 1.1% of the population of Ukraine from the total number of residents received 1 DDD of oral hypoglycemic drugs daily. Taking into account the official statistics, the consumption of OHDs for patients with diabetes should cover 2.81% of the population, but real consumption of OHDs 2.6 times less than is necessary for all officially registered patients. When recalculating the consumption of OHDs, taking into account unregistered patients with type 2 diabetes in Ukraine (7.6% of the population), their consumption was 6.9 times less than the required amount. Thus, the calculated indicator of the consumption of OHDs in Ukraine is 2.6 to 6.9 times lower than necessary for the treatment of patients with diabetes.

CONCLUSIONS: The incidence of diabetes in Ukraine in 2015 was significantly higher than the consumption of OHDs, which indicates an insufficient level of OHDs consumption.
PDB69: IMPLICATIONS OF THE GERMAN HTA-PROCESS ON MARKET-UPTAKE OF ORAL TREATMENTS FOR TYPE-2 DIABETES (T2DM) SINCE 2007

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OBJECTIVES: Since 2011, all new pharmaceuticals are subject to early benefit assessment in Germany. During 2013 some antidiabetics that were launched before 2011 also had to undergo benefit assessment. We aimed to understand the impact of early benefit assessment on market-uptake (sales in units) of new oral treatments for T2DM during the first 24 months. METHODS: We used IMS Pharmascop® data to analyze the number of packs sold during the first 24 months after launch of oral antidiabetics. We compared substances launched during the four years before and after the introduction of early benefit assessment. In addition, we analyzed the impact of benefit assessment for substances launched before 2011 and all re-assessments. We distinguish between mono substances and combination therapies with the therapy standard metformin. RESULTS: Between 2007 and 2014, twelve new oral antidiabetics - seven mono substances and five combinations with metformin – entered the market. Sitagliptin, vildagliptin, saxagliptin, vildagliptin/metformin and sitagliptin/metformin were launched before 2011. Among these sitagliptin and sitagliptin/metformin were most successful. HTA-assessment acknowledged good efficacy and safety profile of sitagliptin and supported sales. A positive assessment of saxagliptin did not boost sales. Vildagliptin exited the market after a negative assessment. With exception of the re-assessment of empagliflozin, all products got a negative evaluation. However, dapagliflozin and empagliflozin had a market-uptake similar to sitagliptin during the first two years after launch (about 25,000 units sold per month). With the exception of sitagliptin/metformin all combinations with metformin did not reach a relevant market share within two years. CONCLUSIONS: HTA assessment lead to market exits of five out of twelve products due to negative evaluations. Positive assessment might have improved the sales of sitagliptin, sitagliptin/metformin and empagliflozin. Saxagliptin did not gain from a positive evaluation. Despite a negative evaluation, dapagliflozin reached a relevant market share.

PDB70: ASSESSMENT OF LIPID-LOWERING THERAPY PRESCRIBING AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS IN MALAYSIAN PRIMARY CARE SETTINGS

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OBJECTIVES: Dyslipidemia is a major contributor to the evolution of cardiovascular disease (CVD) among patients with type 2 diabetes mellitus (T2DM). There is a guideline recommendation to offer statin therapy to all T2DM patients between 40 to 75 years old for either primary or secondary CVD prophylaxis. Nevertheless, the suboptimal management of diabetic dyslipidemia in the Malaysian primary care settings has been reported. This study aimed to describe the statin therapy prescribing pattern among patients with T2DM, evaluate the appropriateness of statin therapy prescribing, and assess the level of achievement of the primary target (LDL-C) for diabetic dyslipidemia treatment. METHODS: A cross-sectional study involved 404 T2DM patients from four primary health clinics in the state of Pahang, Malaysia. The patients were considered for the study if they met the age requirements (between 40 to 75 years), and had no clinical contraindications to receive statin therapy. The Diabetes Registry and patients’ medical records were reviewed to assess the pattern of statin therapy prescribing from January 2015 till December 2016. RESULTS: The overall percentage of T2DM patients receiving statin therapy was 83.6% (338/404). Approximately 16.4% of study cases were not receiving any lipid-lowering therapy. The most common pattern change noted in lipid-lowering therapy prescribing was the switching between different types of statin treatment (24%). Statin therapy was appropriately prescribed in 67% of the cases. About 16% of the lipid-lowering therapy prescriptions have at least one significant drug interaction with co-prescribed medications. Finally, the lipid-lowering therapy prescribing achieved the primary target of LDL-C levels in only 40% of T2DM patients. CONCLUSIONS: Lipid-lowering therapy prescribing in the primary care settings needs to be further improved to cover all eligible patients, and to decrease the incidence of drug-drug interactions. Additional statin therapy intensification or use of combination therapy may be needed to enhance the achievement of LDL-C targets among patients with T2DM.

PDB71: QUANTIFYING THE TRADE-OFF BETWEEN IMPROVED GLYCEMIC CONTROL AND SEVERE HYPOGLYCEMIA RISK IN PATIENTS WITH TYPE 1 DIABETES: A HEALTH ECONOMIC ANALYSIS IN THE UK

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OBJECTIVES: The Diabetes Control and Complications Trial (DCCT) established that intensive glycemic control results in improved long-term microvascular outcomes in patients with type 1 diabetes (T1D). The DCCT also, however, reported a threefold increase in severe hypoglycemia rates in intensively-managed patients relative to conventionally-managed patients. The present analysis used modern computer simulation techniques to quantify this trade-off between glycemic control and severe hypoglycemia risk. METHODS: A complication cost analysis was conducted with the PRIME Diabetes Model, a long-term, externally audited and validated patient-level simulation.
model of T1D. A Poisson regression model from the DCCT was used to establish the expected glycated hemoglobin (HbA1c) levels attained in populations with average severe hypoglycemia rates of 0.4 and 0.6 events per year. These scenarios were used as the basis of the analysis, modeling incremental costs associated with diabetes complication incidence in the two scenarios over patient lifetimes. Costs were reported in 2016 pounds sterling, with future costs and effects discounted at 3.5% per annum. **RESULTS:** Populations of patients with average severe hypoglycemia rates of 0.4 and 0.6 events per year would be anticipated to have mean HbA1c levels of 8.54% and 7.38% respectively based on DCCT data. The increased hypoglycemia (low HbA1c) scenario improved quality-adjusted life expectancy relative to the lower hypoglycemia rate scenario, yielding an improvement of 0.30 quality-adjusted life years, despite an increase in cumulative incidence of hypoglycemia-related mortality from 0.78% to 0.91%. Average complication costs decreased by GBP 928 from GBP 23,632 to GBP 22,703 with improved glycemic control. **CONCLUSIONS:** The present analysis demonstrated the utility of computer simulation models such as the PRIME Diabetes Model in evaluating treatment guidelines. The analysis showed that the trade-offs of increased hypoglycemia and hypoglycemia-related mortality are more than offset by improvements in quality of life and reductions in cost at the population level.

**PDB72: THE IMPACT OF BIOSIMILAR LAUNCH ON MOLECULE PRICE AND PHARMACEUTICAL EXPENSE: THE CASE OF THE INSULIN GLARGINE IN ITALY**

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**OBJECTIVES:** Italian Medicines Agency (AIFA) sets the ex-factory price of hospital drug and negotiates discounts for the purchases to public institutions. Hospital and local health authority (ASL) are allowed to purchase drugs with a discount on the official selling price. Lower prices can be obtained through tenders, which are organized by groups of hospitals or at regional level. This research aims to analyze the impact on tender discounts and on the pharmaceutical expense of the therapeutic area following the biosimilar launch. **METHODS:** An overview analysis of the insulin market was conducted, to individuate the market share (in terms of volume) covered by the originator insulin glargine from Jan 2016 to Mar 2017. An analysis of the monthly real purchase discount in tender was conducted to calculate the actual hospital expenditure and the changes in tender discount after the biosimilar introduction. The real tender price was statistically calculated starting from a QuintilesIMS database, which gathers sales data of hospital and local healthcare unit distribution. **RESULTS:** Since February 2016, the biosimilar introduction involved an increase of the originator tender discount from 11% to 20% compared to the ex-factory price. The biosimilar presented a price around 13% lower than the originator, remaining almost stable during the period of analysis. At regional level different prices were applied, resulting in a high variability of biosimilar adoption. Finally, tender price decreased among other long-acting basal insulins. **CONCLUSIONS:** The biosimilars launch increases the level of competition of the market, pushing the originators to reduce their prices through tender discounts. This effect seems to involve not only the originator but also the other molecules within the therapeutic area, showing a common trend of price reduction. This entails an opportunity of saving for the healthcare system, especially for chronic and high spending therapeutic areas.

**PDB73: HEALTH ECONOMICS EVIDENCE IN PEER-REVIEWED JOURNALS: INCREASE IN REPORTING OF REAL-WORLD DATA OVER TIME IN TYPE 2 DIABETES**


**OBJECTIVES:** With the rising need to contain health care costs, health economic (HE) studies are of increasing interest to a variety of audiences. This study analyzed trends over time in HE information in type 2 diabetes (T2D) being published in peer-reviewed journals. **METHODS:** A literature search was performed using EMBASE to identify published original HE articles in T2D. The inclusion criteria of HE studies was based on definition by ISPOR and the search strategy was derived from previously published recommendations. Year 2008 was selected as the “baseline” year and compared to 2012 and 2016. Included studies were reviewed and categorized into research types (economic evaluation, cost analysis, clinical+cost study, other), data sources (trials, real-world, survey, literature, other), study perspective (payer, healthcare provide, patients, societal, other) and journal types (HE, general medicine, disease-specific, pharmacy, based on journal scope). Chi-square tests were used to compare the proportion of articles grouped by different categories during 2008-2016. **RESULTS:** The number of T2D HE studies increased from 63 in 2008 to 176 in 2012 and 199 in 2016. Most studies were economic evaluations (58.7%, 39.8% and 50.8% in 2008, 2012 and 2016, respectively). In 2008, studies mainly used data from trials (42.9%). This proportion decreased to 17.6% in 2012 and 24.1% in 2016. Meanwhile, real-world data became the main data source in HE studies (2008: 34.9%; 2012: 45.5%; 2016: 46.7%, p=0.001). The perspective of the HE studies did not reveal significant changes during 2008-2016 (p=0.180), with approximately 75% studies adopting a third-party payer’s perspective. HE studies more specifically targeted health economists/policy-maker journal audiences during 2008-
CONCLUSIONS: During the period 2008-2016, the number of HE publications increased in T2D with a shift from trial to real-world data sources. Our results suggest an increasing trend of publishing HE information targeting healthcare decision-makers.

PDB74: FACTORS AFFECTING POLYPHARMACY IN ELDERLY PATIENTS WITH DIABETES IN GREECE

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OBJECTIVES: To determine prevalence and factors affecting polypharmacy among elderly diabetic patients in Greece. METHODS: A prospective multi-center cross-sectional study was carried out in the regions of Attica and Western Greece. Data were collected via personal interviews at the outpatients’ and specialized diabetes units of the public, private and university hospitals. A random sample of 702 patients was selected out of 1,134 patients followed up from March to May 2016. A questionnaire was prepared based on the EU SIMPATHY experience including questions on patients’ characteristics, medication use and adherence, adverse drug reactions (ADRs) and self-assessment of health status. The criterion for polypharmacy was defined as the concomitant use of 5 or more medications. Descriptive and multiple regression analyses were performed to examine the impact of studied independent variables on polypharmacy. Data analysis was carried out using SPSS-21. RESULTS: 644 outpatients filled out the questionnaire (RR=91.7%) with mean age of 67.8 (SD 13) years and disease duration of 1 (SD 8) years. The prevalence of polypharmacy among the sample is 22.5%. Mean number of medications used by each elder was 4.2 (SD 2.5). Approximately 6/10 patients received antidiabetic drug as monotherapy, and 4/10 received at least one more medication for other chronic diseases. The majority of the sample suffered from cardiovascular diseases. The findings showed that polypharmacy is associated significantly by gender (P ≤ 0.01; β = 2.093), age (P = 0.005; β = 0.226), presence of ADRs (P = 0.085; β = 0.778), caregiver help in taking medicines (P = 0.025; β = 0.491), increased drug dosage in order to feel better (P = 0.028; β = 0.403) and self-assessment of health status (P ≤ 0.01; β = 0.451). CONCLUSIONS: Change management practices and integrated healthcare networks are needed to be introduced in Greece in order to support health providers to medication decision making as well as to educate elderly about the consequences of polypharmacy.

PDB75: ANALYSIS OF THE G-BA DECISION-MAKING CRITERIA ON THE BENEFIT ASSESSMENT OF DIABETES TREATMENTS: IS COST AN INFLUENCING CRITERION?

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OBJECTIVES: Since 2011, manufacturers have been required to submit a value dossier for clinical assessment to the Joint Federal Committee (G-BA). All new medical products, except hospital use only, orphan drugs and medicines with less than €1 million annual sales are assessed. The objective of this research was to explore the reasons why treatments in diabetes have received a low G-BA assessment score (score below 5) and to assess whether the proposed cost of a treatment may be influencing factor in the G-BA assessment. METHODS: All completed G-BA assessments for diabetes indicated products between Jan-2011 to May-2017 were reviewed. For treatments scoring below 5 (no additional benefit proven), the key reasons behind the score were explored using the G-BA “Tragende Gründe zum Beschluss” documentation. Furthermore, the percentage difference in the annual average cost per patient of the new treatment versus the manufacturer selected comparator was assessed for the scope treatments using the G-BA “Beschlussextx”. RESULTS: The main reasons for treatments receiving a low benefit score were due to the study design and population, the comparator chosen by the manufacturer, a worse clinical outcome versus the selected comparator or no data to prove additional benefit. On average a ~300% i.e. ~700€ increase in the proposed annual cost per patient of the new therapy versus to the manufacturer selected comparator was observed. CONCLUSIONS: No clinical data to prove additional benefit and the “inappropriate” study design for new treatments were the main reasons for the G-BA to assign a low benefit assessment score in indicated treatment populations. The differences in annual cost per patient between the new therapy and the comparator were found not to be significantly dissimilar for drugs/indications that received a positive benefit rating and those that received a negative rating. Therefore, cost does not seem to be an influencing factor in the benefit assessment.

PDB76: EVALUATING THE LONG-TERM IMPACT OF IMPROVING CARE FOR PATIENTS WITH TYPE 2 DIABETES IN CHINA

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OBJECTIVES: The United Nations has set a number of Sustainable Development Goals (SDGs), including reducing premature mortality due to non-communicable diseases (NCDs) by one-third by 2030. Diabetes is associated with significant clinical and economic burden in China, and therefore the aim of the present analysis was to examine the health economic impact of improving care for patients with diabetes in China, and how this relates to meeting the SDG. METHODS: Long-term outcomes were projected for patients with type 2 diabetes meeting treatment targets recommended by the Chinese Diabetes Society versus remaining at the current standard of care. Baseline cohort characteristics were taken from patients with diabetes in the China NCD Surveillance study, supplemented with data from A1chieve and DiabCare. Costs of treating diabetes-related complications were taken from a study conducted in 20 Chinese hospitals and were inflated to 2015 values. Outcomes were discounted at 3% annually where appropriate. RESULTS: Bringing patients to treatment targets was associated with improved mean undiscounted life expectancy compared with current standard of care (18.50 versus 18.08 years). Nationally, discounted cost savings of up to CNY 540 billion could be generated as a result of reduced onset of diabetes-related complications if all patients with diabetes achieved treatment targets. Bringing patients to treatment targets reduced premature mortality due to diabetes by 6% compared with current standard of care. Therefore improving care is not sufficient to meet the SDG. In addition to improving care, a 29.1% of reduction in the prevalence of diabetes was required to meet the premature mortality target. CONCLUSIONS: Long-term projections suggested that bringing diabetes patients to treatment targets resulted in improved life expectancy and significant cost-savings. Diabetes prevention should form one of the key aims in order to achieve the 2030 SDG premature mortality target in China.

PDB77: PATIENT CHARACTERISTICS OF PREMIX INSULIN USERS IN CHINA: AN ANALYSIS OF ELECTRONIC MEDICAL RECORD DATA

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OBJECTIVES: Premix insulins (premix), which can be classified as low-mix and mid-mix based on the proportion of prandial and basal insulins, are widely used in China for type 2 diabetes mellitus (T2DM) patients poorly controlled by oral antidiabetic drugs. This study aimed to assess patient characteristics of premix users in China. METHODS: A large electronic medical record database from four tertiary hospitals in major cities (2009-2015) was used. Adult T2DM patients with ≥1 premix prescription were selected and classified into mid-mix and low-mix groups based on their first premix received in the database. The index date was the first premix prescription date. Prescription trend was described. Patient demographics and clinical characteristics and resource use prior to premix use, daily dose, and concomitant medication use were compared between the two groups using two sample t-tests and Chi-square tests/Fisher's exact tests. RESULTS: Among the selected 7,453 premix users, 495 (6.6%) used mid-mix as their first premix. The proportion of mid-mix use increased in recent years (2010-2012: 4.0% vs 2013-2015: 12.0%, p<0.0001). Age and gender were comparable among mid-mix vs low-mix patients (Mean±SD: 55.8±11.5 vs 55.6±11.3 years, p=0.1763; female: 41.4% vs 45.5%, p=0.0796). The mid-mix group had lower prevalences of diabetic nephropathy and diabetic neuropathy/diabetic peripheral circulatory disorders, a higher prevalence of dyslipidemia during the 12-month baseline period (16.6% vs 33.9%, 17.0% vs 37.9%, 18.4% vs 10.3%, all p<0.0001), and comparable baseline HbA1c (8.7±2.2% vs 8.7±2.3%, p=0.7777). The mid-mix group had a lower daily dose (23.4±18.4 vs 34.8±26.1 units, p<0.0001) and fewer concomitant non-insulin antidiabetics use (21.0% vs 35.4%, p<0.0001) on the index date. The mid-mix group had fewer baseline outpatient visits (4.1±1.5 vs 7.1±15.3, p<0.0001). CONCLUSIONS: Mid-mix was less prescribed with an increasing trend. Mid-mix users started with a lower dose and had lower rates of concomitant non-insulin antidiabetics use and fewer baseline outpatient visits.

URINARY/KIDNEY DISORDERS - Clinical Outcomes Studies

PUK1: A COMPARATIVE STUDY ON THE EFFECT OF VAREE VIDARYADI KASHAYAM AND BRIHATHYADI KASHAYAM IN LOWER URINARY TRACT INFECTION

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OBJECTIVES: To evaluate the clinical effectiveness of Varee Vidaryadi Kashayam and Brihathyadi Kashayam in Lower Urinary Tract Infection METHODS: A randomized single blind clinical study with pretest and posttest design in 3 groups' standard and trails were adopted, where the patients were given treatment with specific duration with follow up. In total 480 diagnosed Lower urinary tract infection patients were selected irrespective of their sex and age
group of 16-70 from the OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences, Manipal, enrolled for the present study out of which 27 were dropped out. Routine hematological, Bio-chemical, urine analysis were recorded. The main signs and symptoms frequent micturition, yellowish urine, reddish blood mixed, Painful micturition, Burning micturition, were taken for the assessment as symptoms grade parameters. Urine RBC and Pus cells, ESR also taken for the assessment as Laboratory parameters. Data obtained from the above mentioned study was statistically analyzed by using the Z and t tests. RESULTS: In group A-Varee Vidaryadi Kashayam 10% were assessed under Complete cured 15% under Marked improved and 45% under Moderate improved category, in group B-Brihathyadi Kashayam 5% were assessed under complete cured 20% under Marked improved and 20% under Moderate improved category. In group C Norfloxacine 15% were assessed under Complete cured 60% under Marked improved and 25% under Moderate improved category. The study reveals Urine RBC 60.53%, 75.68%, 74.19% Urine pus cells 51.22%, 48.89%, 72.97% ESR 36%, 35%, 70% in 3 groups respectively which were statistically highly significant result p<0.001. CONCLUSIONS: Study concluded both the groups are effective treatment in Lower urinary tract infection and Group A Varee Vidaryadi Kashayam was more effective than group B Brihathyadi Kashayam

PUK1: PATTERNS OF ESTIMATED GLOMERULAR FILTRATION RATE AND ALBUMINURIA IN RELATION TO PROGRESSION TO SERIOUS OUTCOMES: HOSPITALIZATION FOR INFECTION, MAJOR ADVERSE

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OBJECTIVES: To determine the role of corticosteroids in the management of urolithiasis in terms of stone expulsion rate and stones expulsion time. The present study also aims to evaluate the pharmacoeconomic impact of corticosteroids in urolithiasis management. METHODS: A literature search using electronic databases including PubMed, Medline, Google Scholar, and Science Direct was undertaken. An initial limited search of MEDLINE/Pubmed was conducted following medical subject headings (MeSH). Studies published in the English language included with no restrictions on date. The review followed the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement. RESULTS: Initial search identified 1261 records. By excluding duplicates, irrelevant titles, and abstracts screening; final review included six articles. The studies included were conducted in four countries which published between 2000 and 2016. All studies sampled patients with ureteral stones. Corticosteroids agents used were (Deflazacort, Methylprednisolone, and Prednisolone); each trial used one of them as monotherapy or in combination with medical expulsive therapy. Retrieved studies achieved their objectives by looking for stone expulsion rates and stone expulsion time, among other outcome measures. CONCLUSIONS: Corticosteroids might improve the action of medical expulsive drugs when combined together for the treatment of ureterolithiasis. Corticosteroids reduction of the time for stone passage was statistically significant in most studies. Future prospective research and pharmacoeconomic studies are required to determine the corticosteroids actual role in the management of urinary tract stones, and if their combination is worth it.

PUK2: DOSE APPROPRIATENESS OF ANTIBIOTICS: DECIPHERING INFECTIONS IN RENAL IMPAIRMENT

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OBJECTIVES: To assess the impact of dose appropriateness on clinical outcome and evaluation of direct costs involved in antibiotic therapy in renal impairment. METHODS: A prospective study was conducted on in-patients in the nephrology department, prescribed with antibiotics in a tertiary care hospital. The creatinine clearance (CrCl) was calculated by Cockroft Gault and Jelliffe method. The dose appropriateness was checked by using standard databases and literature from the manufacturer. The direct cost involved in the antibiotic therapy was calculated by accessing IP bills from the finance department. RESULTS: A total of 163 cases were collected of which 139 was taken for analysis. 80.6% (112) cases were diagnosed with chronic kidney disease (CKD) and 19.4% (27) were diagnosed with acute kidney injury (AKI). The mean age of the population is 54±13 and the mean duration of hospitalization was 6±2 days. Urinary tract infection was the most common infectious complication in the clinical setting. Mono therapy (54.7%) was the most preferred choice, followed by dual therapy (40.3%) and triple therapy (5%). A positive clinical outcome of 79.1% was achieved. Cefoperazone sulbactam was the most widely used antibiotic. A mean difference of 4.55ml/min was obtained when creatinine clearance was calculated by Cockroft Gault and Jelliffe method. The dose appropriateness is a significant factor in achieving a positive clinical outcome. The direct cost involved in the management of CKD was much higher than that of AKI. The management of systemic infections involved maximum costs INR 70,040. 00. CONCLUSIONS: There is an overestimation of CrCl measured by conventional methods in AKI. Dose appropriateness is a significant factor in achieving a positive clinical outcome. Medicine cost was found to be maximum in comparison to the other costs involved.

PUK3: A SYSTEMATIC REVIEW OF CORTICOSTEROIDS’ ROLE IN THE MANAGEMENT OF UROLITHIASIS PATIENTS

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OBJECTIVES: To determine the role of corticosteroids in the management of urolithiasis in terms of stone expulsion rate and stones expulsion time. The present study also aims to evaluate the pharmacoeconomic impact of corticosteroids in urolithiasis management. METHODS: A literature search using electronic databases including PubMed, Medline, Google Scholar, and Science Direct was undertaken. An initial limited search of MEDLINE/Pubmed was conducted following medical subject headings (MeSH). Studies published in the English language included with no restrictions on date. The review followed the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement. RESULTS: Initial search identified 1261 records. By excluding duplicates, irrelevant titles, and abstracts screening; final review included six articles. The studies included were conducted in four countries which published between 2000 and 2016. All studies sampled patients with ureteral stones. Corticosteroids agents used were (Deflazacort, Methylprednisolone, and Prednisolone); each trial used one of them as monotherapy or in combination with medical expulsive therapy. Retrieved studies achieved their objectives by looking for stone expulsion rates and stone expulsion time, among other outcome measures. CONCLUSIONS: Corticosteroids might improve the action of medical expulsive drugs when combined together for the treatment of ureterolithiasis. Corticosteroids reduction of the time for stone passage was statistically significant in most studies. Future prospective research and pharmacoeconomic studies are required to determine the corticosteroids actual role in the management of urinary tract stones, and if their combination is worth it.

PUK4: PATTERNS OF ESTIMATED GLOMERULAR FILTRATION RATE AND ALBUMINURIA IN RELATION TO PROGRESSION TO SERIOUS OUTCOMES: HOSPITALIZATION FOR INFECTION, MAJOR ADVERSE
CARDIOVASCULAR EVENTS AND RENAL FAILURE

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OBJECTIVES: The purpose of this retrospective, observational study was to evaluate the association between two key measures of kidney disease: estimated glomerular filtration rate (eGFR) and albuminuria, and serious adverse outcomes. METHODS: Data were extracted from routine UK primary care and linked hospital data. Patients with a record of chronic kidney disease (CKD) were identified and their eGFR and albuminuria records classified, respectively, as G1 (normal/high) to G5 (end stage) and A1 (normal/mild) to A3 (severely increased) in accordance with international guidelines. Time-dependent Cox proportional hazard models were used to estimate risk and account for potentially confounding factors, incorporating eGFR and albuminuria staging, diabetes status, age, gender, prior comorbid events, smoking status, BMI, and prior antihypertensive therapy with ACE inhibitors or angiotensin receptor blockers (ARBs). eGFR category G2 (mildly decreased eGFR) and A1 were used as referents. Outcomes were kidney failure (dialysis or transplant), hospitalization for infection, and hospitalization for major adverse cardiovascular event (MACE; myocardial infarction or stroke). RESULTS: We identified 106,419 patients with a record of CKD. For kidney failure, the adjusted hazard ratio (aHR) was 1.28, 1.06, 2.68, 15.01, and 114.14 for G1, G3a, G3b, G4, and G5, respectively, and 1.69, 2.52, and 3.56 for A2, A2/3, and A3, respectively. For MACE, the aHR was 1.40, 1.05, 1.28, 1.52, and 2.22, respectively, and 1.23, 1.06, and 1.60, respectively. For infections, the aHR was 0.88, 1.16, 1.40, 1.76, and 2.56, respectively, and 1.16, 1.20, and 1.28, respectively. All aHRs were significant at the conventional level of significance. CONCLUSIONS: eGFR was a distinct marker of adverse outcome in all three serious clinical endpoints, and albuminuria was an independent marker of adverse outcome.

URINARY/KIDNEY DISORDERS - Cost Studies

PUK5: PHARMACOECONOMIC ANALYSIS OF USING SOLIFENACIN AND MODIFIED-RELEASE TAMLSULOSIN FIXED DOSE COMBINATION FOR TREATMENT OF STORAGE SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA

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OBJECTIVES: Approximately 1 million men in Russia suffer from storage symptoms associated with benign prostatic hyperplasia (BPH). Most of them are eligible for α-blockers monotherapy, but approximately 250,000 men have insufficient response to it. Modern guidelines suggest treating them with combination of α-blockers and muscarinic receptor antagonists that are available as free or fixed-dose combination (FDC). The aim of the current study was the budget impact analysis of using FDC for treatment of patients with storage symptoms associated with BPH, who do not respond to first-line tamsulosin monotherapy in Russia. METHODS: We considered three therapy scenarios: 1) FDC of solifenacin 6 mg + tamsulosin 0.4 mg modified-release tablets; 2) free combination of solifenacin (5 mg) and tamsulosin (0.4 mg modified release capsules, MRC); 3) free combination of solifenacin (5 mg) and tamsulosin (0.4 mg prolonged-release tablets, PRT). We employed 1-year Markov model of storage symptoms associated with BPH, as proposed in Nazir et al (2015). Drug, GP visits and prostate resection costs were considered. RESULTS: 35,400 out of 250,000 men suffering from storage symptoms associated with BPH are eligible for government reimbursement. FDC drug was cost saving, as the annual cost was $384 per patient, which is $35 less than the free combination involving MRC and $195 less when using free combination involving PRT. The overall healthcare annual expenses of using the FDC drug was $96 million or $9 million less than free combination with MRC ($49 million less than free combination with PRT). Government reimbursement costs for FDC were $10 million or $1 million less when using free combination with MRC ($7 million less when using free combination with PRT). CONCLUSIONS: Using the FDC drug for treatment of patients with storage symptoms associated with BPH is a cost-saving alternative to the free combination of solifenacin and tamsulosin.

PUK6: THE SITUATION AND IMPORTANCE OF PERITONEAL DIALYSIS IN RENAL FAILURE: ECONOMIC ANALYSIS

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OBJECTIVES: Determination of direct and indirect costs and cost effectiveness of dialysis treatments in renal
failure. METHODS: In the study, costs are divided into direct costs and indirect costs. Indirect costs are defined as costs to the patient and society while direct costs constitute of to the public payer institution, Social Security Institution(SGK). Direct costs are catheter placement cost, laboratory examination list for transplantation, dialysis session costs and drug costs. Indirect costs are loss of workforce, productivity loss, accompanying costs, transportation costs, home caring costs and benefits. Markov model used for cost-effectiveness analysis in the 60-month period. RESULTS: Direct costs of PD, HD and HHD are per year 36120.25 TL (10261.43 USD), 31701.88 TL (9006.22 USD), and indirect costs are per year 29244.91 TL (8308.21 USD), 8812.50 TL (2503.55 USD), 7474.34 TL (2123.99 USD), 12132.95 TL (3446.69 USD) respectively. Total costs of PD, HD and HHD are 44932.75 TL (12764.99 USD), 39176.22 TL (11129.61 USD), 43177.26 TL (11754.9 USD) respectively. According to the cost-effectiveness analysis, the total cost of 5 years was calculated as 139,226.60 TL (39553.01 USD) for HD, 185,028.19 TL (52564.83 USD) for PD and 200,640.13 TL (57000.04 USD) for HHD and the total QALY for the same period was again calculated as 2.3618522, 2.8917368 and 3.6634681 respectively. Cost per QALY is 58,948.05 TL (16746.60 USD) for HD, 63,985.14 TL (18177.60 USD) for PD and 54,767.81 TL (15559.04 USD) for HHD. CONCLUSIONS: According to ICER analysis, the most cost effective method was found to be HD. According to PD, HD was found as the second cost effective method with 86436.91 TL (24555.94 USD ) per QALY of offering ICER. According to PD, HHD was found to be the third cost effective method of ICER-offering with 20229.76 TL (5747.09 USD) per QALY.

PUK7: COMPARISON OF POST-CREATION PROCEDURES AND RELATED COSTS BETWEEN TRADITIONAL SURGICAL VERSUS A NEW ENDOVASCULAR APPROACH TO CREATING AN ARTERIOVENOUS FISTULA: A USRDS COMPARISON
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OBJECTIVES: For hemo dialysis patients, it is common to require two or more additional procedures to facilitate maturation and maintain functionality after the initial arteriovenous fistula (AVF) creation. A new endovascular method to create an AVF using a catheter-based system with radiofrequency energy, instead of open surgery, has been developed (endoAVF). This study used administrative data from the United States Renal Data System (USRDS) to assess the difference in AVF post-creation maintenance and estimated associated costs between patients receiving a traditional surgical AVF (SAVF) and an endoAVF. METHODS: USRDS files were abstracted to determine post-creation procedure rates and associated costs for SAVF created from 2011 to 2013. Medicare enrollment within the USRDS during the 6 months prior to and after the AVF creation was required. Patients’ follow-up inpatient, outpatient, and physician claims were used to identify post-creation procedures and estimate average procedure costs using Medicare fee schedule provider costs. Comparative procedural information on endoAVF patients was obtained from the Novel Endovascular Access Trial (NEAT). Sixty Medicare patients from the USRDS database were matched to 60 NEAT patients using one-to-one propensity score (PS) matching based on demographic and clinical characteristics. RESULTS: From 103,420 USRDS SAVF patients, 60 SAVF patients were successfully matched to endoAVF patients (PS overlap 99.6%). The total post-creation procedural event rate was 0.59 per patient-year for endoAVF patients compared to 5.59 per patient-year in the matched SAVF cohort (p=0.05). The endoAVF cohort had significantly lower event rates than the SAVF cohort for the following procedures, p<0.05: angioplasty, thrombectomy, revision, catheter placement, arteriovenous graft creation, new SAVF, distal revascularization and interval ligation, embolization, stent placement and vascular access-related infection. Average cost per patient-year associated with post-creation procedures was US$14,090 lower for endoAVF than for SAVF. CONCLUSIONS: Compared to patients with SAVF, patients with endoAVF required fewer post-creation procedures and had lower associated mean costs.

PUK8: RETROSPECTIVE STUDY ON ITALIAN ADPKD DISEASE MANAGEMENT COST (REINA STUDY)
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OBJECTIVES: The aim of this study was to estimate the economic burden of Autosomal dominant polycystic kidney disease (ADPKD) in Italy, analyzing direct costs according to progression stage of chronic kidney disease (CKD). The primary endpoint was the average annual cost per patient with ADPKD in Italy. The secondary endpoint was represented by the average annual cost per patient suffering from ADPKD for CKD I to CKD V (not under dialysis), dialysis and post-transplant stage. METHODS: This retrospective, observational study was carried out by gathering data through a pre-specified Case Report Form (CRF) in six Italian hospitals. Costs associated with ADPKD were
estimated based on identified cost drivers and the analysis was performed using the Activity-Based Costing method. Inpatient and outpatient resource consumption was collected for each patient during the period 2012-2015. Direct costs were then calculated from the perspective of the Italian National Health Service (NHS). RESULTS: 191 patients were enrolled. The analysis estimated an average annual cost associated with ADPKD management of € 7,921. The average annual cost of patients under dialysis was € 27,353, followed by post-transplantation and CKD V patients (respectively € 22,793 and € 12,658), CKD IV (€ 7,320) and finally CKD II, CKD I (respectively € 723.75, € 674.5 and € 159.7). Costs increased with disease progression, except for post-transplant stage. The outpatient specialist care (including dialysis) represented the highest impact on total costs, followed by pharmacological therapies and hospitalizations. CONCLUSIONS: The study underlined the relevant economic burden of ADPKD and its direct correlation with disease stage, suggesting the importance of slowing down disease progression, both for patient in terms of quality of life and the NHS budget.

**PUK9: ECONOMIC EVALUATION OF EGFR CONTROL IN PATIENTS WITH CHRONIC KIDNEY DISEASE IN JAPAN**

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OBJECTIVES: The aim of this study was to estimate economic impact of eGFR control in patients with chronic kidney disease (CKD) in Japan based on an epidemiological study and cost of medical care at each CKD stage. METHODS: Of the 2410 CKD patients, ≤-53% change in eGFR during 2 years was seen in 87 patients, >-53~≤-30% in 314 patients, and >-30~≤0% in 1153 patients. Baseline eGFR for each group of eGFR changes were 24.4, 22.2, and 30.0, respectively (K. Matsushita et al, Kidney Int., 2016). A Markov model for 60 age CKD patient which consists of health states for CKD stage III to V (end stage renal disease) was used to estimate the economic impact when the patients do not experience the eGFR reduction. The risk of CKD stage progression (e.g., from III to IV) in the model was based on the predicted absolute risk previously reported from Japanese CKD study. Information on costs for each CKD stage was extracted from Japanese literature. RESULTS: Expected total cost during lifetime horizon per patient was 78,675,229 yen, 76,902,293 yen, and 21,140,589 yen for patients experienced ≤-53%, >-53~≤-30%, and >-30~≤-0% change in eGFR, respectively. If the patients do not experience the eGFR reduction, expected total cost during lifetime horizon per patient was 2,861,213 yen, 42,919,151 yen, and 8,792,078 yen, then the expected total cost reduction for patients of each category were 50,063,127 yen, 33,983,142 yen, and 12,348,511 yen, respectively. Therefore, the weighted average cost reduction of patients experienced ≤-30% change in eGFR was 18,831,423 yen. CONCLUSIONS: Our results demonstrate significant economic impact if the eGFR declines can be prevented in patients with CKD and suggest the importance of appropriate management to prevent CKD progression.

**PUK10: ESTIMATING THE ECONOMIC BENEFIT OF TREATMENT WITH ALPHA-BLOCKER PLUS ANTIMUSCARINIC AS A FIXED-DOSE COMBINATION (FDC) TABLET VERSUS CONCOMITANT COMBINATION THERAPY (CCT) IN MEN WITH LOWER URINARY TRACT SYMPTOMS (LUTS) ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA (BPH)**

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OBJECTIVES: European guidelines recommend combination therapy with an alpha-blocker plus antimuscarinic in men with LUTS/BPH and residual storage symptoms after monotherapy treatment with either drug. Using predominantly real-world evidence, this study estimated the cost of treating men with LUTS/BPH with alpha-blocker plus antimuscarinic therapy given as a FDC tablet or as CCT in the Netherlands from a societal perspective. METHODS: A Markov model with monthly cycles and 1-year time horizon was developed. Men with LUTS/BPH (n=100) receive daily treatment with FDC solifenacin 6mg plus TOCAS 0.4mg or CCT alpha-blocker plus antimuscarinic (fesoterodine 4mg, oxybutynin immediate-release [IR] 15mg, solifenacin 5mg, tolterodine extended-release [ER] 4mg, tolterodine IR 4 mg, darifenacin 7.5mg). At the end of each cycle, men persist on treatment, discontinue treatment, switch combination therapy or undergo surgery. Model inputs, derived from the literature and real-world evidence, included 1-year treatment persistence and switching, mortality, direct medical costs and lost productivity. A one-way sensitivity analysis determined the influence of key inputs on the results. RESULTS: A higher proportion of the cohort persisted on treatment with FDC solifenacin plus TOCAS versus the comparators (52.1% vs. 25.8~32.6%). FDC solifenacin plus TOCAS was associated with reduced resource use, including fewer surgeries (n=20.8 vs. 29.0~31.8) and work hours lost (n=1,387 vs. 2,073~2,348), and higher drug acquisition costs (€31,110.13 vs. €4,935.58~25,984.60) versus the comparators. Overall, total estimated annual costs were €117,603.48 (~€3.22/patient/day) for FDC solifenacin plus TOCAS versus €122,723.28~153,854.48 (~€3.36~4.21/patient/day) for the comparators. Key drivers of the results were 1-year persistence and switching treatment. CONCLUSIONS: In the
PUK11: COST-EFFECTIVENESS ANALYSIS OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY VERSUS RETROGRADE INTRARENAL SURGERY IN THE MANAGEMENT OF SMALL MODERATED-SIZED RENAL STONES

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OBJECTIVES: To compare the safety and cost-effectiveness of retrograde intrarenal surgery with Holmium:YAG laser (RIRS) vs extracorporeal Shock Wave Lithotripsy (SWL) in the treatment of small-moderrated renal stones. METHODS: 345 patients who were diagnosed and treated for small-moderrated-sized renal stones (< 20 mm) between June 2012 and December 2014, participated in a prospective study. 201 patients (52,26%) were in SWL group and 144 patients (41,74%) were in RIRS group. SWL was performed under mild sedation with pethidine hydrochloride for a maximum of 4 sessions, and RIRS was performed with flexible ureterorenoscope (Flex-X2 Storz) and intracorporeal Holmium:YAG laser (Stone light-AMS) lithotripsy under general anesthesia. The safety and effectiveness of both treatments were assessed and calculated. The direct cost analysis included costs of: hospitalization, operating theatre and lithotrap procedure, health staff, materials and re-treatments for each procedure applied. RESULTS: Both groups were comparable in terms of side, size, composition of the stone and need for a previous double J ureteric stent. The global stone-free rate for renal uroteroscopy was 91.72% and 79.25% for SWL. In patients with stones <1 cm, the RIRS was significantly better than the SWL with stone-free rates of 91.14% and 83.13% respectively. For stones >1 cm there were also differences: 92.31% stone-free rate in the URS group and 75.2% in the SWL group. The overall complication rate was significantly higher in SWL group (28.95%) as compared to the RIRS group (7.8%). The average cost of the SWL group was 1,069.53 euros, while in the RIRS group it was 2,841.06 euros. The estimated ICER showed that SWL was more cost-effective than RIRS. After performing the Monte Carlo simulation, the dominance of SWL prevailed regardless of the size of stone. CONCLUSIONS: The results of this study indicate that SWL was more cost-effective than RIRS for the treatment of small-moderrated sized renal stones.

PUK12: THE ECONOMIC EVALUATION OF CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD) AND HEMODIALYSIS IN INDONESIA

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OBJECTIVES: To determine costs of Continuous Ambulatory Peritoneal Dialysis (CAPD) and Hemodialysis (HD) treatment, as well as to determine cost-effectiveness between CAPD and HD modality in treating patients with Chronic Kidney Disease in Indonesia. METHODS: Patients with End-Stage Renal Diseases, aged >50 undergoing each modalities, CAPD and HD, were observed retrospectively. Clinical records were taken during the observation, as well as questionnaire used to gather cost description during CAPD and HD treatment. Costs’ were calculated and utility was measured using Quality-Adjusted Life Years (QALYs), using Markov as analytic decision model. In the end of analysis, Incremental Cost-Effectiveness Ratio (ICER) was calculated using costs and QALYs of each modality, as well as probability sensitivity analysis. RESULTS: Using societal perspective, it can be concluded from ICER calculation, CAPD may save IDR 48,850,332 per QALY gained, compared with HD. From the sensitivity analysis, CAPD can be categorized cost-effective when the calculation was plotted in the cost-effectiveness plane. Using five projections in five different parameter scenarios, it is concluded that as the transition of probability to CAPD increases, CAPD will still be cost-saving compared to HD. CONCLUSIONS: Although the average direct medical costs of CAPD is higher than HD, in terms of cost-effectiveness, the results suggest that offering PD as an initial treatment for chronic kidney disease patients would be a better choice than offering HD in the long run.

PUK13: PHARMACOECONOMIC ASSESSMENT OF SUCROFERRIC OXYHYDROXIDE VS SEVELAMER CARBONATE IN PATIENTS WITH CHRONIC KIDNEY DISEASE IN BELGIUM AND THE NETHERLANDS

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Netherlands, FDC solifenacin plus TOCAS is associated with lower resource use, fewer work hours lost, and lower total costs. These results may suggest a clinical and economic benefit of FDC solifenacin plus TOCAS compared with concomitant alpha-blocker plus antimuscarinic therapies in men with LUTS/BPH.
OBJECTIVES: Sucroferric oxyhydroxide (SFOH) is a non-calcium, iron-based phosphate binder indicated for the control of serum phosphorus (sPhos) levels in chronic kidney disease patients on hemodialysis or peritoneal dialysis. A US retrospective analysis demonstrated that, after 3 and 6 months, switching from sevelamer (SEV) to SFOH increased the proportion of patients with in-range sPhos (3.5-5.5 mg/dl) by 74-98%, while reducing pill burden (PB) by 61-62%. Post-hoc analyses of SFOH showed no apparent interaction with oral Vitamin D (VDRAs) contrary to SEV’s potential interactions. The objective of this analysis is to quantify the economic impact of using SFOH vs. SEV in Belgium and the Netherlands. METHODS: Drug acquisition costs were obtained from official list prices and applied to the PB observed in the retrospective analysis. SEV cost was weighted for market shares amongst originators and generics. Number needed to treat to achieve in-range sPhos were used to calculate 3 and 6-monthly costs per responder. Sensitivity analysis (SA) for the PB was conducted. Cost-savings from preventing patients switching from oral to IV VDRAs were calculated, excluding administration and adverse events costs. RESULTS: In Belgium, the 3 and 6-monthly cost per responder for SFOH was EUR2,865 and EUR5,032, respectively, and for SEV was EUR4,699 and EUR7,9412, respectively. In the Netherlands, the 3 and 6-monthly cost per responder for SFOH was EUR2,273 and EUR3,992, respectively, and for SEV was EUR3,650 and EUR7,299, respectively. SA showed lower cost per responder for SFOH, when relative PB was varied, for both countries. The average annual cost-savings of preventing one patient from switching to IV from oral VDRAs were EUR217 (Belgium) and EUR72 (Netherlands). CONCLUSIONS: SFOH appears to attain in-range sPhos at a lower cost compared to SEV and may result in additional cost-savings due to less patients switching from oral to costlier IV VDRAs, suggesting favorable cost-effectiveness.

PUK14: A COST-UTILITY ANALYSIS OF RAASI ENABLING-PATIROMER IN PATIENTS WITH HYPERKALEMIA

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OBJECTIVES: Chronic kidney disease (CKD) affects 6.0% of the United Kingdom’s (UK) population, and includes clinically relevant sub-populations of chronic heart failure (CHF) and diabetic nephropathy (DN). Optimal renin-angiotensin-aldosterone-inhibitor (RAASI) therapy has been shown to be a cost-saving intervention in CKD. However, RAASis induce hyperkalemia leading to dose reduction or discontinuation of RAASis, curtailing potential benefits. The OPAL-HK and AMETHYST-DN trials demonstrated that patiromer maintains normokalaemia and enables RAASI therapy in CKD populations. This analysis aims to evaluate the cost and health benefits that patiromer may provide by from a national health service perspective in the UK. METHODS: An economic analysis, using a Markov model examining renal and cardiovascular events, was conducted over a lifetime horizon. Outcomes of quality-adjusted life years (QALYs) and costs discounted at 3.5% were calculated as per incremental cost-effectiveness ratios (ICERs). Annual rates of clinical events in nephropathy related to mortality, morbidity, and utilities were derived from published literature. Life expectancy was calculated based on age from national lifetables. It was assumed that the RAASI-enabling effect continues as long as the patiromer treatment was given. Clinically relevant subgroups (CHF, DN) were further assessed and uncertainty of the base-case results was examined via univariate sensitivity analysis (SA), probabilistic sensitivity analysis (PSA) and varying scenarios. RESULTS: Including patiromer within a RAASI regimen across the hyperkalemic populations, yielded net gains of £9,540 to £9,950 and 0.33 to 0.54 QALYs demonstrating the intervention to be cost-effective within cost-effectiveness thresholds between £20,000 to £30,000 per QALY. Univariate SA and PSA demonstrated the robustness of the base case results, and that results were probable above 50% chance according to thresholds of cost-effectiveness in the UK. CONCLUSIONS: Patiromer demonstrates potential as a cost-effective intervention for long-term maintenance of RAASI in patients at risk of hyperkalemia, at thresholds defined in the UK.

PUK15: IMPACT OF END-STAGE RENAL DISEASE ON HEALTH ECONOMIC OUTCOMES OF HYPERKALEMIA MANAGEMENT IN PATIENTS WITH CHRONIC KIDNEY DISEASE

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OBJECTIVES: Patients with chronic kidney disease (CKD) experience progressive decline in renal function and are at elevated risk of hyperkalemia (HK). As renal function declines, CKD patients progress to end-stage renal disease (ESRD) which is associated with significant quality of life reductions and healthcare costs. This study aimed to explore the impact of ESRD on estimated health and cost outcomes of managing HK among CKD patients. METHODS: A lifetime patient-level simulation was developed to model CKD progression via declining estimated glomerular filtration rate (eGFR). Simulated time-dependent trajectories of serum potassium (K+) were
linked to cardiovascular events and mortality via published rates. Published utilities and direct healthcare costs (UK, 2015) were applied from a payer perspective independent of K+ management and discounted at 3.5%. The impact of ESRD (eGFR<15 ml/min/1.73m2) on predicted life expectancy (LE), quality-adjusted life years (QALYs) and total disease costs (TDC) was assessed for the comparison of maintained normokalaemia (NK) against fluctuating K+ levels, resulting in HK rates consistent with clinical practice. RESULTS: Among CKD patients aged 60, with eGFR 50 ml/min/1.73m2 at baseline, estimated LE was extended by 0.6 years/patient in the NK group compared to the HK group, resulting in a greater percentage of patients reaching ESRD (49% versus 43%). Prior to patients reaching ESRD, QALYs and TDC were 5.5 and £38,050 (NK group) compared to 5.3 and £37,667 (HK group), corresponding to incremental QALYs and TDC of 0.2 and £383, respectively. Post-ESRD survival led to incremental QALYs of 0.4 (2-fold increase) and incremental TDC of £5,148 (>10-fold increase), driven by dialysis costs in the NK group. CONCLUSIONS: The health economic benefit of improved survival associated with NK in CKD is offset by the high costs associated with dialysis. Consequently, the long-term cost-effectiveness evaluation of effective K+ management in CKD is accurately described when partitioning the results by ESRD status.

PUK16: A COST-UTILITY ANALYSIS OF DUTASTERIDE PLUS TAMulosin COMBINATION THERAPY VERSUS TAMulosin MONOTHERAPY IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA IN IRAN

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OBJECTIVES: Benign prostatic hyperplasia (BPH) is a very common disorder in elderly men. About 23.8% of Iranian male population are suffering from BPH. Common treatment options for BPH include α-blockers like tamsulosin and 5-alpha reductase inhibitors such as dutasteride. This study was planned to estimate the cost-utility of combination therapy for BPH from the Iran Health System perspective. METHODS: A Markov model was designed to calculate costs and outcomes, for patients aged≥40 years with moderate to severe BPH and repeated over 1 year cycles for 35 years. The model, comprised four mutually exclusive health states comparing tamsulosin (0.4 mg/day) and dutasteride (0.5 mg/day)/tamsulosin (0.4 mg/day). A meta-analysis was conducted to estimate ADRs and After Surgery Events (ASEs) probabilities. Utilities were estimated by fulfilling a meta-analysis of studies which had used EQ5D method. Total Cost contained direct costs of medications, inpatient and outpatient services. All utilities and costs were discounted by the rate of 3% and 5% respectively. RESULTS: The annual probabilities of AUR syndrome and TURP surgery incidence were calculated 0.0169 and 0.0193 in monotherapy as well as 0.0055 and 0.0060 in combination therapy respectively. The utilities were accounted 0.86 in mild, 0.79 in moderate, 0.72 in severe states and 0 in death. Regarding meta-analysis results, the ASE probabilities were estimated as follows: TUR syndrome (0-0.0109), Urinary incontinence (0.0198-0.1894), urethral stricture (0.0392-0.0769), UTI (0.0169-0.0787), Urinary retention (0.0296), Erectile dysfunctions (0.1895), clot retention (0.0198-0.0488). Eventually, the ICER for combination therapy was $5159, and Probabilistic sensitivity analysis showed that cost-effectiveness probability, was between 89% and 94% given the threshold range ($3700–$11000 per QALY) applied in Iran. Performing one-way sensitivity analysis, the model was most sensitive to dutasteride unit price and surgery incidence with monotherapy. CONCLUSIONS: Dutasteride/tamsulosin therapy has a high probability of being cost-effective in comparison to tamsulosin monotherapy in Iran.

URINARY/KIDNEY DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PUK17: THE RELATIONSHIP BETWEEN SEVERITY OF CHRONIC KIDNEY DISEASE AND HEALTH RELATED QUALITY OF LIFE AMONG A NATIONALLY REPRESENTATIVE SAMPLE OF COMMUNITY DWELLING ADULTS IN ENGLAND

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OBJECTIVES: Several studies have examined the relationship between health-related quality-of-life (HRQoL) and the severity of chronic kidney disease (CKD) experienced by the individual. While contributing to the literature these studies exhibit limitations related to sample selection and failure to control for the censored nature of the outcome. In this study we examined the relationship between HRQoL and kidney function among a representative sample of community dwelling individuals living in England. METHODS: Data on 2796 individuals from the 2010 Health Survey for England with respect to HRQoL, kidney function and a range of socio-demographic characteristics were obtained. EuroQol 5D-3L data were converted to a utility score using the English national tariff. Severity of CKD was based on estimated glomerular filtration rate (eGFR) and albuminuria status with respondents categorised into one of six levels of kidney disease. A multivariate tobit model was used to examine the relationship between utility scores and severity
of kidney disease controlling for age, gender, socio-economic status, marital status and ethnicity. RESULTS: Those with more advanced CKD were found to have lower HRQoL than those with better kidney function. Compared to those with normal/low normal eGFR and Stage 1 CKD, those with Stage 2 CKD experienced a decrement of approximately 0.09 in their utility index while those with Stage 3a/3b CKD and micro- or macro-albuminuria and those with Stage 4/5 CKD experienced decrements of 0.17 and 0.29 respectively, controlling for other variables. CONCLUSIONS: Among individuals with and without CKD we find that kidney function is related to quality of life in a manner consistent with intuition. The utility (uncontrolled) weights generated in our analyses have the potential to be of value in the evaluation of new technologies being developed for the treatment of kidney disease.

PUK18: SENTIMENT ANALYSIS OF SOCIAL MEDIA POSTS FROM RENAL CELL CARCINOMA (RCC) PATIENTS

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OBJECTIVES: Social media are increasingly used by patients and the content of these postings uniquely reflects the views and perspectives of patients. Historical discussions span several years, are updated in real time and are available for large numbers of patients. We examined the valence or sentiment of the language patients use over their treatment history utilising natural language processing (NLP) and sentiment analysis. METHODS: We analysed a corpus of 8,433 postings from 483 Stage 4 RCC patients. Mean sentiment scores over time were computed for all patients for two distinct cases: Over follow-up from time since diagnosis and longitudinally over the 6-year period prior to 2016, regardless of time of diagnosis. The analysis of overall sentiment is presented with reference to a time-line representing regulatory approval of key targeted therapies. RESULTS: Language used over time since diagnosis showed a positive sentiment with a mean value of +1.2 at time of diagnosis (range -5 for negative to +5 for positive), with a gradual decline toward neutral over time. Longitudinal mean sentiment change over time showed a distinct increase in positive sentiment (+0.8 to +1.4 over two years) occurring directly following the approval of 3 targeted therapies in 2010. CONCLUSIONS: Sentiment is much used in other industries, although its use in medical fields is less well explored. The results showing an increase in mean sentiment following the approval of three targeted therapies in 2010 indicate that sentiment scoring can provide information regarding changes in the valence of language used over time, and potentially thereby quantifying a reaction to important events in a patient population. Patient mean sentiment remained positive over time since diagnosis, an overall positive sentiment may be a slightly counter intuitive finding (to non-patients) and is reflective of a predominance of positive wording being used by RCC patients.

PUK19: RISKY BUSINESS: WHAT FACTORS INFLUENCE DECISION-MAKER’S WILLINGNESS TO PAY FOR NEW TREATMENTS ON THE HOSPITAL FORMULARY?

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OBJECTIVES: Hospital Drugs and Therapeutic Committee (DTC) or its equivalent are responsible for making recommendations to fund new medicines on the hospital formulary. These decisions are complex. While safety, efficacy and cost-effectiveness are key considerations, there is limited information surrounding the trade-offs and relative importance of other factors that influence their decisions. This study aimed to understand hospital decision makers (HDMs) stated preferences and the value placed on specific attributes of new treatments for hyperkalaemia to a relevant comparator. Other factors influencing their decision-making were explored. METHODS: Six HDMs were involved in qualitative interviews to inform the design of the discrete choice experiment (DCE). HDMs (n=60) from public and private hospitals in Australia were recruited through a specialist healthcare panel to complete the survey. HDMs were members of the DTC or equivalent and/or had made applications to the hospital formulary. Survey questions elicited treatment attitudes, decision-making criteria and the evidence considered. The DCE required HDMs to trade-off attributes including hospital resource use, frequency and mode of administration, onset of action, side effects, drug interactions and cost. The relative priority HDMs place on different attributes and estimate their willingness to pay for new treatments was assessed using latent class models. RESULTS: HDMs primary clinical role and hospital funding model influenced the key factors driving funding decisions. HDMs were less willing to trade off safety, efficacy and administration to competing considerations such as access and cost-effectiveness. CONCLUSIONS: HDMs preferences were consistent with clinical roles and treatment experience. Overall, HDMs were willing to trade-off between the benefits (clinical and patient), risks (safety) and cost (resource use and treatment cost) when considering the funding of new treatments in the hospital setting.

PUK20: HEALTH VALUATION OF DIALYSIS WITH THE EQ-5D: DETERMINANTS OF DISCREPANCY BETWEEN PATIENTS AND SOCIETY
OBJECTIVES: This study evaluates the discrepancy of self-reported health valuation by incident dialysis patients and the societal valuation of the health states of these patients. Subsequently, it investigates which socio-demographic and medical characteristics explain this discrepancy. METHODS: We used data from the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD-2), a prospective multicenter cohort study on incident end-stage renal disease patients. Health valuation was measured with the EuroQol (EQ-5D) questionnaire. The discrepancy in valuation, ΔEQ-5D, was calculated by subtracting the health valuation by patients (EQ-5D Visual Analogue Scale; EQ-5D VAS) from the societal valuation (EQ-5D Index). Mean ΔEQ-5D scores were stratified by problem level, socio-demographic and medical characteristics. Univariable and multivariable regression analyses were performed to explain the discrepancy by socio-demographic and medical characteristics. RESULTS: 1,441 dialysis patients were included. Overall, the societal (EQ-5D Index) score was higher than the patients’ (EQ-5D VAS) score (mean ΔEQ-5D=10.86, SD=23.63). The discrepancy in valuation was largest for patients who reported no problems on the five health dimensions, were younger, male, never married, highly educated, employed and completed the form without help. CONCLUSIONS: Our results showed that the societal valuation of the health states of dialysis patients is generally higher than patients’ own health valuation, especially for patients who are younger, male, have never been married, a better kidney function and reported no problems. This indicates that using societal valuation with the EQ-5D may underestimate the impact of dialysis on the quality of life of this patient group.

PUK21: QUALITY OF LIFE IN PATIENTS WITH KIDNEY TRANSPLANTATION IN CZECH REPUBLIC

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OBJECTIVES: There are about 40000 patients with chronic kidney disease (CKD) in Slovakia and about 4500 patients are treated by dialysis. More than 120 patients undergo kidney (KT) transplantation per year. The objective of this study was to find out the level of quality of life (QoL) in patients and other relevant characteristics in patients with KT. METHODS: The primary method used for the analysis of QoL was the own original combined questionnaire. Statistical methods from Excel 2010 (Student, Dunn, Friedman, Spearmann tests) were used in results evaluation. RESULTS: There were 100 patients in the examined group, 61 men, 39 women, with age average 49.1 years. The average of CKD duration was 12.17 years, symptoms before diagnosis - 5.8 months, waiting time to transplantation - 3.81 y, time after transplantation - 5.8 y, outpatient visits (nephrology, urology, GP, others) - 7.2 per year. Present level of QoL was identified as 7.22 on the scale from 0 to 10, in the time of the diagnosis - 4.57, in the time of KT – 5.86, in the time without CKD – 8.85 and in optimal state of health – 8.99. Comparative to the QoL was examined the ability to work (AW) – 5.53 vs 4.82 vs 3.87 vs 8.91 vs 9.28. The impact of KT on family QoL reached 6.11. The level of information about the disease was 4.3, physician care - 4.65, nursing care - 4.76 (0-the worst, 5-the best). Disability per month was 3.1 days vs 1.3 days from other diseases. The average income was 339.7 € and the willingness to pay for 1 month of full health was 305.4 € per month. CONCLUSIONS: KT had a significant positive impact on patients’ QoL and AW. QoL and AW had strong correlation each other. The others parameter had no impact on QoL – gender, duration of dialysis, time before transplantation.

PUK22: THE ASSOCIATION HEMOGLOBIN LEVELS WITH HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH CHRONIC KIDNEY DISEASE

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OBJECTIVES: Improvement of hemoglobin in non-dialysis chronic kidney disease (CKD) patients was associated with an increase in health-related quality of life (HRQoL), but in dialysis patients it was still a debate. The purpose of this study was to determine the relationship of hemoglobin levels to HRQoL. METHODS: The research design is cross sectional study, conducted on CKD patients who performed dialysis at two hospitals in Yogyakarta Indonesia. This study examined the relationship between HRQoL and hemoglobin (Hgb) levels in 61 patients with CKD performed hemodialysis. Patients’ hemoglobin levels were categorized into 3 levels, ie < 9, 9 to <10, and ≥10. HRQoL was measured using KDQoL-SF36 when patients visited the hospital for hemodialysis. ANOVA was used to test the relationship between HRQoL score and hemoglobin levels. RESULTS: The results showed that the quality of life scores on the domains of the quality of social interaction and sleep (p < 0.05) were significantly different based on the category of hemoglobin level. Scores of cognitive functions improved with increasing Hb levels. With increasing Hb levels, general health scores, social function and energy/fatigue also increased but not statistically significant. CONCLUSIONS: Higher hemoglobin levels are associated with an increase in the HRQoL domain of the KDQoL-SF36 questionnaire. These findings have implications for the care of CKD patients in maintaining hemoglobin levels.
**PUK23: SEVERITY OF KIDNEY DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS**

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**OBJECTIVES:** Systemic lupus erythematosus (SLE) is autoimmune disease and sometime affects kidney function. The objective of this study is to assess the severity of chronic kidney disease in SLE over time. **METHODS:** In Japan, SLE has been one of designated diseases for the Specified Disease Treatment Research Programme (transferred to Intractable Disease Health Care in 2015) that provides co-payment reduction or exemption according to disease severity and patients’ income levels. To be eligible for the programme, a doctor’s statement should be submitted. Registration data for the programme with indication for SLE were extracted from fiscal years 2004 to 2008. Extracted data were analysed and compared in terms of patients’ age, gender, CKD stages and treatment history. **RESULTS:** 140,286 records were extracted. Total numbers of patients were 56,517 and the male/female ratio was 1:3.1. 7096 patients newly applied for the programme, which implies new-onset SLE. 6818 records (5%) showed symptom of kidney disease. 6056 cases fell in GFR category G1 (88%), 339 cases fell in G2 (5%), 133 cases are fell in G3a (2%), 104 cases fell in G3b (2%), 82 cases fell in G4 (1%) and 104 cases fell in G5 (2%). **CONCLUSIONS:** Prevalence of kidney disease among patients with SLE in Japan is 5%. Considering that GFR category G1 makes up most of the patients with kidney disease, prevention of aggravation is important.

**PUK24: POTENTIAL MEDICATION TRIGGERS OF DETERIORATED RENAL FUNCTION AMONG PATIENTS WITH TYPE 2 DIABETES: USING REAL WORLD DATA**

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**OBJECTIVES:** Identification of medication risk factors for a deteriorated renal function is important to prevent chronic renal damage. The objective of this study was to identify and confirm drug exposure as potential triggers for a deteriorated renal function among type 2 diabetes mellitus (T2DM) patients using real world data (RWD). **METHODS:** A nested case-control study within a T2DM cohort was conducted using the PHARMO Database Network. Between 1999 and 2014 cases with a deteriorated renal function were matched on sex, birth year and geographic region to controls without a decline in renal function. Date of renal decline among cases was set as index date; controls were assigned the index date of their matched cases. Exposure to drugs associated with renal function based on literature and drugs for which additional monitoring of safety is mandatory according to the European Medicines Agency in the 6 months before index date was compared between cases and controls. **RESULTS:** 3,179 cases were matched to 6,106 controls (50% male, mean±SD age 75±9). The following known medication triggers, based on literature, were associated with deteriorated renal function: anti-inflammatory drugs (OR 1.41 (95%CI 1.28-1.55)), contrast agents (OR 2.37 (95%CI 1.81-3.10)), antibiotics (OR 2.82 (95%CI 2.58-3.09)), anti-hypertensives (OR 2.67 (95%CI 2.42-2.93)), PPI’s (OR 2.45 (95%CI 2.24-2.67)) and statins (OR 1.35 (95%CI 1.23-1.48)). Among drugs requiring additional monitoring of safety, domperidone was associated with deterioration in renal function (OR 5.09 (95%CI 3.74-6.91)). **CONCLUSIONS:** Real world data is an important source for identification and confirmation of medication risk factors for deterioration in renal function.

**PUK25: REAL WORLD TREATMENT PATTERNS IN THE NEUROGENIC BLADDER POPULATION: A SYSTEMATIC LITERATURE REVIEW**

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**OBJECTIVES:** To describe the treatment patterns and management strategies of neurogenic bladder (NGB) in real-world settings. **METHODS:** A systematic review (SR) was conducted using MEDLINE and EMBASE (1996-2017). Key terms included a combination of neurogenic bladder, treatment patterns and epidemiological study. The inclusion criteria for studies were: 1) published in English; 2) conducted in human subjects; 4) reporting the treatment patterns/use in NGB (any neurogenic condition listed in the EAU guidelines); 5) conducted in a real world setting. Articles were reviewed for inclusion by an independent reviewer (AJ) and 10% were cross examined by a second independent reviewer (FF). A narrative synthesis of results was conducted and percentage of treatment use was reported in ranges. **RESULTS:** A total of eight studies met the inclusion criteria. Study designs, setting, and patient
groups were notably heterogeneous and all data was collected before 2008. This SR found that the most commonly used management method amongst NGB patients was reflex voiding (RV) methods and catheterisation (CIC and IndUC). Data and commentary from three studies show that a notable amount of patients switched treatments. The most popular oral pharmacotherapies were alpha-blockers and antimuscarinics used for neurogenic detrusor overactivity (NDO) and detrusor sphincter dyssynergia (DSD). One study which focused on spina bifida reported that the majority of patients underwent surgery. **CONCLUSIONS:** With passing time, clinicians have moved away from techniques associated with higher rates of complications and mortality. This has meant that in recent years, the survival chances of patients with NGB have increased. This suggests that current treatment patterns will be different from what was uncovered in this review. Epidemiological studies using electronic healthcare records (EHRs) are necessary to advance our understanding in how NGB patients are managed in current practice, and how well patterns relate to practice guidelines.

**PUK26: BURDEN OF ILLNESS ASSOCIATED WITH ANAEMIA IN CHRONIC KIDNEY DISEASE IN JAPAN: A LITERATURE REVIEW**

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**OBJECTIVES:** Identify the disease burden and treatment patterns associated with anaemia in Japanese patients with chronic kidney disease (CKD). **METHODS:** According to PICO criteria, Medline®, Embase®, and Igaku Chuo Zasshi (ICHUSHI) databases were searched for observational studies, database analyses, and economic evaluations conducted in Japan, published from 2004 onward. Patient populations included Japanese CKD patients with anaemia, on or not on dialysis. Outcomes were epidemiological, economic, and humanistic burden, and treatment patterns. **RESULTS:** Of 1030 references screened, 48 (Japanese, n=27; English, n=21) reported epidemiological (n=23); economic (n=36); and humanistic (n=1) burden; or treatment patterns (n=26). Anaemia prevalence, when defined as haemoglobin (Hb) <10 or <11 g/dL, varied widely (13.8–95%; n=5) among haemodialysis (HD) patients; four studies reported mortality rate (7.2–50%) in HD patients and two evaluated cardiovascular events. While 33 economic studies reported medication dosing, nine reported cost data; one reported a monthly cost of JPY 29,313–37,285 for anaemia management in peritoneal dialysis and HD patients, respectively, and none evaluated the direct impact of anaemia. One humanistic study reported quality of life using the Kidney Disease Quality of Life Instrument, and indicated that patients with Hb <8 g/dL scored 1.6 points lower on the physical and mental component summaries than patients with Hb 11–12 g/dL. Fourteen of the 26 studies reporting treatment patterns included data on responsiveness to erythropoiesis stimulating agents (ESAs; darbepoetin alfa, epoetin alfa and beta, and epoetin beta pegol), ten reported dialysis duration, two reported time to dialysis initiation, four reported supplementary treatments, and one reported ferric citrate hydrate use. **CONCLUSIONS:** This literature review identified an abundance of data on medication dosing and treatment patterns, particularly regarding ESAs. However, the lack of humanistic and cost data reveals a need for further investigation of these outcomes among Japanese patients with anaemia and CKD.
OBJECTIVES: The main objective of this study was to assess the knowledge, attitude of participants towards ADR and to determine the common barriers towards reporting an ADR in Malaysia. METHODS: A descriptive, cross-sectional study was carried out for a period of 3 months in an area of Cheras, Malaysia. The data was collected by a self-administered questionnaire which consisted of 3 sections. RESULTS: Among the 400 respondents, 144 (36%) were male and 256 (64%) were female. The majority of the respondents were Chinese (n=227, 57%). About (n=243, 60.75%) participants reflect inadequate knowledge about what is an ADR. A significant number of the participants (n=333, 83%) were unaware of the ADR reporting center in Malaysia and about (n=344, 86%) stated that they were not aware of the ADR reporting procedure. Participants considered that inadequate knowledge regarding drugs (n=395, 87.4%), their unawareness of reporting procedure (n=320, 80%) and proper access to ADR reporting form (n=299, 75%), could be the main reasons for under-reporting. CONCLUSIONS: As the main loophole for under-reporting an ADR is the lack of public awareness about the reporting centre and its procedure. So there is a dire need that MADRAC should make certain modifications to the existing ADR reporting system in order to identify the aspects to overcome the problems of the present layman reporters. It must also ensure that a separate ADR reporting form for consumers using layman language should be made available apart from encouraging the healthcare professionals to motivate their patients to report ADRs.

OBJECTIVES: In 2011/2012, a single-blind, cluster randomised controlled trial (RCT) was conducted in a tertiary referral Irish hospital to evaluate the Screening Tool of Older Persons’ Prescriptions (STOPP) and Screening Tool to Alert Right Treatment (START) criteria compared to usual hospital care. This intervention demonstrated positive outcomes in terms of reduction of adverse drug reactions (ADRs). The aim of this study was to compare the cost-effectiveness of a physician implementing the STOPP/START criteria to unselected older hospitalised patients in 2011/2012 with the cost-effectiveness of this intervention if applied within the Irish hospital setting using the most currently available (2015) healthcare costs (CAHC). METHODS: Cost-effectiveness analysis (CE) alongside conventional outcome analysis in a cluster RCT. The screening tool was applied to medicines of intervention arm patients (n=360); control arm patients (n=372) received routine medical care. Incremental cost-effectiveness was examined in terms of 2011/2012 costs and CAHC to the Irish healthcare system and an outcome measure of ADRs during an inpatient hospital stay in 2011/2012. Uncertainty in the analysis was explored using a cost-effectiveness acceptability curve (CEAC). RESULTS: On average, the intervention arm was more costly but was also more effective for both 2011/2012 costs and CAHC. The associated incremental cost-effectiveness ratios (ICER) per ADR averted were €5,358 and €5,469 applying 2011/2012 costs and CAHC respectively. The probability of the intervention being cost-effective in 2011/2012 at threshold values of €0, €10,000 and €20,000 was 0.236, 0.680 and 0.926 respectively. The probability of the intervention being cost-effective using CAHC at threshold values of €0, €10,000 and €20,000 was 0.236, 0.672 and 0.921 respectively. CONCLUSIONS: Despite intervention implementation having a slightly greater ICER when using CAHC, such accompanying ADR reductions may possibly result in satisfactory
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PHS5: REPORT OF LOW DENSITY LIPOPROTEIN (LDL) LEVELS IN PATIENTS DIAGNOSED WITH HYPERTENSION, DIABETES MELLITUS AND CHRONIC KIDNEY DISEASE IN COLOMBIAN POPULATION

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PHS4: COMPREHENSIVE KNOWLEDGE AND UPTAKE OF CERVICAL CANCER SCREENING IS LOW AMONG WOMEN LIVING WITH HIV/AIDS IN NORTHWEST ETHIOPIA

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OBJECTIVES: IN ETHIOPIA, CERVICAL CANCER IS RANKED AS THE SECOND MOST COMMON TYPE OF CANCER IN WOMEN AND IT IS ABOUT 8 TIMES MORE COMMON IN HIV INFECTED WOMEN. HOWEVER, DATA ON KNOWLEDGE OF HIV INFECTED WOMEN REGARDING CERVICAL CANCER AND ACCEPTABILITY OF SCREENING IS SCARCE IN ETHIOPIA. HENCE, THE PRESENT STUDY AIMED AT ASSESSING THE LEVEL OF KNOWLEDGE OF ABOUT CERVICAL CANCER AND UPTAKE OF SCREENING AMONG HIV INFECTED WOMEN IN GONDAR, NORTHWEST ETHIOPIA. METHODS: A CROSS SECTIONAL, QUESTIONNAIRE BASED SURVEY WAS CONDUCTED ON 302 HIV INFECTED WOMEN ATTENDING THE OUTPATIENT CLINIC OF UNIVERSITY OF GONDAR REFERRAL AND TEACHING HOSPITAL FROM MARCH 1 TO 30, 2017. DESCRIPTIVE STATISTICS, UNIVARIATE AND MULTIVARIATE LOGISTIC REGRESSION ANALYSIS WERE ALSO PERFORMED TO EXAMINE FACTORS ASSOCIATED WITH UPTAKE OF CERVICAL CANCER SCREENING SERVICE. RESULTS: OVERALL, ONLY 64 (21.2%) OF RESPONDENT WERE KNOWLEDGEABLE ABOUT CERVICAL CANCER AND SCREENING AND ONLY 71 (23.5%) OF RESPONDENTS WERE EVER SCREENED IN THEIR LIFE TIME. AGE BETWEEN 21–29 YEARS OLD (AOR = 2.78, 95% CI = 1.71–7.29), PERCEIVED SUSCEPTIBILITY TO DEVELOP CERVICAL CANCER (AOR =2.85, 95% CI=1.89–4.24) AND COMPREHENSIVE KNOWLEDGE OF CERVICAL CANCER (AOR = 3.02, 95% CI = 2.31–7.15) WERE FOUND TO BE STRONG PREDICTORS OF CERVICAL CANCER SCREENING SERVICE UPTAKE. CONCLUSIONS: THE KNOWLEDGE AND UPTAKE OF CERVICAL CANCER SCREENING AMONG HIV INFECTED WOMEN WAS FOUND TO BE VERY POOR. TAKING INTO CONSIDERATION THE HEIGHTENED IMPORTANCE OF COMPREHENSIVE KNOWLEDGE IN PARTICIPATING IN CERVICAL CANCER SCREENING SERVICES, DIFFERENT STAKEHOLDERS WORKING ON CANCER AND HIV/AIDS SHOULD PROVIDE A CUSTOMIZED HEALTH PROMOTION INTERVENTION AND AWARENESS CREATION TO HIV-INFECTED WOMEN, ALONG WITH IMPROVING ACCESSIBILITY OF CERVICAL CANCER SCREENING SERVICES IN RURAL AREAS.

PHS3: INVESTIGATION OF DEMOGRAPHIC DIFFERENCES FOR NON-SMALL CELL LUNG CANCER PATIENTS WITH AND WITHOUT TYPE 2 DIABETES

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OBJECTIVES: The incidence of type 2 diabetes (T2D) in patients with non-small cell lung cancer (NSCLC) may be higher compared to the general population as there is a likely association with hyperinsulinemia, which is a result of insulin resistance characteristic of T2D. Insulin’s role in cell proliferation through the action of insulin-like growth factor-1, as well as inhibition of apoptosis, could play a significant role in the development of cancerous tissues. Our objective was to characterize the demographic differences in incident NSCLC patients with and without T2D. METHODS: We conducted a cohort study design utilizing Medicare claims from the SEER - Medicare linked database (2007 - 2014). Univariate statistics was completed for descriptive analyses of patient characteristics. We compared NSCLC patients with and without T2D using chi-square test of association. RESULTS: Of 17,176 NSCLC patients, 6,096 patients had T2D in the pre-period (prior to incident NSCLC diagnosis). A greater proportion of NSCLC diabetic patients were males 51% vs.41% (p<0.001) compared to their non-diabetic NSCLC-peers. Diabetic NSCLC patients had a similar distribution in cancer stage, (0.3820). Diabetic NSCLC patients had significantly greater mortality, 81% vs. 77% (p<0.001) and greater number of mean comorbidities 7.45 (SD:4.05) vs. 4.74 (3.72). CONCLUSIONS: These data suggest that NSCLC patients with T2D have a greater number of comorbidities and mortality compared to those without diabetes. Clinical strategies to better manage T2D in NSCLC patients could lower mortality rate, reduce hospitalization time, and lower healthcare costs.

PHS2: SMALL CELL LUNG CANCER (SCLC) PATIENTS WITH TYPE 2 DIABETES (T2D) HAVE A HIGHER DISEASE PROGRESSION RATE, A LOWER MORTALITY RATE, REDUCE HOSPITALIZATION TIME, AND LOWER HEALTHCARE COSTS

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OBJECTIVES: Small cell lung cancer (SCLC) may be small cell lung cancer (NSCLC) may be higher compared to the general population as there is a likely association with hyperinsulinemia, which is a result of insulin resistance characteristic of T2D. Insulin’s role in cell proliferation through the action of insulin-like growth factor-1, as well as inhibition of apoptosis, could play a significant role in the development of cancerous tissues. Our objective was to characterize the demographic differences in incident NSCLC patients with and without T2D. METHODS: We conducted a cohort study design utilizing Medicare claims from the SEER - Medicare linked database (2007 - 2014). Univariate statistics was completed for descriptive analyses of patient characteristics. We compared NSCLC patients with and without T2D using chi-square test of association. RESULTS: Of 17,176 NSCLC patients, 6,096 patients had T2D in the pre-period (prior to incident NSCLC diagnosis). A greater proportion of NSCLC diabetic patients were males 51% vs.41% (p<0.001) compared to their non-diabetic NSCLC-peers. Diabetic NSCLC patients had a similar distribution in cancer stage, (0.3820). Diabetic NSCLC patients had significantly greater mortality, 81% vs. 77% (p<0.001) and greater number of mean comorbidities 7.45 (SD:4.05) vs. 4.74 (3.72). CONCLUSIONS: These data suggest that NSCLC patients with T2D have a greater number of comorbidities and mortality compared to those without diabetes. Clinical strategies to better manage T2D in NSCLC patients could lower mortality rate, reduce hospitalization time, and lower healthcare costs.

PHS1: THE IMPORTANCE OF ACCESSIBILITY OF CERVICAL CANCER SCREENING SERVICES IN RURAL AREAS

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OBJECTIVES: The present study describe the report of Low-density lipoprotein cholesterol (LDL-c) in patients with Chronic Kidney Disease (CKD), Diabetes Mellitus (DM) and Arterial Hypertension in Colombian Health System in 2016. METHODS: All the information was analyzed from the database of the account of high cost, an organization created by the Ministry of Health and the Ministry of Finance. We describe people with confirmed diagnosis of the three pathologies by the insurers of the national territory through the years 2014-2015 and 2016. RESULTS: We found different results in each of the evaluated years, in 2014 we obtained 809,119 LDL records, for the year 2015 the database counts with 1,456,751 which means an increase of 647,632 people, the year 2016 counts with 1,866,396, which constituted an increase of 409,645 records. Between the first year and the second of registration there was an increase of about 45% and between the second and third year 22%. CONCLUSIONS: The registration of complete lipid profiles that include LDL of the high cost account has improved the opportunity and the data through the years, which shows the importance of those data, the fact of having this type of paralines in patients with diagnosis of Chronic Diseases will allow progress in preventive actions, programs and follow-up of patients.

PHS6: CHARACTERIZATION OF LOW DENSITY LIPOPROTEIN (LDL) LEVELS IN PATIENTS DIAGNOSED WITH ARTERIAL HYPERTENSION AND DIABETES IN COLOMBIAN POPULATION IN THE YEAR 2016

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OBJECTIVES: To identify and describe low-density lipoprotein cholesterol (LDL-C) levels in patients diagnosed with hypertension and diabetes in the Colombian health system in 2016. METHODS: A descriptive, observational study of 299,770 patients over 18 years of age with a diagnosis of hypertension and diabetes mellitus reported by 48 insurers in 2016. RESULTS: 37% of the population between 60-69 years of age had altered levels of LDL-C with values between 160-189 and ≥190; While 1.3% of people aged 30-39 reported the lowest proportion. Almost 80% were classified as overweight or obese. Levels of high and very high LDL-C were more frequently found in people with systolic blood pressure between 120 and 139 mmHg followed by the group between 120 mmHg and in a third position in the 140-159mmHg group. CONCLUSIONS: High levels of LDL-C were identified in 9% of the population with hypertension and diabetes. It was determined that the increase in body mass index is related to LDL levels; for 7 years, these patients have been monitored through prevention programs, which must be focused on the management of the disease and evaluation of indicators that show the management of the insurers in the care processes.

PHS7: THE OCCURRENCE AND TERRITORIAL DISTRIBUTION OF ACUTE MYOCARDIAL INFARCTIONS IN HUNGARY

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OBJECTIVES: The aim of the study was to analyze the county distribution of acute myocardial infarctions’ occurrence per 10 000 inhabitants in Hungary in 2016 according to the Hungarian Diagnosis-Related-Groups (DRG) system. METHODS: Data were derived from the financial database of National Institute of Health Insurance Fund Administration and covering the year of 2016. We examined the occurrence and regional distribution of those cases where the main care-justifying diagnosis was acute myocardial infarction. We took those cases into account with the codes I21-I22 in the international classification of diseases. RESULTS: Regarding the analyzed period 20 507 events were recorded in the database. 59.82% of the patients were men, 40.18% of them were women. The average age of the participants was 67.36 years, the men’s being 64.79, the women’s 71.19. Regarding the classification of diseases in the majority of the examined cases the diagnosis was recorded for the first time in 99.42% (I21) while in 0.58% the disease had a repeated occurrence (I22). In the latter group the average age of the patients was higher than in the I21 group (72.21 vs. 67.34). In 2016 an average of 20.7 events came about regarding the patient’s residence per 10 000 inhabitants. The number of cases per 10 000 inhabitants was the lowest in Vas (13.08), Zala (14.98), and Borsod-Abaúj Zemplén (16.18) counties while the highest number was in Békés county (32.09), followed by Heves (30.75) and Komárom-Esztergom counties (29.25). CONCLUSIONS: In the examined sample the occurrence of acute myocardial infarctions was more frequent among male than female patients. In the repeated events the patients’ average age is higher than in the cases where the disease appeared for the first time. We can find significant differences in the disease’s occurrence among counties which fact may be related to the economic situation of the given area in certain cases.
**PHS8: OPTIMAL INTERVAL OF ENDOSCOPIC SCREENING BASED ON STAGE DISTRIBUTION OF DETECTED GASTRIC CANCER**

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**OBJECTIVES:** Although the effectiveness of endoscopic screening for gastric cancer has been shown in Korea, China, and Japan, the screening interval varies. The optimal screening interval was investigated based on the stage distribution of screen-detected gastric cancer. The optimal screening interval of endoscopic screening for gastric cancer was investigated according to the stage distribution of gastric cancer as well as survival rates of patients with screen-detected gastric cancers using the Niigata City Medical Association database. **METHODS:** Patients with gastric cancer detected by endoscopic and radiographic screenings were selected from the Niigata City Medical Association database. The stage distribution of the detected gastric cancers was compared among patients with different screening histories in both screening groups. Gastric cancer specific survival rates were analyzed using the Kaplan-Meier method with the log-rank test. **RESULTS:** There were 1,585 and 462 subjects in the endoscopic and radiographic screening groups, respectively. In the endoscopic screening group, the stage IV proportion was lower in patients with screening history 1 and 2 years previously than in patients without screening history. Although stage IV development was related to the absence of endoscopic screening history (p < 0.001), there were no differences between patients who had screening history 2 and 3 years previously. The survival rates were not significantly different between patients with endoscopic screening 1 and 2 years previously (p = 0.7763). The survival rates were significantly higher in patients with screening history than in patients without screening history (p < 0.001), and in patients with endoscopic screening 3 years previously (p = 0.0069). **CONCLUSIONS:** The endoscopic screening interval for gastric cancer can be expanded to at least 2 years based on the stage distribution of detected cancers and the patient survival rates.

**PHS9: EFFECT OF PHARMACIST CARE ON MEDICATION ADHERENCE AND CARDIOVASCULAR OUTCOMES AMONG PATIENTS POST-ACUTE CORONARY SYNDROME: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** The impact of collaborative and multidisciplinary health care on the outcomes of care in patients with acute coronary syndromes (ACS) is well-established in the literature. However, there is lack of high quality evidence on the role of pharmacist care in this setting. This systematic review aimed to evaluate the impact of pharmacist care on patient outcomes in patients with ACS at or post-discharge. **METHODS:** The following databases were searched from their inception to September 2016: PubMed, EMBASE, Cochrane Central Register of Controlled Trials, ISI Web of Science, Scopus, Campbell Library, Database of Abstracts of Reviews of Effects (DARE), Health System Evidence, Global Health Database, Joanna Briggs Institute Evidence-Based Practice Database, Academic Search Complete, ProQuest, and PROSPERO, and Google Scholar. Studies were included if they evaluated the impact of pharmacist’s care (compared with no pharmacist’s care or usual care) on the outcomes of readmissions, hospitalization, emergency visits, mortality, and medication adherence in patients post-ACS discharge. **RESULTS:** A total of 17 studies [13 randomized controlled trials (RCTs) and four non-randomized clinical studies] involving 8,391 patients were included. The studies were of variable quality (poor to good quality) or risk of bias (moderate to critical risk). Nature and intensity of pharmacist interventions varied among the studies including medication reconciliation, medication therapy management, discharge medication counseling, motivational interviewing, and post-discharge face-to-face or telephone follow-up. Pharmacist-delivered interventions significantly improved medication adherence in four out of 12 studies. However, these did not translate to significant improvements in the rates of readmissions, hospitalizations, emergency visits, and mortality among ACS patients. **CONCLUSIONS:** Pharmacist care of patients discharged after ACS admission was not associated with significant improvement in medication adherence or reductions in readmissions, emergency visits, and mortality. Future studies should use well-designed RCTs to assess the short- and long-term effects of pharmacist interventions in ACS patients.

**PHS10: EFFECTIVENESS OF A PHARMACIST-DELIVERED SMOKING CESSATION PROGRAM IN THE STATE OF QATAR: A RANDOMIZED CONTROLLED TRIAL**

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**OBJECTIVES:** To test the effect of a structured smoking cessation program delivered by trained pharmacists on smoking cessation rates in Qatar. **METHODS:** A prospective randomized controlled trial was conducted in eight ambulatory pharmacies in Qatar. Eligible participants were smokers 18 years and older who smoked one or more
cigarettes daily for 7 days, were motivated to quit, able to communicate in Arabic or English, and attend the program sessions. Intervention group participants met with the pharmacists four times at 2 to 4 week intervals. Participants in the control group received unstructured brief smoking cessation counseling. The primary study outcome was self-reported continuous abstinence at 12 months. Multinomial logistic regression model was fitted to assess the predictors of smoking at 12 months. Analysis was conducted using IBM-SPSS® version 23 and STATA® version 12. RESULTS: A total of 314 smokers were randomized into two groups: intervention (n=167) and control (n=147). Smoking cessation rates were higher in the intervention group at 12 months; however this difference was not statistically significant (23.9% vs. 16.9% p=0.257). Nevertheless, the daily number of cigarettes smoked for those who relapsed was significantly lower (by 4.7 and 5.6 cigarettes at 3 and 6 months respectively) in the intervention group as compared to control group (p=0.041 and p=0.018 respectively). At 12 months, the difference was 3.2 cigarettes in favor of the intervention group but was not statistically significant (p=0.246). Years of smoking and daily number of cigarettes were the only predictors of smoking as opposed to quitting at 12 months (p= 0.005; p=0.027 respectively). CONCLUSIONS: There was no statistically significant difference in the smoking cessation rate at 12 months between the groups. However, the program led to higher (albeit non-significant) smoking cessation rates compared with usual care. More research should be conducted to identify factors that might improve abstinence.

PHS11: ASSOCIATION BETWEEN MONTHLY JOINT REPLACEMENT VOLUME AND PATIENT OUTCOMES

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OBJECTIVES: Reducing variations in outcomes for total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures will be critical for providing high-value care. While research has found that hospital outcomes are better for patients treated by high-volume providers, most research has examined annual volumes, despite the fact that volumes may fluctuate substantially by month. The objective was to evaluate the association of monthly surgeon and hospital volume on hospital outcomes, including the presence of complications, readmission within 30 days, hospital length of stay and hospital cost of care. METHODS: Patient discharge-level data were obtained from the Vizient Clinical Database for 264 academic medical centers and their affiliated hospitals. The sample included all discharges with a THA or TKA procedure between June 2013 and May 2016. Surgeon and hospital volumes were assessed on a monthly basis and classified into monthly volume quartiles. A composite volume variable was created for surgeon and hospital volume quartiles (high surgeon-high hospital, high surgeon-low hospital, low surgeon-high hospital, and low surgeon-low hospital volume). Multivariable regression models were fit to test the association between each hospital outcome with volume, controlling for patient and hospital characteristics. RESULTS: Fifty-nine percent of 146,336 THA patients and 50% of the 224,652 TKA patients were treated by a high surgeon-high hospital volume provider. Patients with high surgeon-high hospital volume providers were less likely to be readmitted within 30 days, have shorter LOS and lower hospital costs than patients treated by lower volume providers for both THA and TKA procedures. Outcomes were the worst for patients treated by low surgeon-low hospital volume providers CONCLUSIONS: Maintaining consistently high surgeon and hospital volumes may be a strategy for improving the value of care for THA and TKA procedures.

PHS12: MICROBIOLOGICAL, CHEMICAL ANALYSIS AND COMPARISON OF PUBLIC BATH WATERS IN BARANYA COUNTY BETWEEN 2010-2016

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OBJECTIVES: In the pools of public baths it is critically important to decrease the microbiological and chemical risks to the minimum that frighten human health. This is the reason why we should ensure the microbiological and chemical parameters of pool water. The aim of the study is to characterize the water quality of public baths in Baranya County (n=28 bath, n= 151pool water) and to analyse the rate of microbiological and chemical risks between 2010 and 2016 (n=636). Furthermore we would like to analyse the effectiveness of chloric disinfection in function of microbiological qualification, the pH value of water and examine the amount of bound active chlorine refers to by-products of chloric disinfection. METHODS: Our data consist of microbiological and chemical parameters of specimens taken from public baths operating in Baranya County. The microbiological and chemical parameters of water samples were identified by an accredited laboratory. The examined parameters and the results were categorized into an optimal and a disputed group in every case. Among the chemical parameters we focused on parameters in relation with disinfection such as pH value, concentration of free active chlorine and bound active chlorine. RESULTS: During the analysis of data between 2010 and 2016 it has been found that the microbiological parameters of water of draining-refilling pools (optimal: 67%, disputed: 33%) are worse than the microbiological parameters of water of rotating pools (optimal: 95%, disputed: 5%) which is a significant result (p=0.009). We claim that elaborating chemical data between 2010 and 2016, the chemical parameters of draining-
OBJECTIVES: Failure to intensify treatment in patients with type 2 diabetes (T2D) in a timely manner is common. If newer oral antidiabetic drugs (OAD) such as dipeptidyl peptidase-4 inhibitors (DPP-4i) and sodium/glucose cotransporter 2 inhibitors (SGLT-2i) do not achieve metabolic control, injectable therapy like insulin or glucagon-like Peptide 1 (GLP-1) analogues are required. We investigated the time in poor glycaemic control (PGC, HbA1c >7%) in adult patients with T2D treated with DPP-4i or SGLT-2i until treatment intensification. METHODS: T2D patients ≥18 years treated with DPP-4i and/or SGLT-2i who have been switched to injectable therapy after a period of PGC from the German-Austrian diabetes follow-up registry (DPV) were studied. Patients were divided into three groups based on OAD therapy prior to injectable therapy: DPP-4i only, SGLT-2i only, combination (DPP-4i+SGLT-2i). PGC was defined as the time from the first HbA1c measurement >7%, with no improvement thereafter, until treatment intensification. RESULTS: We identified 16,591 patients (documented until March 2017) treated with DPP-4i and/or SGLT-2i, of these 2,434 (14.7%) patients with HbA1c continuously >7% were not initiated and 1,130 (6.8%) were initiated on an injectable therapy. Mean diabetes duration was 9.1 years, age was 64.5 years on average and mean HbA1c was 8.5% during period of PGC. Most of the patients were treated with DPP-4i only (91.8%), 4.9% had a combination of DPP-4i+SGLT-2i and 3.3% were treated with SGLT-2i only before intensification. Average time on DPP-4i/SGLT-2i therapy was 2.9 years. Mean time in PGC until intensification with injectable therapy was 1.2 years, corresponding to 41% of time on the previous therapy. CONCLUSIONS: Even with newer OAD, not all T2D patients achieve treatment targets for good metabolic control. In real-life care, time interval until treatment intensification with injectable therapy seems long. This may be due to individualized target setting for HbA1c, or reluctance of patients towards injectable therapy.

PHS14: PERSISTENCE AND ADHERENCE TO ORAL ANTIRESORPTIVE THERAPY IN A FRACTURE LIASON SERVICE: 24-MONTH RESULTS OF A PROSPECTIVE COHORT STUDY

OBJECTIVES: Oral antiresorptive therapies (OART) can reduce the incidence of fragility fractures. However, half the patients discontinue OART after one year and adherence is poor. A Fracture Liaison Service (FLS) could optimize these parameters. We aimed to describe persistence and adherence to OART after 24 months in a FLS. METHODS: A multidisciplinary FLS cohort study was conducted in two hospitals in Montreal, Canada. Fracture fracture patients (men and women) ≥40 years old were prospectively recruited. Patients were investigated for bone fragility and OART was prescribed if applicable. Patients were followed over two years. The date of cohort entry was a few days after the fracture (following consent). Using pharmacy claims data, persistence rate was defined by allowing a 30-day lag period for renewal and censoring switch to non-oral ART, hospitalizations, deaths and end of insurance coverage. The cumulative persistence rate was estimated using a Kaplan-Meier analysis. Drug adherence was measured by calculating the medication possession ratio (MPR). RESULTS: Of 535 enrolled patients, 85.6% were women. Mean age was 63.4±11.2 years. One hundred thirty-nine patients (26%) had at least one prescription for an anti-osteoporosis medication delivered before cohort entry. The cumulative persistence rates after one and two years were 77.8% and 65.9%, respectively. The difference between the cumulative persistence rates of experienced and new users was not significant (71.0% vs 63.2%, p=0.144). Median MPR after two years was 53.9% (22.6-85.7%), where 31.5% had a MPR≥80%. The median MPR over the year before the fracture was 36.5% (0.3-74%). Median MPR in persistent and non-persistent patients were 69.4% (33.7-91.0%) and 28.2% (9.7-60.7%), respectively (p<0.001). CONCLUSIONS: Our intervention led to an increase in persistence to treatment compared to usual care. Despite adherence remaining suboptimal, it was improved in persistent patients. Adjusted analyses will follow to identify determinants of OART persistence and adherence in our cohort.
**PHS15: GROWTH HORMONE PHARMACOECONOMICS AND PRESCRIPTION DATA FOR CHILDREN OUTPATIENTS IN A REGIONAL GENERAL HOSPITAL**

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**OBJECTIVES:** Growth Hormone Deficiency (GHD) patients are provided with Growth Hormone (GH) by the pharmacy of our regional general 560-bed hospital exclusively since August 2012. Our district population is 157,000 inhabitants and according to EMA, incidence of GHD in Europe is 4 in 10,000 people, higher in boys than in girls. This research aims to evaluate GHD's incidence for our district, taking gender into account, and to assess pharmacoeconomic and clinical data relevant to GH administration. **METHODS:** GH administration data of 2013 to 2016 were used, as extracted by Hospital's Information System and provided by National Statistical Authority. Parameters of interest were: number of patients, gender, GH total cost and cost per patient; DDDs were also calculated. **RESULTS:** GHD incidence for our district was estimated as the average of last 4 years to be 2.8 per 10,000 people, which is lower than European mean. From 2013 to 2015 boys who needed GH were more than girls (for 2013 25 boys and 21 girls and for 2015 20 boys and 18 girls). The number of patients, GH total cost and DDDs are higher in 2014 (49 patients, 222,569 €, 20,065 DDDs, respectively); no statistical significance for linear regression slopes for GH total cost and DDDs was found; cost per patient and DDD per patient are growing while cost per DDD is rather stable for the last 3 years (10.81€/DDD), perhaps due to children's weight gain with advancing age. **CONCLUSIONS:** In our district, GHD incidence per 10,000 people is lower than European mean, with slightly more boy-patients than girl-patients, as reported in literature. A passing to higher cost GH formulations is not confirmed. Further investigation of GHD incidence per 1,000 births is needed, which would contribute to a better understanding of GHD epidemiological characteristics.

**PHS16: A CROSS SECTION STUDY ON PREVALENCE OF NEURO-PSYCHIATRIC DISORDERS AND QUALITY OF LIFE IN POST STROKE PATIENTS**

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**OBJECTIVES:** To determine the prevalence of neuropsychiatric disorders and the quality of life after stroke. **METHODS:** The patients diagnosed as stroke and wished to participate were identified from Neurology Department of Government Hospital, Trivandrum and consent was obtained. Cross-sectional study for six-month duration after getting clearance from the Human Ethical Committee (order no: IEC no.07/22/2/MCT). The patients and caregivers found suitable for inclusion were included and were interviewed using the twelve-subscale version of the Neuropsychiatric Inventory (NPI) for the prevalence. Quality of life were assessed using Stroke Specific Quality of Life scale. Data processing tabulation of descriptive statistics did on statistical software. **RESULTS:** 52 patients enrolled, 37 were males (71.15%) and 15 were females (28.84%). The total NPI score of patients ranges from 1 to 39. The total NPI mean score was 8.6 with a standard deviation of 10 and median was 4. Total Neuro vegetative Changes score of patients' ranges from 4 to 6. The total Neuro Vegetative Changes mean score was 5 with a standard deviation of 1 and median was 5. The patients with age group 40-44 and marital status single shows better QOL scores in health and functioning. **CONCLUSIONS:** The improvement of QOL after the completion of the treatment, may not be restored optimally, since majority of the patients are above 60. From the study, it is clear that majority of the stroke patients have adequately severe neurological impairment and need assistance to carryout activities of daily living.

**PHS17: HEALTH CARE USE AMONG INCIDENT CASES OF HEART FAILURE: A POPULATION-BASED COHORT STUDY FROM 1997 TO 2010**

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**OBJECTIVES:** Heart failure (HF) is associated with substantial morbidity and high rates of hospital readmission. However, few data assess the trends overtime of readmission, mortality, emergency use and pattern of drug use. The study objectives are to assess the incidence rate of HF hospital readmission, mortality, all-cause emergency visits (ER) and pattern of drug use in 12 months following hospital admission of HF incident cases from 1997 to 2010. **METHODS:** We used a cohort of HF incident cases being hospitalized for a primary diagnosis of HF and discharge in community from 1997 to 2010. Linked Quebec administrative health care databases were analyzed to estimate incidence rate of HF readmission, mortality and ER stratified by sex in the 12-month period following discharge. We reported data as rates per 100,000 persons and age standardized. We assess the pattern of drug use in a 3-month period after discharge. **RESULTS:** A cohort of 12,807 HF patients with median age of 71 years,
ischemic heart disease (56%), atrial fibrillation (35%), diabetes (34%), MPOC (30%) and hypertension (23%). Among men, age-standardized incidence rate of readmission and mortality rate within 12-month period varied from 2,506 to 1,505 per 100,000 and from 2,522 to 1,079 per 100,000, respectively. Overall annual mortality rate was close 10%. Age-standardized ER rate increased from 7,850 to 9,497 per 100,000 for men. Lower values were noted for women. Significant changes were seen for β-blockers and renin-angiotensin inhibitors overtime. **CONCLUSIONS:** Patients seeking care for HF hospital admission seen overtime a reduction of readmission and mortality but increase in ER rate in the next 12- month period.

**PHS18: EFFECTS OF LOW SALT DIET ON GENE EXPRESSION IN DOG HEART**

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**OBJECTIVES:** Low-salt (LS) always be abided as dietary principle by hypertension patients. However, recent studies found that the incidence of cardiopathy and stroke increases in subjects with LS diet(<3g/d), meanwhile, LS can accelerate the development of atherosclerosis. It is essential to study deeply on the relationship between the amount of salt intake and cardiovascular diseases. We performed an analysis to explore the possible molecular mechanism of salt-induced cardiovascular disease. **METHODS:** Microarray datasets (GSE17149) of heart tissue from LS diet dogs was obtained from NCBI’s GEO Database. The data was analyzed by QOE, STRING and Genclip 2.0. The protein-protein interactions (PPI) networks of the differentially expressed genes (DEGs, $p<0.05$, $q<0.05$, Fold change$>$2) between the LS group and control group (normal diet) were conducted to screen the key biomarkers between the two groups. **RESULTS:** Compared with the control group, the gene expression profile of heart tissue from dogs was changed in the LS group (0.05% of sodium chloride, approximately 150 mg/d). 1,343 (3.12%) DEGs were found from 43,035 genes in total. The results also revealed that NFKBIA and NR1H2 were the cores of the PPI networks, which were mainly related to reduce the function of macrophage-derived foam cells and to promote cholesterol discharge and decomposition. The signaling pathways such as MAPK, PI3K-Akt, NF-kappa B were activated when the dogs received LS diet, which resulted in lower risk of cardiovascular disease through anti-apoptosis, anti-inflammation, anti-oxidative stress, et al. **CONCLUSIONS:** The gene expression of heart tissue in LS diet dogs is significantly changed and LS diet may reduce the risk of cardiovascular disease by up-regulating the expression of NFKBIA, NR1H2 and oxidative stress-related signaling pathways. More rigorous and independent experiments are needed to validate the conclusions of the present study.

**PHS19: CASE-CONTROL STUDY ON RISK FACTORS FOR CANCER FROM THE EPIDEMIOLOGICAL SURVEY CARRIED OUT ON BENEFICIARIES OF A PRIVATE HEALTH CARE PLAN IN BRAZIL: 10 YEARS OF FOLLOW-UP**

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**OBJECTIVES:** The development of cancer is a worldwide health problem and involves known risk factors. In Brazil, it’s the second leading cause of death. To evaluate the association of cancer with risk factors (smoking, sedentary lifestyle, alcoholism, excessive sun exposure, overweight and obesity) from a 10 years epidemiological survey (self-referenced morbidity) performed on beneficiaries. **METHODS:** Observational case-control study involving 4,685 individuals diagnosed with cancer. For each case, we selected three controls (same age and sex), who used medical and hospital services for non-oncological reasons (14,055 individuals). Statistical analysis used OpenEpi version 3.01 software, by calculating the relative and absolute frequencies, means and standard deviation. For analytical statistics, Chi-square tests (Mantel-Haenszel and Fisher’s Exact), when $p<0.001$. **RESULTS:** Mean age was: cases, 57.6 ± 0.4 years (male, 60.5 ± 0.5 years, female, 54.7 ± 0.6 years); Controls, 57.3 ± 0.2 years (male, 60.4 ± 0.3 years, female, 54.7 ± 0.3 years). Tumor frequencies by primary localization in men: prostate (36.4%), colorectal (6.8%), kidney (4.1%) and bladder (3.8%); in women: Thyroid (7.3%), colorectal (7.0%), lung (2.5%) and ovary (2.4%). Statistically significant tobacco association with lung cancer ($p<0.001$, OR 2.248), larynx ($p<0.001$, OR 3.929) and esophagus ($p<0.001$, OR 4.876) were found. Regarding obesity, the only statistically significant association observed was with ovarian cancer ($p=0.042$; OR 2.170). Alcohol consumption was associated with female breast cancer ($p=0.016$, OR 1.859). No association between sedentary behavior and evaluated types of cancer were found. **CONCLUSIONS:** Epidemiological profile’s information of the health plan users contributes to develop adequate preventive programs. These modifiable risk factors may be associated with some other types of cancer diagnosed in the population.

**PHS20: BETWEEN-HOSPITAL VARIATION OF IN-HOSPITAL MORTALITY AND 30-DAY READMISSIONS IN ACUTE MYOCARDIAL INFARCTION IN PORTUGAL: 2012-2014**

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OBJECTIVES: To study the variation of in-hospital mortality and readmission across Portuguese public hospitals after an acute myocardial infarction (AMI) using contemporary data, assessing the impact of hospital characteristics in between-hospital variability. METHODS: Retrospective study of acute care hospital discharges occurring between 2012 and 2014 of adult inpatients admitted with a primary AMI. Two cohorts were defined, one to study 30-day all-cause unplanned readmission and another to study in-hospital mortality after an AMI. Patient-Level (demographic and comorbidities) and hospital-level (teaching status, provision revascularization procedures, size and geographical location) characteristics were described for each hospitalization. Crude readmission and mortality rates were computed overall, across years and across hospital characteristic levels. Logistic mixed models were implemented to incorporate the natural clustering of the data at the hospital level and to estimate between-hospital heterogeneity. We used a step-up strategy starting with an empty model and incrementing patient and hospital characteristics to assess their impact on between-hospital variation. RESULTS: We identified 25642 index events in the readmission cohort and 28512 in the mortality cohort. While 8% of patients were readmitted with an unplanned event within 30 days after an AMI, 10% of patients died in hospital after being admitted with a primary AMI. Between-hospital heterogeneity was observed for the two cohorts, but was higher in the mortality cohort. A patient’s odds of dying in a high mortality hospital were more than twice than that in a low mortality hospital. Relative to the empty model, patient characteristics explained most of the heterogeneity (55%). Moreover, hospital characteristics explained an additional 10% of this heterogeneity in the readmission cohort, yet they increased heterogeneity in the mortality cohort. CONCLUSIONS: Hospital characteristics partially contribute to the heterogeneity in readmissions across hospitals. However, marked disparities across hospitals in terms of the risk of in-hospital mortality remained after adjusting for hospital case-mix and hospital characteristics.

PHS21: THE ROLE OF COMMUNITY PHARMACISTS IN PATIENT COUNSELLING AND HEALTH EDUCATION: A SURVEY OF THEIR KNOWLEDGE AND LEVEL OF INVOLVEMENT IN RELATION TO TYPE 2 DIABETES MELLITUS.

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OBJECTIVES: The present study aimed at evaluating the knowledge and level of involvement of community pharmacists in the provision of patient counselling and health education services for patients with diabetes mellitus and perceived barriers that limit the delivery of such services. METHODS: A self-administered questionnaire based survey were undertaken from January to March, 2017 with 412 pharmacists working in community pharmacies in six cities of Amhara regional state of Ethiopia: Debre Markos, Gondar, Dessie, Bahir Dar, Woldya and Debre Birhan. Descriptive statistics, ANOVA and student t-test were employed to examine different variables. RESULTS: Community pharmacists were found to have poor knowledge and low level of involvement with an overall mean score of 11.54 and 2.06 respectively. A significant number of community pharmacists never practiced promoting smoking cessation (45.2%), counseling on good foot care techniques (33.7%) and counseling on the potential impact of over the counter and herbal drugs on diabetes management (34%). On the other hand, describing the right time to administer anti-diabetic medications (46%) and counseling on suitable administration, handling and storage of insulin (33.7%) were done more frequently. The main reported barriers to the delivery of these services were lack of knowledge or clinical skills, lack of access to additional training programs and lack of personnel or resources. CONCLUSIONS: The present study revealed a poor knowledge and low level of involvement in counselling and health education services for patients with diabetes mellitus. Lack of knowledge or clinical skills was the most commonly reported barrier for providing such services. In order to better integrate community pharmacies into future public health programs and optimize the contribution of pharmacists, interventions should focus on overcoming the identified barriers.

HEALTH SERVICES - Cost Studies

PHS22: INTEGRATED CARE SYSTEM FOR HYPERTENSION IN CHINA: WHAT THE COST WILL BE FOR GOVERNMENT? A BUDGET IMPACT ANALYSIS

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OBJECTIVES: As the pioneer for integrated care for health system, Xiamen city has harvested its own successes in chronic diseases management, especially in Hypertension. The government needs more soundable evidences to scale up the integrated care for health system in national wide. This research aims to generalize the required funds and human resources and estimate the possible cost-saving from the base case in Xiamen for guide government's
PHS23: COMPARISON OF COSTS BETWEEN HOSPITAL AND HOME INFUSIONS IN PATIENTS TREATED WITH LARONIDASE

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OBJECTIVES: Laronidase, the current standard of care for attenuated MPS I patients, is an enzyme replacement therapy infused every week in a hospital or home setting. Home infusions only occur if the patient tolerates the infusion and could still be considered off-label in certain countries. There is little research assessing the differences in associated cost of infusions between the two settings. METHODS: Patients with at least one encounter with laronidase from 2007-2015 were identified in the Truven dataset, a repository of insurance claims data in the United States. Infusions were regarded as separate events and were divided into home or hospital groups. Associated costs occurring on the day of the infusion were considered and codes with <5 encounters during the study period were discarded, as were 5 service dates with codes for both infusion settings deemed errors in coding. The unweighted average cost per infusion was calculated by dividing the total cost per code by the number of infusions and summing the codes. This methodology did not account for differences in patient and procedure counts per code. An F-test was then performed to test the variance between groups, and a two-sample one-tail t-test was used to determine if the cost of home infusion was lower than hospital. RESULTS: The results show an average home infusion cost of $225.10, while hospital infusions were on average $586.50 per patient per infusion. This equates to an average savings of $361.40 per patient per infusion (p≤0.0001) when laronidase is administered in the home setting. CONCLUSIONS: This is the first study to quantify the differences in associated costs between infusions of laronidase in the hospital versus home setting in the United States. The adjusted analysis demonstrates a statistically significant difference in cost of $361.40 per patient per infusion between home and hospital settings.

PHS24: COMPARING THE HEALTHCARE COST UTILIZATION OF PAEDIATRIC PATIENTS WITH HAEMOPHILIA A WITH AND WITHOUT INHIBITORS TREATED AT INSTITUTO DE SEGURIDAD SOCIAL DEL ESTADO DE MEXICO Y MUNICIPIOS

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OBJECTIVES: Compare the healthcare resource utilization of treating paediatric haemophilia A patients versus paediatric patients with inhibitors treated at ISSEMyM. METHODS: Retrospective, observational analysis was performed by abstracting data from medical records of patients with haemophilia. Data were collected by medical professionals from ISSEMyM and included patient demographics, bleeding events and healthcare resource utilization. The healthcare resources were classified in five major groups: Hospitalizations (Urgency room, Hospitalization days, FVIII or rFVIIa), On-demand bleeds (Total bleeds, FVIII or rFVIIa), Specialists consultations (Haematology consultation, Orthopaedic consultation and Rehabilitation session), Prophylaxis treatment (FVIII or rFVIIa) and Other healthcare resources (Laboratory & Diagnosis tests and minor surgeries). Data analysis was descriptive. RESULTS: Data from 19 patients with Haemophilia A and 3 patients with inhibitors were collected. Haemophilia A patients: Hospitalizations (7 patients required 80 hours of emergency room, 52 hospitalization days and 70,750 IU of FVIII [MX$1,145,591]), On-demand bleeds (53 bleeds consume 91,250 IU of FVIII [MX$1,264,725]), Specialists consultations (Patients had 138 consultations [MX$27,010.74]), Prophylaxis treatment (13 patients consume 2,686,225 IU of FVIII [MX$37,231,078.50]) and Other healthcare resources (11 patients required 48 Laboratory & Diagnosis test and 3 patients had 6 minor surgeries [MX$58,588.50]). Patients with inhibitors: Hospitalizations (Patients required 72 hours of emergency room, 36 hospitalization days, 15,250 IU
of FVIII and 290 mg of rFVIIa (MX$3,730,566), On-demand bleeds (31 bleeds consume 12,000 IU of FVIII and 390 mg of rFVIIa [MX$4,739,850]), Specialists consultations (Patients require 213 consultations [MX$41,690.49]), Prophylaxis treatment (2 patients consume 1,401.5 mg of rFVIIa [MX$16,435,390.5]) and Other healthcare resources (16 Laboratory & Diagnosis test required and 2 patients had 4 minor surgeries [MX$36,266.50]). CONCLUSIONS: Paediatric patients with inhibitors consume four times more healthcare resources compared to paediatric patients with haemophilia A. This difference is explained because inhibitor patients experienced more Hospitalizations, On-demand bleeds, Specialist consultations and the cost of the rFVIIa.

**PHS25: COMPARISONS OF HEALTHCARE UTILIZATION AND COST IMPACT OF MANAGING TYPE 2 DIABETES ACROSS THE SYSTEM OF CARE IN MEDICARE BENEFICIARIES**

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**OBJECTIVES:** Care for people with diagnosed diabetes accounts for more than a fifth of health care expenditure in the United States, and the American Diabetes Association estimated that the economic costs of diabetes increased by $71 billion (41%) to $245 billion during 2007 – 2012. While, hospital inpatient care drives the majority of health care spend, limited insight exist into how type 2 diabetes (T2D) patients utilize health care services across care sites. A better understanding of the actual care pathway and costs of T2D patients is essential to optimize care redesign initiatives. This study aimed to compare utilization and costs for different cohorts of T2D patients across care settings.

**METHODS:** This study was a cross-sectional analysis of Medicare claims data from 195,409 fee-for-service T2D beneficiaries aged ≥65 years from the 5% random sample of Medicare beneficiaries in 2014. The diabetes complications severity index (DCSI) was used to assign comorbidity conditions.

**RESULTS:** Patients with a primary or secondary diagnosis of diabetes were on average three-fold more likely to utilize inpatient and hospital outpatient services than non-T2D patients. The average annual cost per T2D beneficiary (versus non-T2D beneficiaries) was higher in the majority of care settings (with the exception of the physician office) including the hospital outpatient ($29,159, 5.9-fold), inpatient ($185,435, 10.7-fold), skilled nursing facility ($105,083, 8.0-fold), home health ($35,609, 4.1-fold) and hospice ($39,150, 8.6-fold). Number of comorbidities dramatically increased overall costs in the T2D cohort with 67% of overall expenditure from less than 25% of patients with 2 or more comorbidities.

**CONCLUSIONS:** Medicare beneficiaries with T2D incur significantly higher Medicare expenditures compared with unmatched non-T2D patients across all care settings except the physician office. Frequency of comorbidities is a major driver of higher expenditures and care redesign programs should involve care management targeting high-risk patients with multiple chronic conditions.

**PHS26: BURDEN OF ULCERATIVE COLITIS IN JAPAN**

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**OBJECTIVES:** Ulcerative colitis (UC) is a chronic inflammatory disease of unknown etiology that often relapses after remission. In Japan, the number of UC patients has increased recently and are expected to rise over the next decade. According to a survey conducted by the Ministry of Health, Labor and Welfare (MHLW), it was estimated to be approximately 171,000 in FY2014. The objective of this study was to estimate the annual medical cost of UC treatment in Japan.

**METHODS:** The annual medical cost of UC treatment (May 2014 – April 2015) was calculated using the claims database of Japan Medical Data Center Co., Ltd.. Inclusion criteria of the analyzed population were 1) UC (ICD-10 code: K51), not Crohn’s disease (K50), 2) diagnosis of UC before May 2014, and 3) more than one visit between May 2014 and April 2015. Hospitalization costs, for which the main disease was UC, and outpatient costs including consulting fee, drug cost, examination fee, administrative fee, and related technical fee accounted for the medical cost. Based on the guidelines for UC treatment granted by MHLW, 5-ASA, SASP, corticosteroids, biological products (infliximab, adalimumab), immunosuppressants agents, and devices for cytapheresis were set as target treatments. Biochemical tests, endoscopic examination, ultrasonic inspection, CT, MRI, enema X-ray inspection, etc. were included as target inspections.

**RESULTS:** The analyzed population was 2,566 (Male 62.2%), and the mean age was 42.8 years. The annual medical cost per patient was $1,457 (1 US$ = 110 yen) (Male: $1,431, Female: $1,501). The annual medical cost of UC treatment in Japan was estimated to be approximately $349 million.

**CONCLUSIONS:** In this study, the direct medical cost of UC treatment in Japan was estimated. As the UC is a lifelong disease that often relapses mainly in young adults, the economic impact including productivity loss is expected to be even greater.

**PHS27: ECONOMIC IMPACT OF ATOPIC DERMATITIS IN ADULTS: A POPULATION STUDY (IDEA STUDY)**

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OBJECTIVES: To determine the use of health resources and social costs of atopic dermatitis (AD) depending on its severity and comorbidities based on clinical practice. METHODS: A retrospective observational study was conducted based on the review of records of adult patients who demanded assistance during 2013-14 in an area of the Catalonia region representing a population of 215,634 people. Three severity groups were established according to the prescribed treatment (mild, moderate, severe). Presence of comorbidities and concomitant specific medication were recorded. Health costs were classified as either direct (health costs) or indirect (productivity loss). Statistical analysis was performed using multiple regression models, p <0.05. RESULTS: A total of 6,186 subjects with AD diagnosis were recruited (mean age: 47.1 years, women: 61.6%). Three groups were considered depending on the severity of the AD: 55.7% were mild, 38.2% were moderate and 6.1% were severe. Comorbidities more frequently detected were dyslipidemia (34.2%), hypertension (25.1%) active smoking habit (21.1%), depression (19.9%), allergic rhinitis (17.2%), obesity (17.0%) and asthma (16.6%). Those comorbidities were higher in severe subgroup. Severe AD was associated with general comorbidity (β=0.192); asthma (β=0.138) and depression (β=0.099), p <0.001. The cost in the geographical area evaluated during this period is estimated to be 9.3 million euros (direct: 75.5%, indirect: 24.5%), with an average / unitary cost of 1,504 €/year. Corrected averages/units (ANCOVA) were higher in severe AD versus moderate and mild respectively (3,397 vs, 2,111 and 885 euros, p <0.001). CONCLUSIONS: AD is associated with a high economic impact, in particular due to the use of health resources and costs for the NHS but also due to indirect costs. This impact is proportional to the severity of the dermatosis, being more than 3 times higher in severe than mild patients. General comorbidity and asthma were the variables that were related to a higher sanitary cost.

PHS28: A SYSTEMATIC LITERATURE REVIEW OF THE SOCIETAL COSTS AND CONSEQUENCES OF HEROIN ADDICTION

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OBJECTIVES: A systematic review was conducted to understand the societal costs and consequences of heroin dependence. METHODS: The systematic review evaluated published literature (2006–2016; Europe, Australia, New Zealand, Canada) of patient populations addicted to heroin or seeking treatment for heroin dependence. Searches were conducted in three areas: healthcare-related costs and resource use; crime; and wider societal impacts. From 1,611 abstracts, 72 full-text papers met inclusion/exclusion criteria. Data were extracted from 25 papers with costs and effects suitable for economic analysis. Costs and consequences from 16 papers (meeting the highest NICE checklist rating for economic appraisals) were evaluated. RESULTS: The review identified six major costs/outcomes associated with heroin addiction: cost/cost-effectiveness of interventions; crime and violence; health and societal outcomes with different interventions; housing, homelessness, employment and education; health and public health outcomes; and maternal and infant care. No study incorporated wider societal costs (housing, employment, etc.) in a comprehensive manner. Making comparisons across papers was difficult because of different data sources, time periods, cost years, cost items included and methodologies adopted, although evidence suggests costs could be reduced through treatment. For example overall cost estimates ranged, depending on what items were included, from £15,805/patient for 26 weeks (health, social services, criminal justice) to £17,290/patient annually for successfully treated patients (victim costs included), to £37,864/patient annually for unsuccessfully treated patients (victim costs included). CONCLUSIONS: The broader societal costs of heroin addiction remain inconsistently estimated in the literature making comparisons very difficult and creating uncertainty in the true cost. A consistent framework for reporting of heroin-associated societal costs would be beneficial (as other studies have suggested) – helping to quantify the impact of heroin addiction, and inform decision-making surrounding its treatment and management.

PHS29: DIRECT MEDICAL COSTS IN THE YEAR OF MORTALITY FOR PATIENTS WITH DIABETES: A POPULATION-BASED PATIENT-LEVEL ANALYSIS

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OBJECTIVES: Estimates of direct medical cost associated with diabetes-related complications in the event and subsequent years have been quantified but costs in the mortality year have never been reported. This study aimed to estimate the direct medical costs of patients with diabetes mellitus (DM) in the year of mortality and the year before mortality. METHODS: We analyzed a population-based, retrospective cohort study including all adults with DM managed under public sector between 2009 and 2013 in Hong Kong. Individuals died between January 1, 2010 and December 31, 2013 were included in analysis. Annual direct medical costs in year of mortality and the year before mortality per patient were analyzed by gender, the presence of co-morbidities, the presence of diabetic complications (heart disease, stroke, diabetic nephropathy, or diabetic retinopathy), and primary cause of death. RESULTS: A total
of 6,919 met the eligibility criteria for analysis. The commonest cause of death among DM patients was neoplasms (2261, 32.7%), followed by diseases of respiratory system (1725, 24.9%) and diseases of circulatory system (1113, 16.1%). On average, the direct medical costs in the year of death were 2,075 times higher than those in the year before death (US$23,256.1 vs US$11,205.2, p<0.001). Female patients had slightly higher costs in the year of mortality (US$23,337.2 vs US$23,172.8) and the year before mortality (US$11,261.5 vs US$11,147.3) than male patients. The increase in Charlson index was associated with greater costs in the mortality year. Patients with any diabetic complications had greater costs in the year of mortality (US$25,909.3 vs US$20,625.2) and before mortality (US$13,218.7 vs US$9,208.5) than those without. CONCLUSIONS: This analysis provided new evidence on incorporating additional direct medical cost in the mortality year, and refining total cost estimation for studies on costing and cost-effectiveness analyses of health interventions for diabetes.

**PHS30: DIRECT MEDICAL COSTS OF HYPOGLYCEMIA HOSPITALIZATIONS IN THE UNITED STATES**

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**OBJECTIVES:** Recent studies have reported a declining trend in the rate of hypoglycemia-related hospitalizations in the United States (US), however little is known about corresponding trends in healthcare costs. This study aims to explore trend in direct medical costs associated with hypoglycemia-related hospitalizations using a nationally representative data from the US. **METHODS:** Data for years 2001 to 2011 were obtained from the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS), a cross-sectional survey based on stratified random sampling of discharges in community hospitals in the US. Hospital discharges with a diagnosis of hypoglycemia for patients aged ≥18 years were queried. Total costs were estimated by applying Medicare average cost-to-charge ratios to reported charges. Costs were adjusted for inflation using medical care component of the US Consumer Price Index. NIS-assigned discharge weights were used to derive nationally-representative estimates. Multivariable generalized linear models were performed to assess total annual and average per patient costs by calendar year for the overall sample and by age group. All models were risk-adjusted for age, sex, and Elixhauser comorbidities. **RESULTS:** An estimated total of 1.5 million patients were admitted for hypoglycemia during the study period; hypoglycemia hospitalizations increased from 115,367 in 2001 to 161,267 in 2011. The total inflation-adjusted annual costs for hypoglycemia-related hospitalizations in 2001 were $1.2 billion, with an average cost of $10,343 (95% CI: $10,187-$10,500) per hospitalization. The total annual costs increased to $1.6 billion in 2011, but with little change in the average cost per hospitalization ($10,139 [95% CI: $10,011-$10,268]). In the age-stratified analysis, the estimated costs were highest in the age group 45-64 years ($12,131 [95% CI: $12,063-$12,198]) and lowest in the age group ≥85 years ($8,401 [95% CI: $8,260-$8,541]). **CONCLUSIONS:** Hypoglycemia-related annual hospitalization costs in the US are substantial and have increased in recent years, driven primarily by growth in hypoglycemia discharges.

**PHS31: CHARACTERIZATION AND APPROXIMATION OF THE DIRECT COSTS OF AXIAL AND PERIPHERAL SPONDYLOARTHRITIS IN A CLINICAL MANAGEMENT CENTER IN COLOMBIA**


**OBJECTIVES:** Determine socio-demographic and clinical characteristics and estimate direct costs in spondyloarthritis patients **METHODS:** This is a retrospective descriptive study involving a convenient sample of 200 patients from Colombia. This study was carried out from the perspective of a public payer with a time horizon of 1 year. Nonparametric tests were used. The cost structure was constructed according to the Colombian tariffs established in the ISS (Instituto del Seguro Social) 2001 plus 30% for the cost of care and procedures and for those services that were not classified in the dataset based on local expert consensus. Drug costs were estimated based on the regulation of prices according to SISMED first 2015 semester. For the calculation of hospitalization and emergency service costs, the average costs for these services across Colombian health insurers in 2015 were taken into account. **RESULTS:** 68% (136) of the patients had axial spondyloarthritis, with an average age of 45 years, of which 67% were men. 32% of the patients had peripheral spondyloarthritis, with a mean age of 50 years, of which 47% were men. 68% of the patients were working. 33% of the patients had a university degree education. 76.2% Vs 48.4% with axial and peripheral spondyloarthritis had HLA B27 positive, respectively. 73.5% of the total patients received anti TNF inhibitors therapy, 63% conventional DMARDs and 46.5% received NSAIDs. The average direct cost per patient per year was USD 5868, thereof 97% were drug costs. The average cost of a patient-year receiving biological therapy was USD 7949 Vs USD 241 in a patient who does not receive it. **CONCLUSIONS:** 97% of the cost correspond to the medicines, therefore new treatment options more cost-effective beyond TNF inhibitors are needed, not forgetting that this expenditure is necessary taking into account that 70% of the study population works contributing to society.
PHS32: HEALTH INSURANCE COST OF MIGRAINE 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 migraine 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. Migraine were identified with the following codes of the International Classification of Diseases 10th revision: G43-G44. RESULTS: The Hungarian National Health Insurance Fund Administration spent 949.9 million Hungarian Forint (HUF) (4.5 million USD) for the treatment of patients with brain cancer. The annual average expenditure per patient was 6305 HUF (30.3 USD) while the average expenditure per one inhabitant was 95 HUF (0.5 USD). Major cost drivers were primary care/general practitioners (56.8 % of total health insurance costs), outpatient care (19.3 %), pharmaceuticals (11.5 %) and CT/MRI examinations (8.0 %). The number of patients with migraine was 150.4 per 10000 populations. We found the highest patient number in primary care/general practitioners (150662 patients), pharmaceuticals (84426 patients) and outpatient care (74424 patients). CONCLUSIONS: Migraine represent a significant burden for the health insurance system. Reimbursement of primary care/general practitioners, out-patient care and pharmaceuticals are the major cost drivers for migraine in Hungary.

PHS33: Economic burden of hospitalized diarrheal disease in Bangladesh

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OBJECTIVES: Diarrheal diseases are a major threat to human health and still represent a leading cause of mortality and morbidity worldwide. Although the burden of the diarrheal diseases is much lower in developed countries, it is a significant public health problem in low and middle-income countries like Bangladesh. The aim of the study is to capture the inpatients and outpatient treatment cost of diarrheal disease and to measure the cost burden and coping mechanisms associated with diarrheal illness. METHODS: This study was conducted in selected district hospitals in Bangladesh. The study was performed from the societal perspective which means all types of costs were identified, measured and valued no matter who incurred them. The study adopted quantitative techniques to collect the household and hospital level data including structured and semi-structured questionnaires, observation checklists, analysis of hospital database, telephone interviews and compilation of service statistics. RESULTS: The average total societal cost of illness per episode was BDT 5,274.02 (US $ 67.18) whereas average inpatient and outpatient costs were BDT 8,675.09 (US $ 110.51) and BDT 1,853.96 (US $ 23.62) respectively. The overall out of pocket expenditure was 11.75 % of monthly household income, however, in poorest quintile, it was exceed 17% of the total household income. The richest (5th) quintile only expend 4.21% of their household income. Considering 10% threshold level, approximately 32% households suffered from catastrophic expenditure while the poorest quintile suffered mostly (49%), even the highest threshold level (at 25%) the poorest 27% of households suffered from catastrophic expenditure due to diarrheal diseases. CONCLUSIONS: Diarrheal diseases continue to be an overwhelming problem in Bangladesh. The economic impact of any public health interventions (either preventive or promotive) that can reduce the prevalence of diarrheal diseases can be estimated from the knowledge generated from this current study.

PHS34: ECONOMIC BURDEN OF HOUSEHOLD FOR TREATING SEVERE PNEUMONIA AMONG UNDER FIVE CHILDREN IN BANGLADESH

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OBJECTIVES: Pneumonia is one of the most common causes of morbidity and mortality in children under 5 years in Bangladesh. The objective of the study was to measure the household economic burden who sought hospital care for treatment of severe pneumonia with/without malnutrition in selected areas of Bangladesh. METHODS: An incidence based cost-of-illness study was conducted from the perspective of household. Ingredient approach was used to identify cost categories, quantifying and for valuing. A prospective survey was conducted among eligible patients (2-59 months children) as defined by the study protocol. Data were collected from their caregivers on duration of illness with detailed cost items i.e direct medical and non-medical costs using structured questionnaire. Indirect costs of
caregivers were also measured by using human capital approach. **RESULTS:** A total of 597 children with severe pneumonia were enrolled from November 2015 to March 2017. Mean age of the children was 12.23 ± 10.41 months, among them, (n=388) 65% were male. The total cost of household for treating one episode of severe pneumonia was estimated to 111.82 whereas direct medical, direct non-medical and indirect cost were 34% (US$ 37.57), 9% (US$ 9.61) and 56% (US$ 64.72) respectively. Among the medical cost, medicine cost was the major cost driver and constituted for 43% (US$16.21) followed by hospital bed cost 15% (US$ 5.44). Household spent about 22% of their average monthly income (US$ 508.18) for treating one episode of severe pneumonia, however, poorest household spent higher proportion (25%) of their monthly income compared to richest households (17%). **CONCLUSIONS:** Preventing one episode of pneumonia could avert US$ 109 cost of household. Findings suggest the necessity of new treatment strategies along with vaccination that would be able to reduce incidence with further reduction of productivity losses of caregivers.

**PHS35: RESOURCE UTILISATION AND RELATED HEALTH CARE COSTS AMONG PATIENTS WITH MULTIPLE MYELOMA WITH ≥ 2 PRIOR LINES OF TREATMENT IN FINLAND: EVALUATION BASED ON FINNISH REAL WORLD DATA FROM AURIA BIOBANK**

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**OBJECTIVES:** To analyse resource utilisation and related health care costs among patients with multiple myeloma (MM) with ≥ 2 prior lines of treatment based on the patients' serum monoclonal protein in Finland. **METHODS:** Real World Data of adult patients diagnosed with multiple myeloma from Auria Biobank during 2009-2013 was collected. The time of disease diagnosis was based on the date of the ISS classification. Patients were divided into non-Active (n-AD) and Active disease (AD) stage based on the median serum monoclonal protein (IgG or IgA) following second line of treatment. Patients were defined as Active if IgG or IgA in the time of follow-up was > 20 g/l. This threshold value was based on a Finnish expert opinion. Data on health care resource utilisation, including hospital treatment periods, hospital days, outpatient visits, medical procedures and laboratories was collected and valued in 2016 prices. **RESULTS:** Of the total 103 patients diagnosed with MM in the Hospital District of Southwest Finland, 33 had received ≥ 2 prior lines of treatment. 13 patients (39.4%) were categorised as n-AD. The total average follow-up (years) and patient years, respectively were 0.79 and 10.31 in n-AD and 0.52 and 10.38 in AD. Patients in n-AD had on average 56% less hospital treatment periods, 63% less hospital days, 18% less outpatient visits, 23% less medical procedures, 74% less radiation therapy and 44% less laboratories per patient year compared to patients in AD. The total average health care costs (without medications) per patient were €15,922 and €18,389 and per patient year €20,078 and €35,432 in n-AD and AD, respectively. **CONCLUSIONS:** The results indicate increased health care resource utilisation and higher related health care costs for patients with multiple myeloma with ≥ 2 prior lines of treatment, who are in an active disease state.

**PHS36: THE EPIDEMIOLOGY OF ADULT IMMUNE (IDIOPATHIC) THROMBOCYTOPENIC PURPURA (ITP) IN FINLAND: RESOURCE UTILISATION, RELATED COSTS AND HOSPITAL MEDICATION ASSOCIATED WITH THE TREATMENT OF NON-SPLENECTOMISED ADULT ITP BASED ON REAL WORLD DATA FROM AURIA BIOBANK**

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**OBJECTIVES:** To study the epidemiology of ITP and resource utilisation, related costs, hospital medication and survival associated with the treatment of non-splenectomised adult ITP patients in Finland. **METHODS:** Real World Data of adult patients diagnosed with ITP from Auria Biobank during 2004-2013 was collected. Medication data including hospital prescriptions (IV & PO) was available from 2010 forward. Patients were distributed to Control (CG) and no-Control (n-CG) -groups according to median platelet count after diagnosis: 0-50 x 109/L (n-CG) and >50 x 109/L (CG). Resource use was valued in 2016 prices. **RESULTS:** A total of 230 patients (52.8% women) with ITP diagnosis were identified, with an average of 23 new patients per year. 40.2% of patients were classified as chronic with a disease duration of > 12 months. 138 patients met the inclusion criteria (e.g. non-splenectomised, ≥18 years) for the survival, resource use and cost analysis, 119 (86.2%) were categorised as Control. The most common concurrent ICD-10 diagnosis was essential hypertension with 31.6% in n-CG and 34.5% in CG. The total average follow-up (years) and patient years were 4.00 and 476.00 in CG and 4.08 and 77.52 in n-CG. Overall survival was comparable between groups (Log rank test p=0.342). The total average health care costs (without medications) per patient were €33,042 and €50,284 and per patient year €8,101 and €12,571, nCG and CG, respectively. Of the medication data population (n=53) 88.7 % were categorised as Control. The most prescribed (hospital) medication in both groups was methylprednisolone with 100% and 40.4% of patients in nCG and CG, respectively. **CONCLUSIONS:** Non-splenectomised adult ITP patients with elevated platelet levels are associated
with higher health care costs mainly due to the higher average number of hospital days. Altogether, pharmacological treatment is more common in patients with a platelet count ≤ 50 × 10^9/L.

**PHS37: RESOURCE USE, HEALTH CARE COSTS AND BURDEN OF DISEASE IN PATIENTS WITH POLYCYTHEMIA VERA IN FINLAND: EVALUATION BASED ON LEUKOCYTE COUNTS USING FINNISH REAL WORLD DATA FROM AURIA BIOBANK**

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**OBJECTIVES:** This study evaluated the burden of disease, health care resource use and associated costs in patients with polycythemia vera (PV) with elevated leukocyte counts in Finland. **METHODS:** Real World Data of adult patients diagnosed with PV from Auria Biobank during 2004-2013 was collected. Patients were defined as in Control if the median leukocyte count after diagnosis was ≤ 15*10^9/L (>15*10^9/L = No-Control). Overall survival, incidence of myelofibrotic and leukemic transformations, thromboembolic complications, myocardial infarction and stroke were estimated. Hospital treatment periods, hospital days, outpatient visits, medical procedures and laboratories were also collected and valued in 2016 prices. **RESULTS:** A total of 186 patients (51.1% men) diagnosed with PV were identified. After diagnosis, a total of 8,058 leukocyte counts had been measured, with an average of 43.3 measurements per patient. 145 patients (78.8%) were categorised as in Control. The total average follow-up (years) and patient years were 5.17 and 765.18 in the Control group (CG) and 4.42 and 167.96 in the no-Control group (n-CG). Overall survival was distinctly worse in the nCG (Log rank test p<0.001) and under half of these patients survived over 5 years from diagnosis. Myelofibrotic transformation occurred in 21.1% (n-CG) and 9.5% (CG) (p=0.0492, 'N-1' chi-squared test) and leukemic transformation in 15.8% (n-CG) and 7.4% (CG) (p=0.1095) of patients. 44.7% and 23.6% (p=0.0099) of patients had experienced thromboembolic complications, 7.9% and 9.5% (p=0.7611) a myocardial infarction and 5.3% and 14.9% a stroke (p=0.1167) in the nCG and CG, respectively. The total average health care costs per patient were €49,051 and €36,275 and per patient year €11,097 and €7,016 in the nCG and CG, respectively. **CONCLUSIONS:** Elevated leukocyte counts are associated with reduced overall survival, increased health care resource use and costs, myelofibrotic transformation and thromboembolic complications in patients with PV in Finland.

**PHS38: THE BURDEN AND COST OF ILLNESS OF GOUT IN SECONDARY CARE IN ENGLAND**

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**OBJECTIVES:** Acute gout is one of the most painful forms of arthritis. Patients with gout frequently have multiple comorbidities including cardiovascular disease (CVD) and hyperuricaemia is an independent risk factor for CVD. In order to manage the underlying disease process, current British Society for Rheumatology guidelines recommend treat-to-target levels of serum uric acid. Suboptimal management of gout may place a substantial burden on secondary care services. The objective of this study was to evaluate the burden of gout on secondary care services in England. **METHODS:** Data captured in Hospital Episode Statistics (HES) for 2015/16 was analysed to estimate the number of patients with gout as a primary diagnosis who were managed in secondary care. Data included the number of interventions recorded for this patient cohort. Hospital Resource Group (HRG) tariff prices (2016/17) were used to calculate the associated costs of gout treatment. **RESULTS:** In total 6,443 patients were admitted with a primary diagnosis of gout, this group accounted for 6,992 spells of which 88% were unplanned non-elective admissions. The average unplanned length of stay was 6.5 days. The main HRGs to which these spells mapped were HD23A and HD23B. The cost of these unplanned spells on the NHS was £10,249,319 (ranging from £30,423 to £227,331 per CCG) with the average cost per patient dependent on the presence and severity of comorbidities. The main co-morbidities being hypertension (49%), atrial fibrillation (22%) and diabetes (21%). Eighty-nine percent of patients with gout in 2011 went on to be admitted for a CVD related primary admission by March 2017, resulting in a further burden on healthcare resources. **CONCLUSIONS:** Gout has a significant burden on hospital care in England. Targeting gout as a metabolic disorder, by treating hyperuricaemia as a risk factor for CVD, may lead to improved management of gout and reduced burden on secondary care services.

**PHS39: SECONDARY CARE RESOURCE UTILIZATION AND COST OF CARE AMONG FINNISH INFLAMMATORY BOWEL DISEASE PATIENTS**

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**OBJECTIVES:** The prevalence of inflammatory bowel disease (IBD) has increased significantly in all Western countries during the past 25 years. Ulcerative colitis (UC) and Crohn’s disease (CD) are the most common IBDs, affecting 46,000 Finnish individuals representing 0.8% of the total population. The appropriate management of IBD is key for preventing relapses and complications, and minimizing costs of care. In this study, we characterized secondary healthcare resource utilization and associated costs of Finnish IBD patients in a real-life clinical setting. **METHODS:** All adult CD and UC patients with secondary care visits at the Hospital District of Southwest Finland between the years of 2013-2014, were included in the study. The 2-year follow-up data on resource use and costs were collected retrospectively from electronic healthcare records via the Turku Clinical Research Centre (TurkuCRC) database. **RESULTS:** A total of 825 CD and 1661 UC patients were included in the study. The mean number of annual outpatient visits per patient was 13.1 for CD and 9.2 for UC. Overall, 24% of CD and 23% of UC patients had inpatient stays during the 2-year follow-up period. The mean number of inpatient visits was 1.9 per year for CD and 1.2 for UC. The mean length of stay was 8.8 days for both CD and UC groups. Mean annual total costs of secondary care resource use were 6486€ for CD and 4454€ for UC. **CONCLUSIONS:** Patients with IBD have substantial healthcare resource utilization and cost in secondary care. Patients with CD had a higher frequency of outpatient visits and inpatient stays compared to patients with UC, which resulted in higher annual healthcare costs. Medication costs will be included in subsequent complete analyses of the economic burden of IBD in secondary care in Finland.

**PHS40: THE UK’S BINGE DRINKING CULTURE: LOSING MORE THAN JUST OUR DIGNITY?**

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**OBJECTIVES:** The public health importance of alcohol-related injuries has been previously reported. In the UK, 7.0% of all hospital admissions were alcohol-related in 2015/16, of which 5.3% were due to unintentional and intentional injuries. This analysis investigated the relationship between binge drinking and total spend by NHS Clinical Commissioning Groups (CCGs) on injuries and primary care prescribing for trauma and injuries. With continued funding pressures on CCGs, understanding and reducing avoidable expenditures is becoming increasingly important. **METHODS:** The following CCG data was extracted from the 2016 focus pack online tool: estimated percentage binge drinkers aged 16 and over, spend per person aged 19 – 64 on injuries (data for head, wrist, hand, shoulder, upper arm, knee and lower leg injuries were combined to give a composite spend), admissions relating to fractures where a fall occurred and injury related primary care prescribing. To determine the relationship between binge drinking and spend on injuries, linear regression analyses were conducted using Microsoft Excel 2013®. **RESULTS:** There were 208 CCGs with data available. The analysis indicated a statistically significant, positive correlation between the estimated proportion of binge drinkers and the NHS spend on admissions relating to fractures where a fall occurred (R2=0.26; p<0.001) and spend on primary care prescribing for trauma and injuries per 1,000 population (R2=0.11; p<0.001). A weaker but statistically significant correlation was also observed between binge drinking and spend on injuries occurring to the head, wrist, hand, shoulder, upper arm, knee and lower leg (R2=0.069; p<0.001). **CONCLUSIONS:** In the UK, the NHS spend on injuries and trauma is significantly higher in areas with a greater proportion of binge drinkers. Given the growing need to improve efficiencies and reduce costs within the NHS, further investigation is needed to understand how the UK can tackle the UK’s binge-drinking culture.

**PHS41: THE COST OF TREATING DIABETIC KETOACIDOSIS IN THE UK: A NATIONAL SURVEY OF HOSPITAL RESOURCE USE**

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**OBJECTIVES:** Diabetic ketoacidosis (DKA) is a commonly encountered metabolic emergency. In 2014 a national survey was conducted looking at the management of DKA in adult patients across the UK. The survey reported the clinical management of individual patients as well as institutional factors that teams felt were important in helping to deliver that care. However, costs of treating DKA were not reported. We estimate these costs here. **METHODS:** We used a combination of bottom-up and top-down costing to estimate the total costs associated with treating DKA in a mixed population sample. The data were derived from the source data from the national UK survey of 283 individual patients collected via questionnaires sent to hospitals across the country. Because the initial survey collection tool was not designed with a health economic model in mind, several assumptions were made when analysing the data. We used multiple imputation methods to account for missing data. **RESULTS:** The mean and median time in hospital was 5.6 and 2.7 days, respectively. Based on the individual patient data and using the Joint British Diabetes Societies Inpatient Care Group guidelines, the cost analysis suggests that for this cohort, the average cost for an episode of DKA was £2064 per patient (95% CI: £1800, 2563). An episode of hypoglycaemia following DKA was the only statistically significant predictor of cost (£-935, p=0.03). **CONCLUSIONS:** Despite relatively short stays in hospital, costs for managing episodes of DKA in adults were relatively high. However, we were unable to account for
prenormalized hospital stays due to co-morbidities or indirect costs such as lost productivity. Therefore, the actual costs to the healthcare system and to larger society are likely to be even higher than these first estimates.

**PHS42: THE COST OF PRESCRIBING DIRECT ORAL ANTAGOAGULANTS (DOACS) – THERE IS A DRUG COST BUT WHAT ELSE?**

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**OBJECTIVES:** In Europe, there are four direct oral anticoagulants (DOACs) available for prescribing to patients with atrial fibrillation. A key advantage of DOACs is the abolition of routine INR monitoring. Nevertheless, some level of follow-up care is required – as advocated by European Heart Rhythm Association. The high drug cost of DOACs is acknowledged and contributes to reluctance for their reimbursement in public health systems. Despite the increased adoption of DOACs there is a lack of information regarding the cost of adopting these new agents into clinical practice, beyond the drug cost. This study aims to ascertain the costs associated with follow-up care for DOAC patients from a health care provider’s perspective. **METHODS:** A cost analysis is used to estimate the follow-up care associated with prescribing patients’ DOACs in Ireland. Primary data is collected from General Practitioner practices in Ireland to estimate resource use. **RESULTS:** Using the EHRA practical guide as a benchmark, 58% of clinics scheduled a follow up with patients once every 3 months, which is well below recommendations. A structured follow up by the physician included checks for compliance, thrombo-embolic events, measure bleeding events, other side effects, monitoring of co-medications and the need for blood sampling in accordance with the EHRA practical guide. The follow-up test completed most frequently, was blood testing by a public health nurse for renal function reporting a time cost of between €65.70 and €8.54 per patient, with 79% of GPs indicating this as follow up/maintenance for DOAC patients. **CONCLUSIONS:** DOACs have emerged as an alternative to warfarin in patients with AF. Although there are many benefits such as fewer food and drug interactions, lack of monitoring etc. the use of DOACs will require support in the clinical setting. The cost of this follow up care needs to be considered and adequately resourced.

**PHS43: FRENCH PEOPLE WITH MS AND THEIR CAREGIVERS HAVE TO FINANCIALLY SUPPORT DIRECT NON-MEDICAL COSTS LINKED TO THEIR DISEASE.**

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**OBJECTIVES:** MS is a neurodegenerative disease with an ALD status in France, i.e., MS-related medical costs are 100% covered by the National Healthcare system. A study has been performed to measure the direct costs and impacts borne by MS patients and their caregivers. **METHODS:** The study was conducted from September to October 2016 via Carenity, a European digital patient community, a network where patients can share information and contribute to medical research in various therapeutic areas, including MS. An online questionnaire of 49 questions devoted to the financial impact of MS on patients and their relatives, was developed and approved by a scientific committee including a multiple sclerosis patient organization representative, a neurologist and a health economist. Participants, either MS patients or their caregivers living in France and registered into the community, were volunteers to participate. **RESULTS:** 436 members of the community answered the questionnaire, 376 had MS and 60 were caregivers. 77% of patients were women, with a mean age of 48.3 years, 24% lived alone, 25% benefited from medical and non-medical support, and 37% benefited from financial and/or material assistance. Direct non-medical costs cover many domains including domestic help, babysitting, homework help, meal delivery, car and home fitting, etc. Over the last 2 months: 20% of patients stayed in healthcare facilities, 15% had to pay for related fees. Nearly one third of respondents benefited from domestic help. Among them, 50% had to pay part of the costs. About 40% of caregivers contributed financially to home services fees. 41% of respondents bought a walking-aid device and 23% a manual wheelchair. **CONCLUSIONS:** These results indicate that, depending upon services, about 60% of patients and 40% of caregivers dedicate part of their financial resources to cover non-medical costs directly linked to MS.

**PHS44: ECONOMIC EVALUATION FOR ESTABLISHING STROKE UNIT FOLLOWED BY EARLY SUPPORTED DISCHARGE IN EGYPT**

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**OBJECTIVE:** When Stroke accounts for 6.4% of all deaths and thus ranks 3rd after heart disease & gastrointestional with a crude prevalence rate of 963/100 000 inhabitants. The clinical characteristics of Egyptian stroke patients are generally similar to those in other populations. Exceptions may include the higher prevalence of vascular risk factors
and a younger mean age of stroke patients (4, 18–20). Due to those facts stroke and its complications may be one of the major economic challenges facing Egyptian health sector. The objective of this study is to evaluate Economic evaluation for establishing stroke unit followed by early supported discharge the outcome was determined as survival with minor disability. METHOD: Integration between A systematic literature review & Descriptive analysis of Data from patients aged (18 -60 years ) for the last 3 years including direct and indirect medical costs for conventional treatment including ( cost of treatment, complications including physical therapy, hospitalization, outpatients costs, rehabilitation ). The total (n) of patients enrolled in the national database = 3212. One way sensitivity analysis was conducted. Level of statistical significance was defined at (p <0.05). RESULT: Mean direct medical cost for ( respiratory, neurological complications including Cerebral Edema, DVT, PE, Hemorrhagic transformation,) increasing ratio was around 3.5% at the last 3 years. Cardiac Complications were second items for cost with increasing rates 2.5%, respiratory Complications ranking 3rd with 1.5 rate at last 3 years. Hospitalization ratio increased with 5.7 % for the last 3 years. CONCLUSION: Establishing stroke unit followed by early supported discharge might be cost saving due to it is significant impact of minimizing economic consequences of

# PHS45: CHARACTERIZATION OF HEALTH CARE UTILIZATION AND COST OF HEMOPHILIA A AND B IN REAL LIFE: A 4-YEAR FOLLOW-UP STUDY IN FINLAND

**Objective:** Though a majority of hemophilia treatment cost comes from factor-replacement therapy, cost savings related to healthcare use may result from optimal prophylactic therapy. We characterized real-life healthcare utilization and costs among Finnish patients with hemophilia A (HA) and hemophilia B (HB).

**Methods:** The data on resource use were collected from patient charts generated over a period of four years (2012-2016). Annual healthcare costs were calculated based on resource utilization and Finnish report of standard unit costs. 

**Results:** A total of 131 HA patients and 39 HB patients were included. Of HA patients, 56% (n=74) received prophylactic therapy (HAP), and 25% (n=31) received on-demand therapy (HAO). Over 90% of HAP and HAO patients had outpatient visits during follow-up. The mean outpatient visits/year/patient was 2.4 for HAP and 1.9 for HAO. Overall, 43% of HAP patients, and 27% of HAO patients had inpatient stays during follow-up; the mean length of stay was 11.9 days for HAP, and 15.3 days for HAO. The total annual healthcare cost were 8,530€ for HAP and 12,584 for HAO. Of HB patients, 31% (n=12) received prophylactic therapy (HBP), whereas 54% (n=21) received on-demand therapy (HBO). Over 90% of HBP and HBO had outpatient visits during follow-up. The mean outpatient visits/year/patient was 1.8 for HBP and 2.1 for HBO. Overall, 25% of HBP patients, and 52% of HBO patients had inpatient stays during follow-up; the mean length of stay was 3.0 days for HBP, and 11.3 days for HBO. The total annual healthcare cost were 1,358€ for HBP and 9,517 for HBO. Except for the results regarding annual healthcare cost between HBP and HBO (p>0.001), statistical significance was not reached.

**Conclusions:** Patients receiving on-demand therapy have higher healthcare costs than patients treated prophylactically. Selecting between prophylaxis and on-demand therapy should be done under careful consideration.

# PHS46: HEART FAILURE MANAGEMENT: IMPACT OF A NEW HEALTH-CARE ORGANISATION ON READMISSIONS AND COSTS

**Objective:** Heart failure (HF) is a major public health issue due to its prevalence in the western world: two to three percent of the European population have HF. To improve patient care, the Montpellier University Hospital (CHU) implemented in 2014 a new organisation of HF management called “optimised pathway”. The aim of our study was to compare costs and readmissions rates between 2013 and 2015, and to assess the new pathway impact.

**Methods:** A retrospective observational and comparative before-after study was conducted. The clinical endpoint was the readmission rate a year after first hospitalisation for HF. CHU databases were used to characterise the patients of interest (526 and 514 for 2013 and 2015 respectively) and their stays: administrative and medico-economic database to collect relevant demographic and medical data, and cost accounting data to value the stays. Clinical and economic outcomes were measured over a one year time horizon.

**Results:** No significant differences were found between 2013 and 2015 regarding the one year readmission rate (18.06% in 2013, 18.48% in 2015, p = 0.18). Time intervals between first hospitalisation and readmission weren’t significantly different (p = 0.18), even if a trend could be observed (114 days in 2013 vs. 142 in 2015). No significant difference were found in terms of total length of stay (p = 0.193). Total patient care cost more in 2015 (646€ vs. 722€, p < 0.01), but incomes were also higher (687€ vs. 636€, p = 0.086), whether not enough to compensate (difference between costs and incomes for 2013 and 2015 were -85€ and -159€ respectively, p < 0.01).

**Conclusions:** There is no evidence to say that the
optimum pathway reduced costs and readmissions rates, but the increasing costs can’t be assigned to it either. Researches must go further to investigate the organisational changes that occurred between 2013 and 2015.

**PHS47: THE COST-EFFECTIVENESS OF SCREENING FOR SEVERE COMBINED IMMUNODEFICIENCY (SCID) IN THE UK NHS NEWBORN BLOODSPOT SCREENING PROGRAMME**

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**OBJECTIVES:** To assess the cost-effectiveness of including screening for severe combined immunodeficiency (SCID) in the NHS newborn bloodspot screening programme. **METHODS:** A decision tree model with life-table estimates of outcomes was built. Model structure and parameterisation were informed by systematic review and expert clinical judgment. A public service perspective was used and lifetime costs and quality adjusted life years (QALYs) were discounted at 3.5%. Standard treatment following screening was hematopoietic stem cell transplantation with additional treatment options for adenosine deaminase deficiency SCID. The model estimated the number of non-SCID cases identified incidentally. Probabilistic sensitivity analyses was undertaken. An exploratory disbenefit analysis was conducted for false positives and those diagnosed with non-SCID T-cell lymphopenia (TCL) who would have presented as healthy at birth. **RESULTS:** Screening for SCID was estimated to result in 310 (72-811) presumptive positive cases per year including 260 (25-760) false positives cases, 7 (1-21) preterm cases, 26 (9-50) non-SCID TCL cases and 17 (14-22) SCID cases. Screening would increase overall QALYs and costs and result in an incremental cost-effectiveness ratio (ICER) of £17,642. The increase in QALYs was driven by improved survival in the screened cohort with mortality reducing from 8 (5.3-12) deaths to 1.7 (0.6-4.1). Results were sensitive to a number of parameters including the cost of the screening test, the incidence of SCID and quality of life estimates. The disbenefit analysis estimated that to push the cost-effectiveness over the £200,000 threshold the 6.5 (1.5-16) healthy at birth cases would need to experience a disbenefit of 2 QALYs and the false positive cases a disbenefit of over 12 quality adjusted days. **CONCLUSIONS:** Screening for SCID is potentially cost-effective at £20,000 per QALY, key uncertainties relate to the impact of false positives and the identification of children with non-SCID TCL.

**PHS48: AN ECONOMIC MODEL TO ESTIMATE THE DIRECT ECONOMIC VALUE OF REDUCING THE SEVERITY OF SEPSIS IN FRENCH AND US HOSPITALS**

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**OBJECTIVES:** In 2013, French (FR) and United States (US) hospitals managed an average of 152 and 316 sepsis hospitalizations annually. While no specific treatment can prevent all sepsis complications, early recognition and treatment is associated with reduced sepsis severity and mortality. This study estimates the benefits of reducing sepsis severity in France and the US. **METHODS:** A deterministic decision tree model was designed to counterfactually estimate the potential cost offsets of reducing sepsis severity. Model inputs included sepsis severity, mortality, length of stay, time in the ICU, and costs. Inputs were based on country-specific data for France and US using a focused literature review, PMSI data (France) and NIS (US) to inform population, clinical and economic variables. The current distribution of sepsis severity [sepsis (FR: 51%; US: 28%), severe sepsis (FR: 22%; US: 66%) and septic shock (FR: 27%, US: 6%)] is used to define the base case. To estimate the potential benefit of improving sepsis severity, the analysis simulated shifts in sepsis severity of 10%, 25%, and 50%, which results in a population shifting from higher (severe and septic shock) to lower levels of severity (sepsis). Analyses were conducted at the patient and hospital in 2017 currency. **RESULTS:** Reduction in sepsis severity resulted in substantial cost offsets. In FR, a 10%, 25% and 50% shift to lower sepsis severity levels resulted in annual savings per patient of €207 to €1,035 and per hospital of €31,480 to €157,399. In the US, a 10%, 25% and 50% shift to lower sepsis severity levels resulted in annual savings per patient of $593 to $2,967 and per hospital of $187,515 to $937,574. **CONCLUSIONS:** Innovations in sepsis diagnosis and management that reduce the severity of sepsis in French and US hospitals may offer significant economic value to hospitals managing sepsis populations.

**PHS49: COST-EFFECTIVENESS OF INPATIENT REHABILITATION COMPARED TO HOME DISCHARGE FOLLOWING LONGER STAY IN GENERAL OR NEUROLOGICAL WARD, AFTER ADMISSION FOR THE FIRST EVER STROKE IN GREECE**

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**OBJECTIVES:** In the UK and Spain, inpatient rehabilitation (ICW) following a longer stay in the general or neurological ward, after admission for the first ever stroke in Greece has been shown to reduce mortality, length of stay, time in the ICU, and costs. Model inputs included sepsis severity, mortality, length of stay, time in the ICU, and costs. Inputs were based on country-specific data for France and US using a focused literature review, PMSI data (France) and NIS (US) to inform population, clinical and economic variables. The current distribution of sepsis severity [sepsis (FR: 51%; US: 28%), severe sepsis (FR: 22%; US: 66%) and septic shock (FR: 27%, US: 6%)] is used to define the base case. To estimate the potential benefit of improving sepsis severity, the analysis simulated shifts in sepsis severity of 10%, 25%, and 50%, which results in a population shifting from higher (severe and septic shock) to lower levels of severity (sepsis). Analyses were conducted at the patient and hospital in 2017 currency. **RESULTS:** Reduction in sepsis severity resulted in substantial cost offsets. In FR, a 10%, 25% and 50% shift to lower sepsis severity levels resulted in annual savings per patient of €207 to €1,035 and per hospital of €31,480 to €157,399. In the US, a 10%, 25% and 50% shift to lower sepsis severity levels resulted in annual savings per patient of $593 to $2,967 and per hospital of $187,515 to $937,574. **CONCLUSIONS:** Innovations in sepsis diagnosis and management that reduce the severity of sepsis in French and US hospitals may offer significant economic value to hospitals managing sepsis populations.
OBJECTIVES: To assess the cost-effectiveness of Inpatient Rehabilitation (IR) versus home discharge following longer stay in general/neurological ward (non-IR) for patients being hospitalized for the first acute stroke in Greece, from a third-party payer perspective (EOPYY). METHODS: A decision analytic model consisting of a 1-month decision tree and 5-year Markov Model was developed in Excel. Decision tree consisted of four nodes: 'Home Independent', 'Home Dependent', 'Hospital', 'Death'. Patients enter Markov model at the health state they exit the decision tree. In the Markov model, they may transit among five health states, at 1-year cycles, with assigned probabilities extracted from literature. The efficacy of IR was taken into consideration only at the 1st month. Resource utilization (i.e. medication, monitoring tests, outpatient rehabilitation, equipment etc) that depends on the health state/node of the model was extracted from experts using a questionnaire developed to serve the purpose of the present study. The respective unit costs, as well as the cost of IR and hospitalization for non-IR were obtained official local sources (€2016). Life-years (LYs), quality-adjusted life-years (QALYs), and cost-effectiveness in terms of life-years gained (LYG) and QALY gained were evaluated. One-way (OWSA) and probabilistic sensitivity analysis (PSA) were conducted to evaluate the robustness of base-case analysis. RESULTS: An average patient transferred to IR, following hospitalization for 1st stroke, was estimated to have higher survival by 0.368 LYs and gained 0.288 QALYs compared to non-IR, at a higher cost of €1,934. Incremental cost-effectiveness ratios were €5,258/LYG and €6,728/QALY gained relative to non-IR. The proportion of patients being home dependent following IR and re-hospitalized (non-IR) influenced the results. The probability of IR to be cost-effective exceeds that of 97% at a willingness-to-pay of €34,000. CONCLUSIONS: Given the assumptions and limitations of this analysis, IR seems to be a cost-effective option in Greece, for patients experiencing their first ever stroke.

PHS50: SCREENING FOR ASYMPOTOMATIC ATRIAL FIBRILLATION: ITS EFFECTIVENESS AND COST-EFFECTIVENESS OF REPEATED ECG IN POLAND

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OBJECTIVES: Atrial fibrillation (AF) is the most common arrhythmia in humans. AF increases the risk of ischemic stroke up to 5-fold. Fortunately, this is highly preventable with appropriate oral anticoagulant (OAC) therapy. However, many patients with AF, despite the presence of risk factors, are not taking OACs, because they are not aware of the occurrence of arrhythmia prior to stroke. Therefore, it seems that the screening for AF in a broad population aimed at the earliest possible detection of asymptomatic arrhythmias, and the implementation of OAC treatment when necessary, could prevent many strokes. To assess the effectiveness of active screening for previously undiagnosed AF when compared to the standard care as well as to estimate the cost-effectiveness of repeated ECG in comparison with the lack of screening in Polish population with average risk of AF. METHODS: We searched multiple databases for studies comparing systematic or opportunistic screening using ECG or pulse palpation, compared to no screening in populations age ≥40 years living in community or attending GP practices. The primary outcome was the incidence of previously undiagnosed AF. The cost-effectiveness analysis of screening in 67-year-old individuals was based on a lifelong decision analytic Markov model. RESULTS: 1056 articles were found and 23 that fulfilled our inclusion criteria were taken into meta-analysis (n=83 323, mean age 64.3, 48.4% males). The incidence of newly detected, clinically silent, AF was 1.5% (95% CI 1.1-1.9%). In the base-case scenario, screening of 1000 individuals resulted in 7 more quality-adjusted life-years (QALYs) and 2 fewer strokes. ICER was 74 001 PLN per one stroke prevented. CONCLUSIONS: It has been shown that active screening for undiagnosed AF is more effective than standard care and that screening with the use of repeated ECG in 67-year old individuals may be cost-effective in Poland.

PHS51: A NOVEL ATRIAL FIBRILLATION EVALUATION MODELLING SOLUTION FOR NHS

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OBJECTIVES: Approximately every fifth stroke in UK is due to AF and costs the UK National Health Service are between $12,000 and $17,500 per stroke. The aim of this study was to undertake a retrospective health economic analysis of the cost-effectiveness and implications related to opportunistic Atrial Fibrillation (AF) screening in primary care and the detection of previously undiagnosed AF cases in patients, and create a novel modelling solution that can empower individual users and organisations in England, Wales and Northern Ireland in their decision making, technology assessment, comparison of various anticoagulation drug groups cost effectiveness decisions METHODS: A model was built on Microsoft Excel suite and it combined advance Excel Functions Data with Visual Basic Macros with assumptions based on a feasibility study and a new patient pathway on which community pharmacist perform opportunistic AF checks using one lead mobile ECG device. Apart from Cost-Effectiveness, Return of investment and QALYS of the new pathway was also calculated. Finally, the model was tested using
through a cost assessment scenario utilizing input data from various well-established sources: Background research into the NHS and NICE guideline content, current clinical practice, published information and available data. Gathering expert opinion. Testing the model, including the assumptions and outcomes. RESULTS: Our results suggested that the opportunistic AF checks can be cost-effective for the NHS presenting a ROI of 60% and the model presents quick and accurate results without sacrificing customisation options. CONCLUSIONS: this innovative modelling solution can provide policy makers with an accurate estimation of the costs related to AF incidences in various CCG population mixtures without sacrificing customisation options empowering users with the flexibility to adopt the model to their own variables findings and organisation.

PHS52: ONE SIZE DOES NOT FIT ALL: WHAT ARE THE APPROPRIATE SCREENING INTERVALS FOR PEOPLE AT RISK OF DIABETIC RETINOPATHY

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OBJECTIVES: Most of the current evidence based for screening is based on T2DM populations. This study explored the impact of increasing screening intervals for diabetic retinopathy (DR) for people with either type 1 diabetes (T1DM) or type 2 diabetes (T2DM) without DR. METHODS: Cost utility analysis (CUA) was undertaken comparing either annual or biennial screening for DR in people with either T1DM or T2DM and no DR, attending the national Diabetic Eye Screening Wales (DESW) program. Data from DESW and Primary Care were linked using secure anonymised information linkage. Regression analysis estimated risks of DR progression requiring referral to hospital eye services (RDR). The CUA was facilitated by a time varying Markov model and DR risk factors (HbA1c, blood pressure, duration of diabetes etc.) enabled estimates of relative costs and quality adjusted life years (QALY) gained associated with an increase to biennial screening for people with T1DM and T2DM. RESULTS: Data from 2,286 and 36,202 people with T1DM and T2DM respectively were analysed. Increasing screening intervals to two years for people with T1DM and HbA1c of 6.5, 8.0 and 9.5 at the time of screening were estimated to lose one QALY for a cost saving to national health services (NHS) of £118,612, £48,449 and £15,818 respectively. For people with T2DM at the same HbA1c level suggested NHS saving of £109,320, £60,482 and £32,510 for each QALY lost. The incremental cost effectiveness ratio for biennial screening for people with T1DM was £30,995 for and £73,475 for people with T2DM. CONCLUSIONS: Our findings, primarily driven by the difference in the risk of progression to RDR between people with T1DM and T2DM, suggest that biennial screening intervals in people with T2DM makes best use of NHS resources. For people with T1DM however annual screening remains justified and should not be increased to biennial.

PHS53: COST-UTILITY ANALYSIS OF ANTIHYPERTENSIVE DOSAGE ADJUSTMENTS BY A PHARMACIST IN A COMMUNITY SETTING

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OBJECTIVES: Hypertension is a chronic disease for which only 68% of treated patients were controlled in Canada in 2013. Pharmacists in the province of Québec recently received legislative authority to adjust the dosage of antihypertensive drugs if there is an agreement with the prescriber on the therapeutic target. This research aims to estimate the incremental cost-utility ratio (ICUR) of this new model of care in Québec. METHODS: A Markov model was developed to extrapolate the impact of this pharmacy practice on strokes, myocardial infarctions and mortality. The model used 1-year cycles over a lifetime horizon. Framingham Risk Equations were used to derive the impact of blood pressure control on strokes and myocardial infarctions. The clinical efficacy of the intervention was derived from the RxAction clinical trial which was conducted in Alberta where pharmacists have a practice similar to Québec’s one. Efficacy was expressed as the proportion of patients with controlled blood pressure. The payer perspective was adopted and only direct costs were included. The main outcome was expressed as the number of quality-adjusted life years (QALYs) gained. Both QALYS and costs were discounted at a 1.5% annual rate. A cohort of 1000 patients entered the model at 65 years old. RESULTS: The model yielded 768 more QALYs in the intervention group for an incremental expense of 3,925,576$. The ICUR was 5,111$/QALY. At a willingness-to-pay threshold of 50,000$/QALY, the intervention is cost-effective. The results were sensitive to the comparative efficacy of the pharmacist intervention against usual care and to the utility of hypertension. CONCLUSIONS: Providing pharmacists the ability to adjust the dosage of antihypertensive drugs within the actual fee-for-service rational appears to be cost-effective. Obtaining data on the efficacy of this pharmacy practice from a trial conducted in Québec would provide better information to inform this economic evaluation.
PHS54: COMPARING COST-EFFECTIVENESS OF A CENTRALIZED VERSUS DECENTRALIZED STROKE CARE SYSTEM: USING PATIENT-LEVEL DATA TO ESTIMATE SHORT- AND LONGTERM EFFECTS

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OBJECTIVES: Centralizing acute stroke treatment increases the chance of treatment and lowers costs from onset to treatment compared to care at community hospitals. It is unclear whether the centralized model is cost-effective in a real-world setting after treatment. METHODS: This study uses observational data from 780 patients in a decentralized system and 267 patients in a centralized system in the Northern Netherlands. Multiple observational datasets were linked to estimate actual healthcare costs and Quality-Adjusted Life Years (QALYs) up to 3 months. Secondary outcomes are lifetime QALYs and healthcare costs, using a probabilistic Markov model. Difference in outcome include 95% Confidence Intervals (CI). RESULTS: Mean healthcare costs up to 3 months are € 6,313 (CI, 5,507 – 7,118) for the centralized system compared to € 7,535 (CI, 7,060 – 8,010) for the decentralized system (P < 0.01). The mean QALYs at 3 months are 0.65 (CI, 0.63 – 0.67) for the decentralized system and 0.69 (CI, 0.65 – 0.73) for the centralized system (P < 0.10). Results remain stable after adjusting both parametrically and non-parametrically for age, gender, stroke severity on arrival, and referrer (P < 0.05). CONCLUSIONS: A centralized system for acute stroke care is cost-effective in a real-world setting. Centralizing acute stroke care significantly improves health of the patients by optimizing care efficiency – thereby substantially saving healthcare costs.

PHS55: DISEASE BURDEN OF FRACTURES IN PATIENTS WITH OSTEOPOROSIS IN JAPAN

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OBJECTIVES: Osteoporosis remains undertreated in Japan, and bone fractures are the most frequent complications imposing heavy burden on individuals and the community. This research investigates the disease burden of fractures in osteoporosis patients (≥50 years old) in Japan with respect to health status, work productivity and activity impairment (WPAI), and healthcare resource utilization. METHODS: This study uses the National Health and Wellness Survey (NHWS) 2012–2014 database in Japan with participants’ demographics, health history and health outcomes assessed. Respondents who were aged ≥50 years old and indicated a physician diagnosis of osteoporosis were included (N=1107). Participants with/without prior fractures after age of 50 were compared with respect to health status (assessed via the mental [MCS] and physical component summary [PCS] scores from the Short Form-36v2), WPAI (assessed via the WPAI-GH instrument) and self-reported healthcare resource utilization in the past 6 months. A secondary analysis was conducted to compare between respondents with ≥2 bone fractures (N=172) and those with 1 bone fracture (N=242) to assess the association between estimated burden and incremental fractures. Comparisons were made using one-way ANOVAs with a significance level of p<0.05. RESULTS: Total 414 osteoporosis patients reported prior fractures (female: 92%; mean age: 66.6). Comparing to those without prior fractures, respondents with prior fractures reported significant lower PCS (46.1 vs. 48.7), MCS (47.2 vs. 49.0), health utilities (0.69 vs. 0.72), and significant greater productivity loss due to presenteeism (26.6% vs. 18.8%), activity impairment (34.6% vs. 28.9%), physician visits (13.4 vs. 10.8) and hospitalizations (3.0 vs. 1.1). Similar results were observed for respondents with ≥2 bone fractures compared with those with 1 bone fracture. CONCLUSIONS: Fractures in osteoporosis patients were associated with poorer health status, greater work productivity loss due to presenteeism and greater healthcare resource utilization. A significant greater burden with incremental fractures was also identified.

PHS56: BURDEN OF DISEASE, HEALTHCARE PATHWAYS AND COSTS OF PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS: AN ITALIAN REAL WORLD STUDY ON 10 MILLION INHABITANTS

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OBJECTIVES: To evaluate the prevalence of primary progressive multiple sclerosis (PPMS) in Italy and to describe the healthcare utilization resources and related costs for National Health Service (NHS). METHODS: A cross-sectional analysis of real-world data collected in the ARNO Observatory database, covering >10 million Italian inhabitants was performed. Starting from a cohort of patients affected by multiple sclerosis (MS) in the 2013 (identified through all available administrative databases). PPMS subjects were defined by the concomitant presence of the following criteria: (i) presence of MS exemption code, (ii) utilization of rehabilitation ambulatory services, (iii) no prescription of Disease-Modifying-Drugs labelled for relapsed remitting MS. For each subject the healthcare utilization
in terms of drug prescriptions, outpatient services and hospitalizations was analyzed. The overall average cost per person was estimated by integrating all expenditure items for NHS. RESULTS: Out of 14,971 patients with MS, a cohort of 941 (6.9%) subjects affected by PPMS was selected, with a prevalence of 9.1 per 100,000 inhabitants. Among these, 24.9% received baclofen, 11.3% azathioprine and 10.4% oxybutynin. Moreover, 8.1% of patients was admitted due to MS complications and 98.2% used at least an outpatient service (excluded rehabilitation therapy). PPMS patients generated an average cost of €4,283 per person. The main cost-driver was hospitalizations, accounting for 55.3% of overall expenditure (€2,370 per person), followed by outpatient services (€1,229 per person, 28.7%) and drug prescriptions (€684 per person, 16.6%). CONCLUSIONS: This study provided real-world data of PPMS in Italy, depicting the actual burden of disease with related healthcare utilization and costs. These findings could be useful to estimate the target population of incoming therapies addressed to PPMS that, to date, represents an unmet clinical need.

**PHS57: HEALTHCARE RESOURCE UTILIZATION AND COST OF PATIENTS WITH ACUTE CORONARY SYNDROMES IN TIANJIN, CHINA**

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**OBJECTIVES:** To evaluate healthcare resource utilization and cost among patients with acute coronary syndromes (ACS) in Tianjin, China. METHODS: Data were extracted from Tianjin Urban Employee Basic Medical Insurance database (2011-2015). Adult patients with primary discharge diagnosis of ACS during 2012-2014, and with insurance coverage of at least 12 months before index hospitalization and after index discharge were included. Optimal medical therapy (OMT) was defined as receiving antiplatelets, statins, ACEIs/ARBs and β-blockers. ACS-related hospitalization and outpatient visit were defined as those with ACS diagnosis, and ACS-related cost as sum of ACS-related hospitalization/outpatient cost and OMT cost from services without ACS diagnosis. Patients were divided into two cohorts according to OMT use at discharge. Propensity-score matching was employed to adjust baseline difference. Generalized linear model (GLM) was conducted to assess the effect of OMT. RESULTS: 22,041 patients (64.7±10.7 years; 45.4% male) were identified, of which 15.1% received OMT at discharge. Within 1 year after discharge, each patient experienced an average of 11.24 ACS-related outpatient visits and 0.24 ACS-related hospitalizations. The ACS-related total cost per patient was ¥8,531, among which OMT cost was ¥2,037 while hospitalization cost was ¥4,666. After matching for baseline of OMT vs. non-OMT patients, there were 3,336 patients in each cohort. During 1-year follow up, OMT patients had more frequent outpatient visits than non-OMT patients (14.24 vs. 13.62, P<0.001), while OMT patients experienced less ACS-related outpatient visits and 0.24 ACS-related hospitalizations. The ACS-related total cost per patient was ¥9,759 vs. ¥10,374, P=0.005. GLM result also indicated that OMT was associated with lower ACS-related total cost (coefficient: -0.12, P=0.039). CONCLUSIONS: Hospitalization cost was the driver even after index discharge. OMT at discharge was associated with less hospitalizations and lower costs. Further strategies are needed to improve the optimal medical care of ACS.

**PHS58: COST OF TREATMENT-RELATED ADVERSE EVENTS (TRAES) IN SECOND-LINE (2L) ADVANCED HEPATOCELLULAR CARCINOMA (AHCC): MATCH ADJUSTED INDIRECT COMPARISON (MAIC) OF NIVOLUMAB AND REGORAFENIB**

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**OBJECTIVES:** Recent therapeutic developments in HCC are positioned to change the treatment landscape. Regorafenib received US approval for 2L aHCC, and early results for nivolumab in this setting indicate efficacy and manageable safety. Given the symptom burden associated with HCC, understanding the comparative safety and related cost is vital when evaluating treatments. In the absence of a head-to-head trial, MAIC was performed to compare the treatments with respect to high-grade TRAEs and associated costs. METHODS: Frequency, grade, and attribution of TRAEs were extracted from patient-level data collected in the sorafenib experienced dose expansion cohort of CheckMate 040, a Phase 1/2 non-comparative study. MAIC was performed to adjust baseline characteristics between the nivolumab (n=145) and the regorafenib RESORCE trial (n=374). Subsequently, odds ratios (OR) comparing nivolumab with regorafenib for grade 3-4 TRAEs and any TRAE were calculated. TRAE costs were estimated from associated principle ICD-9 diagnosis codes from the 2012-2014 Healthcare Cost and Utilization Project National Inpatient Sample data. Per Common Terminology Criteria for Adverse Events guidelines, all grade 3-4 AEs were assumed to require inpatient hospitalization. RESULTS: Based on the MAIC, 10 grade 3-4 TRAEs were attributed to nivolumab compared to 243 with regorafenib. Grade 3-4 TRAEs and any grade TRAEs leading to
discontinuation were significantly less frequent in nivolumab vs regorafenib (OR: 0.23 (95% CI: 0.14–0.39) and OR: 0.25 (0.08–0.83), respectively). No significant between-treatment differences were observed for specific grade 3-4 TRAEs though point estimates tended to favour nivolumab. The per-patient costs of managing grade 3-4 TRAEs were 10.2 times higher for regorafenib compared to nivolumab ($3,946 vs $385). CONCLUSIONS: Nivolumab was associated with reduced odds of grade 3-4 TRAEs and discontinuation due to TRAEs. This translates into reduced inpatient expenditures associated with the management of patients on nivolumab compared with regorafenib.

PHS59: APPROPRIATE DIAGNOSIS AND TREATMENT AS KEY ELEMENTS TO IMPROVE HEALTH AND RATIONALIZE USE OF RESOURCES FOR OBSESSIVE-COMPULSIVE-TIC-DISORDER

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OBJECTIVES: to explore relevant aspects of the burden of OCTD. METHODS: we conducted a Literature review and a pilot study using retrospective demographic, clinical and economic data of patients with OCTD accessing the Galeazzi Hospital in Milan. RESULTS: the literature review provided an overview of the absence of information on OCTD. From 30 patients (80.0% male, 36.7% aged 7-13 years, 63.3% aged 15-48 years), 83.0% declared that obsessions and/or compulsions were the most important factors determining their social impairment. Adult patients refractory to only drug treatment underwent Deep Brain Stimulation plus drugs. The mean clinical scores of patients indicated a severe condition for both tics and OCB/OCD. The mean time elapsed from symptoms onset to diagnosis of OCTD was 5.6 years, reaching up to 11 years in one case. Before reaching the correct diagnosis, the patients were visited several times by different specialists, 93.3% underwent diagnostic examinations and 86.7% took 2/3 different drugs: neuroleptics (40.0%), antidepressants (36.7%), tetrabenazine/tiapride/topiramate (26.7%), anxiolytics (6.7%), 30.0% took antibiotics, homeopathic compounds, vitamins and/or cortisone. Ten patients were hospitalized and 8 underwent psychotherapy. CONCLUSIONS: OCTD has been described recently as an early-onset and highly disabling endophenotype of Tic Disorder and Obsessive Compulsive Disorder. OCTD has a relevant but little known clinical, social and economic burden for patients and their families. Albeit preliminary, these results show that attention is mandatory for establishing correct diagnosis and treatment guidelines to improve health and rationally spend resources for OCTD.

HEALTH SERVICES - Patient-Reported Outcomes & Patient Preference Studies

PHS60: ASSESSMENT OF HYPERTENSION PATIENTS’ ADHERENCE IN BULGARIA – PILOT STUDY

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OBJECTIVES: Patients’ adherence to antihypertensive drug regimens is a complex but important factor in achieving blood pressure control and reducing complications. Approximately one half of patients with hypertension adhere to prescribed medications, and fewer than one in three patients have controlled blood pressure. The aim of the study is to assess the level of antihypertensive medication adherence in two of the biggest cities in Bulgaria. METHODS: A pilot survey was conducted in a sample of individuals aged 22 to 91 (n=441) from the cities of Plovdiv and Varna, Bulgaria that were diagnosed with hypertension. Data were collected via the Morisky Medication Adherence Scale: MMAS-4 from January to June 2017. The MMAS-4 scale was translated into Bulgarian and standardized by forward translation, backward translation, and a pretest. The data collected were processed through SPSS 22. RESULTS: A total of 441 patients were included in the pilot study – 227 males and 214 females. Mean participant age was 63.20 year (59.98 for Plovdiv and 66.41 for Varna). From all the patients, 123 (28 %) had good adherence to antihypertensive agents. Binary logistic regression analysis was conducted. Younger age, shorter duration of antihypertensive agents used, job status being employed, and poor or very poor self-perceived health status were negatively associated with drug adherence. There was no significant association between adherence score and gender (p=0.371). CONCLUSIONS: This study reported a high proportion of poor medication adherence among hypertensive subjects. Patients with factors associated with poor adherence should be more closely monitored to optimize their drug taking behavior.

PHS61: DETERMINATION OF NEEDS AND PRIORITIES IN ORDER TO BETTER ORGANIZATION OF ANTENATAL COURSES
OBJECTIVES: During our research, we assessed how much demand is for antenatal courses, and which parents would like to participate and which topics are they interested in. METHODS: We carried out our quantitative, cross-sectional research in Győr and its surroundings in 2016. Hundred and thirty mothers filled out our own edited questionnaire, who did not attend antenatal courses, received prenatal care, and they were raising a minimum of one month, maximum two-year-old child. The sampling method was random and targeted, expert sampling. Descriptive statistics with frequency range, Chi2-test, and t-test (p<0.05) was performed with Microsoft Excel 2010. RESULTS: 92% of surveyed mothers were raising their child with their partners and half of the families had one child. Mothers have upper-secondary education with almost the same proportion. Nearly identical proportions of the respondents with 40-49%, would participate regularly or occasionally in antenatal sessions. The demand for courses was not affected by the number of children in the family, marital status, maternal age and educational level and the frequency of participation of the father in examinations during pregnancy (c2 p>0.05). We cannot detect any correlation between motivational level towards higher level of subjects of antenatal courses, number of children, education level, and mothers’ intention to participate in antenatal courses (t test p>0.05). However, we found that those mothers who would regularly participate in antenatal course, have a higher interest in the following topics: pregnancy studies, physiological process of labor, presentation of delivery room, natal period events, preparation for the new born and breast feeding (c2 p<0.05). CONCLUSIONS: Based on our research, the primary task of us, as professionals, to raise awareness about antenatal courses for every family expecting a baby, and it is especially important to provide information about somatic - psychic changes during becoming a mother.

PHS62: EXAMINATION OF ADHERENCY OF HIGH-RISK PREGNANT WOMEN WITH GESTATIONAL DIABETES MELLITUS CARE ESPECIALLY WITH RESPECT TO DIET AND PHYSICAL ACTIVITY

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OBJECTIVES: Gestational diabetes mellitus is one of the most commonly occurring conditions in pregnancy. We chose the adherence examination of pregnant women with gestational diabetes mellitus care as topic of our research METHODS: The type of our research was cross-sectional, quantitative nature. Our selected target group included mothers who were previously diagnosed with GDM during their pregnancy and who had 1-7 years old children (n=76). The sampling method was non-randomized, targeted selection. Our research, was carried out between June 2016 and January 2017 in Szombathely, Hungary. Question groups of our own-edited questionnaire: socio-demographic data, lifestyle, care follow-up. We used mean, prevalence and Chi2 test to statistical analysis. Evaluation of the questionnaires was done by MS Excel software. RESULTS: Gestational diabetes have been formed during the first pregnancy in 71% of the cases. In 81% of the cases GDM was also present during their later pregnancies, 13% of cases, type 2 diabetes mellitus developed as well after their GDM pregnancy. Since their GDM pregnancy, 11 people did not check their blood sugar levels. Examining the frequency of the metabolic syndrome, the daily 30-minute physical activity had preventive effect against the development of disease (p <0.05). We could not find a strong correlation between qualification, regular attendance of care and adherence to diet (p> 0.05), between lifestyle changes, including dietary habits change and onset of type 2 diabetes mellitus (p> 0.05). Comparing educational level and therapeutic cooperation, we found a correlation with respect to adherence with prescribed drug therapy (p <0.05). CONCLUSIONS: We would pay more attention to follow up women treated with GDM who has already given birth because with a proper diet and physical activity we can easily reduce or delay the development of type 2 diabetes mellitus and metabolic syndrome.

PHS63: DOES THE STUDY POPULATION AND THE USE OF PROXY RESPONDENT HAVE AN EFFECT ON THE LATENT QUALITY OF LIFE CONSTRUCTS MEASURED BY THE CHU9D AND THE PEDSQLTM 4.0? AN EXPLORATORY FACTOR ANALYSIS

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OBJECTIVES: An important psychometric property of instruments designed to measure health-related quality of life (HRQOL) is that they must accurately capture the latent HRQOL constructs for different subgroups within the instruments' target population. This study examined the latent structures of two generic-paediatric-HRQOL measures [the non-preference-based Pediatric Quality of Life Inventory (PedsQL) and the preference-based Child Health Utility 9D (CHU9D)] when used in subgroups that differed according to age and type of respondent (self versus proxy-
OBJECTIVES: In developed countries, the demand for social care is increasing due to the progression in rapid aging. Our research team developed a Japanese version of the ASCOT SCT4, which can measure social care-related quality of life (SCROQL). We compared scores of the ASCOT with those of the EQ-5D-5L to demonstrate the characteristics of both instruments when applied to elderly care recipients. METHODS: We re-analyzed data that were collected from subjects in a municipality near the Tokyo metropolitan area. Questionnaires were distributed to 2370 care receivers at home, and 1141 responses (48.1%) were collected. We analyzed data from 1102 individuals aged over 65 years (Category 2 insured persons). Summary statistics for ASCOT and EQ-5D-5L were calculated according to the required level of care, which classified elderly care receivers into 7 severity categories. Multivariable analysis was used to examine both ASCOT and EQ-5D-5L scores independently in order to determine which factors influenced the scores. RESULTS: EQ-5D-5L indices were 0.666 (support required 1, N=125), 0.567 (support required 2, N=190), 0.578 (care level 1, N=241), 0.501 (care level 2, N=212), 0.422 (care level 3, N=106), 0.352 (care level 4, N=78) and 0.286 (care level 5, N=48); the corresponding ASCOT scores by care level were 0.746 (N=112), 0.676 (N=178), 0.672 (N=217), 0.655 (N=202), 0.680 (N=101), 0.626 (N=70), and 0.619 (N=38), respectively. Both instrument scores decreased with increasing severity of care level, but the decrease in ASCOT scores was less marked than that for the EQ-5D-5L. The multivariable analysis revealed that age was not associated with either of the scores, while care level, economic conditions, and frequency of eating meals with family members and others were significant factors that influenced both scores. CONCLUSIONS: Several factors associated with both ASCOT and EQ-5D-5L scores were identified, but the degree to which each factor influenced the scores varied.

PHS65: PARENTAL SATISFACTION WITH MEDICATIONS THERAPY AND PARENTING STRESS AMONG PARENTS WITH ASTHMATIC CHILDREN

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OBJECTIVES: The last twenty years have seen increased interest in patient satisfaction in healthcare services as patients become active consumers. One of the main goals of the Expert Panel Report 3 for asthma management was meeting satisfaction requirements of asthmatic patients and their families. This study’s objective was to determine the association between parental satisfaction with medication therapy and parenting stress among parent of children diagnosed with asthma. METHODS: A cross-sectional pre-tested and validated questionnaire using Qualtrics® was administered at 19 asthma/pediatric clinics in Houston, Texas USA, between November 2015- June 2016, to evaluate the association of parenting stress on parental satisfaction. Data were requested on variables such as severity, type of physician (pediatrician), and socio-demographics of the parents and children. Descriptive analysis and multiple linear regression were conducted using SAS® 9.3. RESULTS: A total of 262 parents completed the survey. The average age of parents was 35.1 (±6.9) and that of their asthmatic children was 6.8 (±3.3). More females (approximately 79%) participated and most participants reported being married (66.4%). Whites (34.7%) were the most common racial group. The average parental satisfaction score was 22.1 (±4.1) and for parenting stress scores was 35.9 (±11.9). Multiple linear regression analysis found a negative association between parental satisfaction and parenting stress (β= -0.11421, p=0.0001) and visiting a pediatrician (β= -1.21295, p=0.0115), holding other variables...
such as child’s age and gender as constant. The only positive association was found between parental satisfaction and age of the children (β=0.14830, p=0.0374), after controlling for these variables. CONCLUSIONS: This study revealed negative associations between parental satisfaction with both parenting stress and type of physician. Diagnosing and reducing parental stress levels to improve satisfaction is a vital step because it may affect both parents and the asthmatic children adversely.

PHS66: EASIPRO3 – ENHANCING SATISFACTION WITH PROSTATE CANCER TREATMENT DECISION WITH THE MOBILE HEALTH PROGRAM PROSTANA: A MULTICENTER RANDOMIZED CONTROLLED TRIAL

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OBJECTIVES: Cross specialty primary care of patients with prostate cancer is challenging as patients face difficult treatment decisions due to multiple equivalent treatment options, an individual mix of comorbidities, personal preferences and considerable psychological burden following a cancer diagnosis. Several decision aids exist, but these have primarily been targeted to physicians and their effects have not been studied by means of evidence based medicine. To mitigate, patients increasingly turn to internet-based research before and after consultations. To improve shared treatment decision making and patient’s health literacy a comprehensive German online-program (Prostana) has been developed based on medical guidelines. The program’s key element is a patient centric dialogue software which tailors information to the needs of the patient in a highly patient friendly language. The objective and primary endpoint of the EasiPRO3 study is to evaluate patients’ satisfaction with their treatment decision. METHODS: Prospective multicenter and cluster-randomized controlled trial with cross over-design. To avoid spillover effects, study centers are randomized into either control- or intervention group. In the intervention group patients are offered Prostana, in the control group patients are given a standardized evidence based leaflet. Patients with a first time diagnosis are included in the study. Based on the primary endpoint the sample size has been calculated to 464 patients. The evaluation will follow Intention-to-Treat principle and analyze, among other parameters, differences in satisfaction with treatment decision using the Satisfaction with Decision Scale (SWD). RESULTS: An application for an ethics vote has been submitted in April 2017. The EasiPRO3 aims to start recruitment in September 2017. First interim results are expected by January 2018. CONCLUSIONS: Given the rapid advancements in digital healthcare, high quality outcomes research studies on digital interventions and patient satisfaction are lacking. The EasiPRO3 study can provide insight how innovative online-based software supports patients, relatives and physicians.

PHS67: OLDER ADULTS’ VIEWS ON INCORPORATING LIFE EXPECTANCY IN SCREENING CHOICES – RESULTS FROM A NATIONAL SURVEY USING A DISCRETE-CHOICE EXPERIMENT

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OBJECTIVES: Physicians have been encouraged to consider life expectancy when recommending cancer screening to limit unintended harms of screening for adults with low life expectancy. Older adults’ perspectives related to screening decisions are unknown. This study examined their preferences for different considerations that might go into screening cessation. METHODS: We conducted a national online survey of older adults (age ≥65) using a take-it-or-leave-it discrete-choice experiment. Participants were given 9 choice tasks in which they were presented with the profile of a hypothetical person. Each profile varied in age, life expectancy, quality of life, and doctor’s recommendation. Participants were asked whether they would accept screening if they were in the hypothetical person’s place. A logistic regression was run to identify characteristics of persons that never accepted screening. A conditional logit model using effects coding was used to determine participants’ preferences for the different aspects of the screening profiles. Estimates were converted into odds ratios (OR). RESULTS: 881 participants (response rate 69.3%) with mean age 71.8 completed the survey. 106 participants (12.0%) never accepted the screening. People that never accepted screening had lower odds of self-assessed mortality of more than 50% (OR: 0.43, SE: 0.18) and had lower odds of having been screened in the past (OR: 0.09, SE: 0.02). Age was most influential in the decision to accept a screening profile; the OR of accepting a screening when the person in the profile was 65 instead of 85 years old was 20.03 (SE: 2.33). Life expectancy was the second most influential factor; the OR of accepting a screening with a life expectancy of 10 instead of 1 year was 7.38 (SE: 0.81) CONCLUSIONS: Despite recommendations to stop cancer screening in older adults with limited life expectancy, age might be more influential to older adult when making decisions to get screening.
PHS68: THE POST-TRAUMATIC STRESS DISORDER AND MEDICATION ADHERENCE ENCOUNTERED AT PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: The aim of the study is to evaluate the association between post-traumatic stress disorder and adherence to treatment of Romanian patients with rheumatoid arthritis, without psychiatric comorbidities. METHODS: We examined the association between post-traumatic stress disorder and adherence in a study of 75 patients with rheumatoid arthritis. Post-traumatic stress disorder was assessed using Psychiatric Diagnostic Screening Questionnaire (PDSQ) and medication adherence was assessed with Compliance Questionnaire for Rheumatology with 19 items (CQR-19). Age, gender, pain-indicators, physical and social scores were included in the study, in order to verify the health status of the patients. Linear regression models were analyzed for evaluating the investigated connection between the two quantitative variables. RESULTS: All of our patients were diagnosed with rheumatoid arthritis and are currently under treatment with disease modifying antirheumatic drugs (methotrexate, leflunomide, sulfasalazine), nonsteroidal anti-inflammatory drugs and 11 of them, with biologic agents. Their mean (SD) age was 51.09 (15.93) years. Sex, patient education and demographics was also evaluated: 32% are men, 88% live in urbanized areas and 54% have higher education. It was found that the adherence score was negative associated with the level of post-traumatic stress disorder (r=-0.83, p<0.05) and positive associated with age (r=0.72, p<0.05). Gender, living place and level of education didn’t influence the level of adherence. CONCLUSIONS: There are no cures available for rheumatoid arthritis, nevertheless the psychological effects are very important for the adherence and the good management of this disease. Our study emphasizes the need of a good mental health in order for the patients to adhere correct to the treatment.

PHS69: IMPACT OF A PHARMACIST-LED INTERVENTION ON THE KNOWLEDGE OF APPROPRIATE USE OF PEAK FLOW METER AND ASTHMA ACTION PLAN AMONG PHARMACY STUDENTS: A SIMULATED PATIENT APPROACH

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OBJECTIVES: As the pharmacist-wannabes, the undergraduate pharmacy students must have adequate knowledge and training to counsel the asthma patients on the correct way of using the peak flow meter (PFM) and asthma action plan (AAP). This study was conducted to determine if an educational intervention designed for the final year pharmacy students could improve the students’ counselling abilities to facilitate the correct use of PFM and AAP among asthma patients. METHODS: This study recruited a total of 46 undergraduate final year pharmacy students from MAHSA University, Malaysia. Five simulated patients enacted a standardized scenario of someone with poorly controlled asthma. The knowledge of appropriate use of PFM and AAP was assessed using a self-designed questionnaire where students' scores may vary from 0-8 and 0-10 for PFM and AAP respectively. After the initial assessment, a training session using a didactic approach to self-directed learning and role playing with simulated patients was conducted. At the end of two-hour session, the knowledge regarding the appropriate use of PFM and AAP was re-assessed. The impact of intervention was determined using paired samples t-test through Statistical Package for the Social Sciences (SPSS), version 23. RESULTS: The majority of the respondents were female (n=37, 80.4%) and Chinese (n=27, 58.7%). The results of paired samples t-test showed that there was a significant improvement in the mean knowledge scores (±SD) of PFM (pre-intervention score = 4.24 ± 1.61; post-intervention score = 6.84 ± 1.26; t = 9.474 (45), p < 0.001), and AAP (pre-intervention score = 4.52 ± 1.44; post-intervention score = 6.43 ± 1.29; t = 7.765 (45), p < 0.001). CONCLUSIONS: The substantial improvement in the knowledge score of enrolled students encouraged the introduction of practical training sessions regarding correct use of PFM and AAP in order to maximize the future treatment outcomes in Malaysian asthma patients.

PHS70: DEVELOPMENT OF A TOOL TO QUANTIFY AN INDIVIDUAL’S HISTORY OF SUN EXPOSURE: QUALITATIVE PHASE OF THE DEVELOPMENT OF THE SUN EXPOSURE QUESTIONNAIRE

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OBJECTIVES: The increased risk of developing skin cancers associated with sun exposure is well established. Therefore it is important to understand individuals’ sun exposure and protective behaviours. Given the paucity of measures to evaluate sun exposure retrospectively, this study aimed to develop a tool to quantify sun exposure over various life stages and calculate threshold values for an at-risk individual. METHODS: A literature review was
conducted to identify existing measures evaluating sun exposure. Their content validity was assessed and helped develop a conceptual model of sun exposure quantification. Based on the findings, and discussion with a scientific committee, the Sun Exposure Questionnaire was developed to cover 4 life periods (10-17/ 18-40/ 41-60/ ≥61 years old); holiday/non-holiday, and summer/winter seasons. Two rounds of face-to-face cognitive debrief interviews were conducted with 30 healthy French participants (n=15 in each round) to assess acceptability, comprehension and relevance of the questionnaire. Revisions were made following both rounds of interview. RESULTS: No suitable existing measures to quantify sun exposure were found during the literature review. However, two broad concepts were identified as being important to measure sun exposure: sunbathing history and protective behaviours. The Sun Exposure Questionnaire was developed (first version: 93 items). Feedback indicated that the questionnaire was easy to understand, although some items were considered lengthy. All items were deemed relevant except those related to sun protection behaviours outside summer months. Revisions included simplifying questions, modifying and repeating the age ranges for each group of questions, and systematically assessing voluntary and involuntary sun exposure, to create a final 94-item pilot version. CONCLUSIONS: We developed a unique tool to quantify retrospectively individuals’ sun exposure history in observational studies. A real-life pilot and a validation study are planned to establish the psychometric properties of the questionnaire to determine at-risk individuals in need of a behaviour training programme.

PHS71: THE EFFECT OF EPILEPSY ON THE BULGARIAN PATIENTS – PILOT STUDY

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OBJECTIVES: To understand the impact of epilepsy and improve care for affected patients, it is necessary to identify factors influencing QOL in epilepsy. The aim of our study was to assess the influence of different clinical and demographic variables on quality of life (QOL) in patients with epilepsy in Bulgaria. METHODS: A pilot survey was conducted in a sample of 40 outpatients with epilepsy mean aged 53.05 from Sofia, Bulgaria who visited a neurology department between April and August 2016. Clinical and demographic characteristics were retrieved from medical records. Quality of life was measured by the Quality of Life in Epilepsy Inventory (QOLIE-31). The QOLIE-31 scale was translated into Bulgarian and standardized by forward translation, backward translation, and a pretest. The data collected were proceeded through SPSS 22. RESULTS: There was no significant association between QOLIE-31 score and gender (p=0.516 amd QOLIE-31 score and age (p=0.811). Seizure frequency was strong predictor for all seven subscales. Employability explained 17.5% of the variance in the QOLIE overall score and was the strongest predictor for Overall QOL. CONCLUSIONS: The present study confirms that besides seizure frequency, employability and comorbid psychiatric conditions are strong predictors of QOL in patients with epilepsy. The situation of the Bulgarian patients with epilepsy is the same like the rest of the Europeans from QoL point of view.

HEALTH SERVICES - Health Care Use & Policy Studies

PHS72: CLOSE HER2 HOME: BREAST CANCER PATIENTS PREFERENCES FOR TREATMENT DELIVERY

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OBJECTIVES: This study is currently being undertaken to identify the preferences of people diagnosed with HER2 positive breast for delivery of subcutaneous trastuzumab (Herceptin) therapy. The introduction of a product with a less invasive administration method holds out the prospect of delivering care in non hospital based environments. The design of care pathways that incorporate patient preferences is a key stage in achieving the best clinical outcomes from available resources. METHODS: Important attributes for the delivery of trastuzumab therapy have been identified through two focus groups undertaken with breast cancer survivors attending a cancer support centre. The group will act as a steering group for the implementation of a discrete choice experiment: confirming the delivery of attribute levels; piloting of the questionnaire and commenting on choice sets; providing feedback on the interpretation of data achieved from respondent participation. Given the number of attributes and levels, the number of combinations is 128. A series of 16 choices will be employed using a D-efficient main effects design. The model will be assessed using conditional logistic regression and mixed logit regression in Stata. If possible, latent class modelling will be performed. A community pharmacy pathway will be implemented using data generated from the study and the feasibility of treatment delivery assessed using a realist evaluation approach. Predicted uptake will be estimated and compared to the current situation. RESULTS: Attributes identified by the patient group for delivery of treatment are: travel time; travel cost; identity of provider; treatment site; “They know your name”. CONCLUSIONS: The potential to deliver cancer care in primary care settings is large, given the rise in cancer prevalence due to an ageing population and increasing survivorship amongst cancer sufferers. Design of care
pathways that explicitly meet patients’ preferences for care delivery is therefore a key step to successful service redesign.

**PHS73: FINANCIAL GROUP INCENTIVES IMPROVING MEDICATION PERSISTENCE - HEALTH BEHAVIOR ENGINEERING APPROACH**

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**OBJECTIVES:** In the current study we develop and evaluate different group-based financial incentives based on the concept of loss aversion and social effects. Behavioral engineering approaches have been demonstrated to be key in improving persistence behavior which continues to be a primary target of efforts to improve health outcomes for patients with chronic disease. However, there is limited research trying to successfully design and calibrate group-based incentives in anonymous settings as a sustainable and cost-effective intervention strategy. **METHODS:** The current study follows the procedure of behavioral economic engineering. Based on the findings of the conceptual model of medical non-persistence we engineer two different group-based financial incentive schemes which are predicted to increase persistence. These incentives are derived upon concepts of behavioral economics, in particular social effects, guilt aversion and peer competition, and incorporated into tailored group-contingent bonus schemes. We conduct randomized behavioral laboratory experiments to evaluate the performance and effectiveness of each incentive scheme under controlled conditions. **RESULTS:** Implementing group-contingent bonus schemes in an anonymous setting significantly improve treatment persistence compared to control. Group impact, guilt aversion and peer competition seem to each influence individual behavior to continue with therapy. **CONCLUSIONS:** Previous research demonstrated that individual financial incentive schemes build on principles of behavioral economics, and thus the personally expected consequences, drive treatment persistence. Peer competition is a key underlying mechanism of gamification approaches. The current study shows that peer competition in the context of financial incentives is a vital mechanism to promote individual persistence behavior. Further on, the findings suggest that patients take expected impact on others into account as well. These results do not only seem to be surprising as the impact of peer effects and guilt aversion in anonymous settings is quite often neglected, but open up new opportunities for the design and calibration of consumer/health behavior incentives.

**PHS74: VALUE BASED HEALTHCARE IN ORTHOPAEDIC SURGERY: AN EVALUATION BASED ON THE ECONOMIST INTELLIGENCE UNIT GLOBAL ASSESSMENT FRAMEWORK**


**OBJECTIVES:** Global health care systems are facing a fundamental paradigm shift from volume-based, supply-driven models focused around clinicians to value and outcomes-based initiatives focused on patients and populations. The Economist Intelligence Unit (EIU) Global Assessment provides a global perspective on the alignment of countries with key components of VBHC as well as a standardised framework to evaluate aspects of VBHC within a country. Orthopaedics is well placed to adopt VBHC and places a substantial burden on healthcare systems worldwide. The aim of this study was to collaboratively assess the alignment of VBHC within orthopaedics in different countries, using EIU methodology. **METHODS:** EIU assessed countries on their alignment to VBHC using 17 indicators. In the context of Orthopaedics, 7 relevant indicators for country-specific assessment were selected. Countries were categorised according to their overall alignment to VBHC in orthopaedics. Sources of data included: academic organisations; clinical orthopaedic organisations; national registry organisations; and expert opinion. **RESULTS:** All countries had a national orthopaedic body, but few provided professional training in VBHC. These training programmes were minimal More economically developed countries have multiple centres providing data to formal national and internationally linked orthopaedic speciality registries Most countries had more than one centre with orthopaedic speciality coordinated care services Countries with high levels of healthcare spending also tend towards outcome-based payment approaches in orthopaedics, though bundled-payment systems are not widely implemented **CONCLUSIONS:** Alignment to VBHC in orthopaedics is in its early phases globally Almost universally, countries could improve their alignment with orthopaedic VBHC through the introduction and development of bundled payment models Moving towards coordinated orthopaedic care remains a challenge, though progress in this domain appears to be more developed in orthopaedics than in other specialities Further analysis of this nature aims to generate an understanding of the global landscape of VBHC from a speciality perspective.

**PHS75: ANALYSIS OF HOSPITAL EPISODE STATISTICS TO IDENTIFY HOSPITAL RESOURCE USE DUE TO SKIN CANCER IN IRELAND**

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OBJECTIVES: There were over 10,700 cases of melanoma and first-incidence non-melanoma skin cancer (NMSC) recorded in Ireland in 2013, with incidence rates increasing by 3-4% annually. We aim to identify hospital resource use at a national level, associated with these conditions. METHODS: We obtained and analysed hospital episode statistics (HES) from the national Hospital Inpatient Enquiry (HIPE) service for all discharges with any diagnostic code C43.0-C43.9, C44.0-C44.9, C79.2 (ICD 10th revision), from 2010 to 2014. This data captures daycase and inpatient activity for all patients in acute public hospitals in Ireland. Diagnosis Related Group (DRG) costs were taken from the 2011 Ready Reckoner published by the Health Service Executive inflated to 2017 prices. The data was analysed using Microsoft Excel. RESULTS: There was a consistent increase in total discharges for patients with diagnostic codes C43 and C44 from 2010-2014. This increase was driven by an increase in daycase discharges; inpatient discharges decreased by between 6 and 9% annually. Highest numbers of discharges were for patients aged 65-84 years, in line with the epidemiology of melanoma and NMSC in Ireland. The most common adjacent DRGs for daycase discharges were J11 Other Skin, subcutaneous tissue and breast procedures, R64 Radiotherapy and J69 Skin Malignancy. The largest increase in daycase discharge DRGs was for R63 Chemotherapy, an average of 29% over the period 2011-2014. The most common adjacent DRGs for inpatient discharges were J11Z Other Skin, SC tissue and breast procedures, J69B Skin malignancy without CCC, and J08B Other skin graft &/ debridement procedures –CC. The estimated cost for the day case and inpatient discharges was €44.88 million and €38.5 million respectively, over the 5 year period. CONCLUSIONS: Increasing incidence of melanoma and NMSC is reflected in increasing resource use in the hospital setting, primarily in the daycase setting. Limitation: HIPE excludes outpatient discharges.

PHS77: DOES THE EARLY BIRD CATCH THE WORM: EARLY CANCER DETECTION AND SURVIVAL IN THE UK

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OBJECTIVES: Cancer has a significant burden on NHS resources and there is a need to improve cancer outcomes in the UK. This analysis investigated if there is variation in the early diagnosis of breast, colorectal, and lung cancers across NHS clinical commissioning groups (CCGs) in England, and if this is associated with improved outcomes. METHODS: One-year survival and percentage of breast, colorectal, and lung cancer detected at stage I–II from CCGs was extracted from the 2016 NHS England cancer and tumour focus pack tool. Linear regression analyses were conducted to determine the relationship between the percentage of cancers detected at stage I–II versus 1-year survival. RESULTS: Data were available from 209 CCGs. This analysis revealed significant variation in early detection of cancers across England. The percentage of cancers detected at stage I–II ranged from 36.3% to 88%, 13.5% to 54.4%, and 9.1% to 35.1% in patients with breast, colorectal, and lung cancer, respectively. Similarly, 1-year survival rates varied, and ranged from 93.2% to 98.6%, 68.2% to 85.3%, and 23.5% to 47.1% for breast, colorectal, and lung cancer, respectively. A statistically significant positive correlation between the percentage of cancers detected at stage I–II and 1-year survival for lung cancer was observed (R=0.28; p<0.001). No similar correlation was found for breast and colorectal cancer (R=0.10; p=0.15 and R=0.07; p=0.32, respectively). CONCLUSIONS: These data indicate that rates of detection of cancers at stage I–II vary considerably. We find that detection at stage I–II is associated with improved survival in lung cancer which has poorer outcomes at later stages of disease versus breast and colorectal cancer which have more favourable outcomes at later stages. CCGs should continue to take action to improve detection rates and thus survival outcomes in difficult-to-treat cancers.

PHS78: REAL WORLD DATA ANALYSIS OF A PATIENT-TAILORED, POST-DISCHARGE SUPPORT PROGRAM FOR PATIENTS UNDERGOING AN OSTOMY SURGERY IN LOWERING readmissions and emergency room visits

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OBJECTIVES: Most patients undergoing ostomy surgery have experienced life adjustment difficulties and post-operative complications, resulting in emergency room (ER) visits. A patient-tailored, post-discharge support program (Coloplast Care) has been developed as an adjunct to nurse-led ostomy care to provide patients with post-operative education and easily accessible assistance. This study investigated the effectiveness of the patient support program on real-world, preventable healthcare utilization in patients living with an ostomy. METHODS: This study employed a cross-sectional online survey design. Coloplast, an ostomy patient support program provider, maintains an ostomy patient database. Patients in this database were eligible to participate in the survey; they were stratified into program enrollees and non-enrollees. Both patient groups received a survey containing questions addressing the following
domains: characteristics of ostomy surgery, readmissions and ER visits within the first month or after the first month of discharge including reasons for preventable events; and level of healthcare access. Two multivariate logistic regressions controlling for covariates were applied to assess any association between program enrollment and ostomy-related readmissions or ER visit rates. **RESULTS:** Of 7,026 surveys sent to program enrollees, 493 (7%) responded compared with 225 (5%) out of 4,149 surveys sent to non-enrollees. The two groups were similar in demographics; there were no statistically significant differences in gender, race, the medical condition requiring ostomy surgery, whether the patients visited an ostomy clinic after surgery, or received other patient support programs. Logistic regressions showed that compared with non-enrollees, program enrollees had a significantly lower likelihood of being readmitted and visiting the ER due to ostomy complications one month or more following discharge (odds ratio, 0.45; 95% CI, 0.27-0.73 and 0.37; 95% CI, 0.22-0.64, respectively). **CONCLUSIONS:** This study suggests that enrolling patients with an ostomy in the post-discharge support program is effective in reducing potentially preventable healthcare utilization.

**PHS79: INVOLVEMENT OF COMMUNITY PHARMACISTS IN PUBLIC HEALTH PRIORITIES: A MULTI-CENTER DESCRIPTIVE SURVEY IN ETHIOPIA**

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**OBJECTIVES:** Located in the heart of the community and widely distributed geographically, community pharmacies provide a platform for a more proactive involvement in public health services. So far, little information has been gathered in Ethiopia on community pharmacists’ level of involvement in public health services. The aim of the present study was, therefore, to document the level of involvement of community pharmacy professionals in the provision of public health services and the barriers to such involvement. **METHODS:** This study employed a self-administered questionnaire based survey, which asked participants to indicate their frequency and level of involvement in providing public health services and their perceived barriers in providing such services. Surveys were undertaken from May to July, 2016 with 472 community pharmacy professionals working in community pharmacies in six cities of Amhara regional state of Ethiopia: Debre Markos, Gondar, Dessie, Bahir Dar, Woldya and Debere Birhan. **RESULTS:** Among 472 community pharmacy professionals approached, 412 (233 pharmacists and 179 pharmacy technicians) completed the survey with a response rate of 87.3%. Most respondents reported as being either “not at all involved” or “little involved” in counselling on smoking cessation (79.3%), and screening for hypertension (86.9%), diabetes (89.5%), and dyslipidemia (88.9%). On the other hand, they reported a higher level of involvement in the management and screening of infectious diseases (72.8%) and counseling with partners when initiating treatment for sexually transmitted diseases (68.9%). Lack of knowledge or clinical skills and lack of personnel or resources were the most commonly reported barrier for expanding such services. **CONCLUSIONS:** This survey revealed a low level of involvement of community pharmacists in public health services. In order to better integrate community pharmacies into future public health programs and optimize the contribution of community pharmacy professionals, interventions should focus on overcoming the identified barriers.

**PHS80: TOOLS FOR IMPROVING EFFICIENCY IN CLINICAL MANAGEMENT AND SAFETY OF HYPERTENSIVE PATIENTS. EFIEG-HTA PROJECT**

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**OBJECTIVES:** Hypertension, due to its high prevalence, is estimated to account for 5.6%-7.5% of the total health spending in Spain. The objective of this study is to detect areas for improvement in the management of hypertensive patients within the Spanish National Health System (SNHS), so it may help clinicians, health managers and decision-makers to get the best possible clinical results. **METHODS:** A web-site tool for self-diagnosis was launched in 2015, with access to primary healthcare centres to detect their hypertension-related areas for improvement. Health managers could complete an ad hoc questionnaire, and compare their answers to three different scenarios: “control” (ideal results based on literature and a committee of experts), “national” (results from participating centres) and “regional” (results from centres from the same region). Areas for self-evaluation were: information systems, diagnostic tests, organizational aspects, resource consumption and training for patients and healthcare professionals. After any intervention implemented by centres to solve an area for improvement, a before-after results comparison could be made, also in economic terms. **RESULTS:** A total of 31 centres participated in the pilot project at national level. Related to diagnosis, 57.1% of centres followed any Preventive Care Program, 45.7% hadn’t easy access to ambulatory monitoring for diagnosis and management of hypertension and 42.9% of clinicians didn’t ask patients about substances that may modify blood pressure. Most of centres (82.9%) were not provided by any clinical expert
in hypertension or cardiovascular risk. Related to patient training, many centres didn’t carry out health education activities (60%), nor workshops on diet (68.6%) and only 28.6% developed physical activity workshops aimed to hypertensive patients. **CONCLUSIONS:** The SNHS has undergone important advances in recent years. However, in terms of clinical management and prevention, there is scope for improving efficiency, which is the future challenge in primary care.

**PHS81: THE COORDINATED MANAGEMENT OF PATIENT WITH MENTAL ILLNESS IN SPAIN BY HOSPITAL, PRIMARY CARE AND COMMUNITY PHARMACISTS (3PH), A RESOURCE OPTIMIZATION MODEL**

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**OBJECTIVES:** All chronic diseases, including mental illness, need to be followed with a continuity of care by different care providers, the coordination of which would improve the monitoring of the treatment. In Spain, 9% of the population suffer from schizophrenia, about 400,000 people. Adherence is the major predictive risk factor for relapses in this population. Since patients hide their disease to avoid social stigma, it is important that the patient does not feel alone and contributes to treatment decisions. This proposal aims to evaluate if coordinated care improves drug management and treatment compliance. **METHODS:** This project is a new model within the existing structure and should take place at the local level (county, district) so as to be close to the patient. It consists of a group of responsible for drug evaluation, management, dispensation and pharmacovigilance: the “3Ph” group, composed of Hospital, Primary Care and Community Pharmacists. **RESULTS:** This group must meet once a year, base their work in Health Plans for Chronicity, Mental Health and Adherence and review with a certain methodology: (a) Treatments: Objective criteria for drug selection, the adjustment of treatments to patient’s life routines, factors leading to non-adherence, conciliation at the time of the discharge, treatment reviews; (b) Management: Quality indicators, drug utilization rates, methodology of Pharmaceutical Care and responsibilities and functions of each health care level to assure the continuity of care; (c) Evaluation and redesign. **CONCLUSIONS:** The proposal for the creation of “3Ph” groups at local level, a Mental Health collaborative project that is fully aligned with current Spanish Health trends. The first step is to set up its specific methodology. Therefore, it will be further possible to evaluate their benefits in terms of adherence, prevention of relapses and improvement of patient’s satisfaction, quality of life and disease outcomes.

**PHS82: REAL WORLD TREATMENT PATTERNS IN METASTATIC AND/OR UNRESECTABLE GASTRIC CANCER PATIENTS IN RUSSIA**

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**OBJECTIVES:** Little evidence is available on the management of patients with metastatic and/or unresectable gastric cancer (mGC) after failure of 1st-line treatment. This study presents real-world data on patient characteristics and treatment patterns for these patients in Russia. **METHODS:** Eligible patients were ≥18 years old, diagnosed with mGC on or after January 1, 2012, had received 1st-line chemotherapy including platinum analogue/fluoropyrimidine followed by 2nd-line chemotherapy or best supportive care (BSC), had ≥3 months of follow-up after the start of 2nd-line chemotherapy or BSC (except in cases of death), and had not participated in a clinical trial. Data were obtained from the patients’ charts, and summarized using descriptive statistics. **RESULTS:** Data from 202 charts were collected. Mean age was 53.7 (standard deviation [SD]: 11.2) years. 70.8% of patients were male. ECOG performance status (PS) at the start of 1st-line therapy was 15.5% PS=0, 58.3% PS=1, 16.7% PS=2, 8.9% PS=3. Reasons for 1st-line treatment discontinuation included disease progression (50.5%) and adverse events/toxicity (39.1%). There were 52 unique treatment regimens prescribed in 2nd-line; capecitabine (14.5%), paclitaxel (9.3%), and capecitabine+oxaliplatin (8.7%) were the most frequent. Reasons for 2nd-line treatment discontinuation included disease progression (39.8%) and patient refusal to continue (37.5%). During 2nd-line treatment, the most common treatment-related symptoms were nausea/vomiting (75.0%), while pain (73.8%) was the most common disease-related symptom. Antiemetics (63.4%), chemotherapy (61.8%), non-narcotic analgesics (48.3%), endoscopy (45.9%), and nutritional support (35.5%) were used as supportive care. Most patients were hospitalized at least once during 2nd-line treatment for drug administration (74.5%) or other cancer-related care (24.4%). **CONCLUSIONS:** Second-line treatment patterns for patients with mGC in Russia are highly heterogeneous. The results of this study indicate the need for more intensive implementation of the most active regimens in 2nd-line treatment of mGC according to international and national guidelines.

**PHS83: BURDEN OF ENDOMETRIOSIS AND RELATED SYMPTOMS IN A NATIONWIDE HEALTH PLAN WITH 2 MILLION MEMBERS**
**PHS84: BRIDGING THE GAP BETWEEN INTERNATIONAL STANDARDS OF QUALITY OF CARE AND PRACTICES IN THE INPATIENT UNIT OF THE NATIONAL TB CONTROL CENTER IN ARMENIA**

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**OBJECTIVES:** Providing high-quality TB care is an important step toward improving patients’ quality of life and decreasing TB morbidity and mortality. Introduction of international standards and guidelines for TB care ensures access to high-quality TB services serving as a comparison benchmark for the national program’s performance assessment. This study aimed at assessing the adherence of TB Inpatient Treatment Services in Armenia to the standards, for defining quality of provided care and developing quality improvement programs. **METHODS:** We assessed the largest TB inpatient facility in Armenia to evaluate its compliance with the Joint Commission International Accreditation Standards for Hospitals, International Standards for TB Care, and WHO framework for conducting TB program reviews. Data was collected through 24 in-depth interviews and eight standardized checklists to explore practices of healthcare professionals, assess inpatient treatment experience of patients and their family members, evaluate the facility’s environmental conditions and define the level to which policies were applied. Data were analyzed using scoring system converted to percentages for both patient-centered and organization-management functions. **RESULTS:** In the hospital, several processes were not standardized, leading to minimal levels in meeting the standards: Quality Improvement and Patient Safety (25%), Patient and Family Education (26%); partially meeting the standards: TB-Tobacco Control (35%), Patient and Family Rights (39%), Assessment of Patients (61%), and Medication Management and Use (62%); Staff Qualifications and Education (42%), and Governance, Leadership and Direction (53%); or satisfactorily meeting the standards: Patient care (71%), Prevention and Control of Infection (75%), Access and Continuity of Care (87%), and Management of Communication and Information (79%). These functions require major, several, or some improvements respectively. **CONCLUSIONS:** Interventions on two levels of the organization’s operation are needed: structure-related improvements (development of policies, procedures, written documentations and establishment of modern infrastructures) and process-related improvements (actions towards improving the patient care processes).

**PHS85: THE FLOW OF EU-28 COUNTRY CLUSTERS IN TERMS OF INFECTIOUS AND CHRONIC DISEASES DURING A REFUGEE CRISIS**

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**OBJECTIVES:** With the current refugee crisis, European countries are tasked with handling displaced persons as well as the infectious, chronic diseases they carry. This study seeks to understand the flow of European country groups in terms of infectious, chronic diseases and migration integration indicators. **METHODS:** Eurostat statistics data were assessed for the year 2014. Turkey and 28 European countries were examined. The Expectation
Maximization clustering algorithm was used for clustering, and the U test was used to identify the differences between country clusters in terms of study variables. A flow (Sankey) diagram was created to visualize the flow of European country clusters. **RESULTS:** Study results indicate two different clusters in terms of infectious, chronic diseases and migration integration indicators. Country clusters differ in the total number of reported cases of measles (U=47, p<0.05) and total number of migrations (U=45, p<0.05). **CONCLUSIONS:** Study results pose several implications for future studies concerning the refugee crisis. Health policy makers in European countries should focus on building cost-effective services to provide primary health care for refugees. Measures to address health inequalities, integration of refugees to reduce threats from infectious and chronic diseases, and increased collaboration are essential strategies to maximize quality care during the refugee crisis.

**PHS87: COSTS AND EFFECTIVENESS OF AN INTEGRATED CARE INTERVENTION FOR MUSCLE-SKELETAL DISEASES TRANSITION FROM PRIMARY CARE TO SPECIALIZED HOSPITAL CARE**

**OBJECTIVES:** Integrated Health Organisations (IHO) match reference hospitals and primary care (PC) in the Basque Public Health System since 2012. Integrated care refers mainly to the new approach of care delivery for patients with chronic diseases; however, it might be also beneficial to empower PC with the objective of reducing unnecessary resource consumption in specialized consultations related to muscle-skeletal diseases. **METHODS:** This was a retrospective observational comparative effectiveness study carried out in the IHO Goierri-Alto Urola, Gipuzkoa, Spain. All the patients with an incident muscle-skeletal episode in PC in 2012 and 2016 were included in the study. The intervention was implemented from 2013 onwards and consisted on a specific clinical pathway for knee and shoulder related diagnosis as well as for osteoporosis and low back pain. At the same time PC was enabled for direct access to magnetic resonance image and bone densitometry. Electronic health records were used in order to obtain resource consumption data for the patients included in the study. Genetic matching algorithm was applied in order to avoid selection bias. **RESULTS:** 4058 patients were diagnosed in 2012 and 4493 in 2016 in PC. Referrals to specialized consultations decreased 11% from 19% in 2012 to 17% in 2016. Specially, referrals to Traumatology and Rheumatology services decreased, 20% and 35% respectively. Patients’ derived to Rehabilitation from PC increased 32%. Multivariate analysis carried out with weighted populations show that both referral probability and total costs had a statistically significant reduction in the studied period. **CONCLUSIONS:** The implemented integrated model achieved the expected derivation rate reduction together with a shift to move derivations to services other than Traumatology. It was noteworthy, in terms of clinical management, that the value of the decrease in overall derivations was 11%. Therefore, PC empowerment related to muscle-skeletal diseases permitted lowering the bottleneck to Traumatology service consultations and improved efficiency.

**PHS88: TREATMENT PATTERNS AND RESOURCE USE OF TYPE 2 DIABETES PATIENTS MANAGED ON INSULIN IN ENGLAND – RESULTS OF A DELPHI PANEL**

**OBJECTIVES:** Achieving good and quality patient outcomes is a major goal in pharmaceutical care intervention. Well-being index is a humanistic outcome that evaluates patients’ satisfaction, quality of life, attitude, and expectations to health care services. This study assessed the impact of pharmaceutical care intervention on the well-being of type 2 diabetes outpatients in a tertiary hospital in Nigeria. **METHODS:** A randomized controlled intervention study, which lasted for 12 months, was carried out. The World Health Organization’s (five) Well-Being Index Questionnaire was modified for the study. The six-point scale questionnaire in English Language was manually administered to eligible patients and collected same day during clinic, pre and post intervention. Data were summarized using descriptive and inferential statistics at P<0.05 level of significance. **RESULTS:** 122.0 eligible type 2 diabetes patients took part in the study, 61.0 patients each in the intervention and control group. The mean age was 56.4±11.8 for control and 58.8±12.0. The well-being value for the control group at baseline was 39.60±10.05 and 52.89±10.5 after 12 months of intervention. The wellbeing index for the test group was 36.61±12.4 at baseline, and 56.4±11.8 for control and...
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OBJECTIVES: To gain insight into the initiation patterns and resource use at a micro level for insulin-naïve type 2 diabetes (T2DM) patients in England due to the scarcity of information within the literature. This Delphi sought to discover the current clinical practice and how this may differ across health care practitioner (HCP) roles. METHODS: A two-round Delphi technique was employed, using a consensus of opinion of ≥70%. 18 clinical experts across England participated in Round 1; 6% drop-out rate was seen in Round 2. Both open and closed ended structured questions were used to gain both quantitative and qualitative responses. Consensus and non-consensus responses were of value. RESULTS: 148 questions were asked over both Rounds with only 5 questions unable to attain a consensus. On average 50% of insulin-naïve T2DM patients initiate insulin annually. The long-acting insulin is the most frequently prescribed by HCPs, with the largest involvement from diabetologist/endocrinologist (65% of cases). Education provided to T2DM patients was either comprehensive, tailored or both involving a multitude of HCPs and requiring 1-4 hours. Whilst GPs and diabetologists were the main prescribers, visits to other HCPs occurred once every 3-6 months. Accessory units such as insulin injection devices and meters are generally replaced on an ad hoc basis with an average daily use of 1 needle, 2 blood glucose test strips, and 1 blood glucose lancet per patient. CONCLUSIONS: The high consensus rate highlights this was a successful application of the Delphi process. A third of T2DM patients are initiated on insulin annually, the preferred option being the long-acting insulin. Principal involvement in initiation is the diabetologist/endocrinologist, whilst an array of HCPs are involved in education. An interesting finding arose where HCP roles are often interchangeable. However, more research would be needed to determine the impact of this from a patient perspective.

PHS89: ANALYSING UPTAKE OF NEW MEDICINE SERVICE IN ENGLISH COMMUNITY PHARMACIES

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OBJECTIVES: English pharmacies can claim money from the National Health Service (NHS) to provide New Medicine Service (NMS). A NMS aims to improve medication adherence and consists of two pharmacist-led consultations conducted after the patient is issued a new medicine for one of four therapy areas. Both the number of NMS a pharmacy can claim for and the reimbursement tariff (£20-£28 per NMS) are calculated based on their monthly number of dispensed prescriptions (1). While there are limited English health-economic data available for NMS, models suggest they are cost-effective for some therapy areas (2, 3). We analysed the uptake of NMS in England and opportunity loss associated with suboptimal uptake. METHODS: Monthly dispensing data for English pharmacies that had (i) submitted NMS data to the NHS Prescription Services for the whole of 2016 and (ii) made at least one NMS claim during this period were retrieved from the NHS Business Authority. This resulted in monthly data for the calendar year 2016 being retrieved for 9,609 pharmacies. The data were used to calculate the number of NMS each pharmacy could be reimbursed for and their reimbursement tariff. Opportunity loss was calculated by subtracting the number of NMS declared from the maximum number the pharmacy could have claimed, and multiplying the subtraction with the pharmacy’s reimbursement tariff. RESULTS: The median English pharmacy only claimed for 17% of the NMS they could have, resulting in a median annual opportunity loss of £8,340 per pharmacy (£0-£16,780). The total opportunity loss across English pharmacies was £83,037,532. CONCLUSIONS: There is suboptimal uptake of NMS in English pharmacies, which is associated with lost revenue for individual pharmacies. More studies are needed to understand the impact of this on patient outcomes and indirect NHS cost. REFERENCES: (1) PSNC (2017) https://psnc.org.uk/funding-and-statistics/funding-distribution/advanced-service-payments/ (2) Wright (2016) https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/12/rapid-evdnc-rev-dec-16.pdf (3) Brinkmann (2015) http://www.valueinhealthjournal.com/article/S1098-3015(15)04414-9/pdf

PHS90: WHAT UNDERLIES THE OBSERVED HOSPITAL VOLUME-OUTCOME RELATIONSHIP?

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OBJECTIVES: Studies of the hospital volume-outcome relationship (VOR) have highlighted that greater volume activity improves patient outcome. While this finding has been known for years in health services research, most VOR studies to date have failed to delve into what underlies this relationship. This study aimed to disentangle the VOR by comparing treatment modalities (e.g. chemotherapy protocols) for epithelial ovarian carcinoma (EOC) patients. METHODS: A comprehensive cohort of 267 EOC patients diagnosed in 2012 in the Rhone-Alps region of France was used. Three outcomes were considered: progression-free survival, re-operation, and tumor resection. Discrete choice and count data models were first applied to underscore different treatment approaches. VOR was then estimated with instrumental variable (IV) analysis while controlling for the different treatment approaches. Hospital volume activity was instrumented by the distance of the patients’ homes to the hospital and the median net incomes in the specific areas where the patients resided. RESULTS: After controlling for selection biases, being
treated in a higher volume hospital significantly improved all three patient outcomes. This can be partially explained by major differences in treatment approaches. On average, patients were more likely to receive neoadjuvant chemotherapy (p<0.001), a higher number of cure (p<0.001), and to be treated with both adjuvant and neoadjuvant chemotherapy (p<0.001) in higher volume hospitals. IV analysis showed that the VOR decreased when we controlled for treatment approaches. CONCLUSIONS: We have highlighted several factors that characterize the observed part of VOR for EOC patients. Higher volume hospitals appear to more often make the right decisions in regard to how to treat patients, which contributes to the positive impact of the hospital volume activity on patient outcomes. Volume alone is, an imperfect correlate of quality. To build volume-based policies, policy makers need to know what volume is a proxy for.

PHS91: PRE-HOSPITAL PAIN RELIEF TREATMENT IN PATIENTS WITH MUSCULOSKELETAL INJURIES EXPERIENCING MODERATE TO SEVERE PAIN IN MEDICAL EMERGENCIES

**OBJECTIVES:** Providing timely pain management to trauma patients is important to avoid unnecessary patient suffering 1-6. Administration of analgesia is often prolonged in the pre-hospital setting due to several factors 7. The aim of this research was to characterize current pain relief treatment timelines in patients with musculoskeletal injuries experiencing moderate to severe pain in medical emergencies requiring paramedic or emergency care assistance. METHODS: A retrospective chart review was conducted to understand pain relief treatments, timelines and outcomes in medical emergency situations across Europe (Belgium, France, Germany, Italy, Spain, and Sweden) and Australia. Ambulance and hospital notes of 856 patients were reviewed by 189 emergency specialists. In Australia where low dose inhaled Methoxyflurane is available for emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain, a sub-sample of 85 patients receiving low dose Methoxyflurane was compared to non-Methoxyflurane patients using propensity score matching. RESULTS: The mean (SD) time to first pain relief treatment after paramedic arrival was 35.6 (35.09) minutes. It was significantly longer for total EU (38.1 [34.65]) compared to Australia (29.9 [35.48]) minutes (p=0.0017). Nonetheless, there was considerable variation in time range for the EU 0-339 minutes, as well as Australia 0-189 minutes. The mean (SD) time from paramedic / emergency arrival to first pain relief treatment in the Australia sub-sample treated with low dose Methoxyflurane was 21.7 minutes (24.24) vs. 39.1 minutes (42.95) in the non-Methoxyflurane group (p-value 0.0013). CONCLUSIONS: There appears to be unmet need for fast pain relief in pre-hospital care in Europe. Further observational research is warranted to monitor how the introduction of low dose Methoxyflurane as a pain relief option in paramedic care in Europe could lead to faster pain relief in emergency care.

PHS92: COST CONTAINMENT AND PRIVATISATION OF PHARMACEUTICAL CARE IN GREECE: A REVIEW OF POLICY REFORMS UNDER THE MEMORANDUMS’ REQUIREMENTS

**OBJECTIVES:** A plethora of measures has been implemented for the purpose of public pharmaceutical cost containment during the recent years in Greece. The main objective of this study was to disaggregate the nature of these policy reforms in terms of cost containment and cost reallocation METHODS: For the period 2010-May 2017, 319 statutes and regulations (FEK) that concerned directly or indirectly pharmaceutical care were retrieved from the Government Gazette. A content analysis was performed on these documents to identify unique pharmaceutical policy reforms. These measures were classified firstly with reference to their character as cost containment (white area) or rationing (black area) or a mixture of those (grey area), and, secondly, with respect to cost reallocation to the tax funded National Health System (NHS) or the social security funds or health consumers. RESULTS: 84 FEK encompassed 115 measures, which were categorised as 82.6% belonging in the white area, 16.5% in the grey area, and 0.9% in the black area. Of those, 51.3% concerned price regulations, 17.4% prescription control, 13.9% cash limits, volume restrictions and benefit caps, 6.1% co-payments, 6.1% waste avoidance, 2.6% exclusion from reimbursement, 1.7% elimination of surplus resources and 0.9% scarcity of resources. 64 FEK were identified to contain 92 unique measures of cost reallocation. 17.4% of them transferred pharmaceutical cost to the NHS, 22.8% to the social security funds, and 59.8% (35.9% directly, 23.9% indirectly) to consumers. CONCLUSIONS: Pharmaceutical reforms during the recent years present a clear tendency to reallocate pharmaceutical cost to consumers. Considering the economic challenges the Greek citizens are facing and the already privatised nature of the Greek health system, policies should focus more on improving health system’s efficiency and effectiveness, instead of increasing out-of-pocket payments, which may exacerbate barriers to pharmaceutical access, especially for the more vulnerable groups.
PHS93: INTEGRATED CARE MODELS IN GERMANY – POTENTIAL MARKET ACCESS ROUTE FOR MEDICAL DEVICES?

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OBJECTIVES: For the market access of innovative medical devices in Germany it plays a key role whether a medical device is applied in the inpatient or in the outpatient setting. There are several possible reimbursement pathways for innovative medical devices, among them Integrated Care Models – ICM (§140 a Social Code Book). Recent research suggests ICMs as a not yet spotted potential access route for medical devices and hence faster access to innovative diagnostics and treatment methods. However, the perception among stakeholders might be quite differential. The key question within the discussion is if the ICM contracts could be an opportunity for market access which might overcome potential issues for market access through regular routes. METHODS: ICMs have been evaluated systematically through a triangulated approach – the analysis of model concepts, the organizational set-ups and by semi-structured interviews with key stakeholders. RESULTS: In 2011, 6339 contracts exist, covering 1.9 Million insured persons. The actual number of ICM contracts is probably higher. An obligation to notify was established 2012. In total 8120 contracts could be reported in 2015 to the Federal Insurance office (BVA). There are two options for a manufacturer (outpatient setting): First, inclusion of a product within existing ICMs or second, setting up a new ICM with potential stakeholders as partners. The systematic development of treatment procedures associated to the product leading to professional case management structures, potentially supporting guideline developments and overall show a reasonable fast access to these innovative medical devices. CONCLUSIONS: ICM contracts are a positive addition to the regular reimbursement possibilities for innovative medical products in cross-sectoral, interdisciplinary care. The extended context of selective contracts makes the implementation of supply innovations possible by bridging the often lengthy and challenging procedures across sectors but primarily in outpatient care, were the current regular route is often still a deadlock.

PHS94: HETEROGENEITY IN GP CONSULTATION COSTS IN HEALTH TECHNOLOGY ASSESSMENTS: EXPLANATIONS AND IMPLICATIONS.

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OBJECTIVES: The comparative analysis of a novel intervention’s cost-effectiveness across jurisdictions is predicated on the existence of comparable measures of cost and outcome. More than 10 years after the Centre for Health Economics at York published a review of methods for estimating the cost of healthcare services considerable heterogeneity remains in the reporting of costs. We compare the estimated cost of the most commonly accessed service - general practitioner services - to demonstrate the degree of heterogeneity and explore the sources and implications of that heterogeneity for cost-effectiveness analysis conducted across jurisdictions. METHODS: A literature review was undertaken to identify the cost of a GP consultation used in health technology assessments. To minimise heterogeneity related to differences in national income, only countries listed among the high-income group by the World Bank were selected for inclusion in the review. The cost of a GP consultation in 20 countries was obtained from published literature located through Pubmed. All costs were adjusted for inflation to their 2015 equivalent and converted to Irish Euro € using the OECD’s PPP conversion rates. RESULTS: Among the 20 countries for which GP consultation costs were found, the reported cost of a consultation ranged from €7 to €142. The mean cost was €46 with a standard deviation of €36. Cost estimates varied in antiquity from 2007 to 2015. A positive weakly significant correlation was observed between GP costs and a country’s per capita GDP. CONCLUSIONS: Evident heterogeneity in the cost of a GP consultation reflects more strongly methodological heterogeneity in the estimation of costs than variations in national income. Adapting model-based estimates of cost-effectiveness using local costs without considering the basis upon which costs are constructed will fail to produce comparable estimates of cost-effectiveness.

PHS95: SURVEILLANCE STATUS, DIAGNOSTIC ACCURACY AND SURVIVAL OF THE NATIONAL LIVER CANCER SURVEILLANCE PROGRAM

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OBJECTIVES: Hepatocellular carcinoma (HCC) is the leading cause of death among people in their 40’s and 50’s in South Korea. To reduce the socioeconomic burden from liver cancer, the National Liver Cancer Surveillance Program (NLCS) has been established since 2003. The purpose of this study was to evaluate the surveillance status, diagnostic accuracy, and survival of NLCS for the high risk group of HCC. METHODS: We used the National Health Insurance Service claims data linked with NLCS from 2005 to 2014. For diagnostic accuracy, sensitivity, specificity, and positive predictability values (PPV) were assessed based on whether the patients diagnosed with HCC within 6 months after undergoing NLCS during the study period. In addition, the impact of the NLCS on survival was examined using a log-rank test and Cox proportional hazards model. The survival period was defined as time from development of HCC to death. A lead-time bias that occurred due to NLCS was adjusted for in the models. RESULTS: The annual NLCS rate resulted that individuals undergoing NLCS have increased consistently from 6.9% in 2005 to 41.2% in 2014. The sensitivity of the surveillance varied (from 33.4% to 74.9%) depending on the assessment criteria, and clinical opinion. There was no significant variation in the trend of diagnostic accuracy during study periods. The risk of mortality for patients who underwent NLCS once within the 2 years prior to being diagnosed with HCC was 22.1% lower (HR: 0.779, 95% CI: 0.758-0.800) compared with the patients who did not participate in NLCS. CONCLUSIONS: This study highlights the mortality benefit in patients who underwent NLCS, and the needs for the continuous improvements of NLCS in South Korea. Although the annual surveillance rate increased during the study periods, the public health efforts to encourage the surveillance participation would be still required to maximize the effects of NLCS.

PHS96: PRESCRIBING PATTERN ALONG WITH PHARMACOECONOMIC EVALUATION IN PRIMARY HEALTH CARE FACILITIES NEPAL

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OBJECTIVES: To assess the drug use pattern in Primary Health Care (PHC) facilities of Nepal and pharmacoeconomic evaluation of drug prescribed. METHODS: A prospective cross-sectional descriptive study was conducted in 11 PHC facilities of Kaski district using WHO core drug use indicators. RESULTS: A total of 301 prescriptions were analyzed. The average age of patients visiting PHC was 33.11 years (female 35.79; male 30.40). The average number of drugs prescribed was 2.29. Percentage of encounters with at least one antibiotic prescribed was 57% whereas encounters with at least one injection prescribed was low 3%. The total percentage of drugs prescribed using generic names was found to be 59.02% and percentage of drugs prescribed from EDL was 85.19% respectively. The average consultation and dispensing time of 109 patients was 2.02 minutes and 42.52 seconds. Only 30% of patients had adequate knowledge of drug whereas none of the drugs were adequately labeled. Percentage of drugs actually dispensed was 89.63%. All health facilities had availability of Essential Drug List (EDL). The total percentage of availability of key drugs in PHCs was 89.69%. CONCLUSIONS: Irrational practice mainly on antibiotics use and non-generic prescribing in most facilities studied were noticed. Patient care provided by health facilities studied was insufficient and thus effective intervention program for promotion of rational drug use practice is recommended in PHC facilities in Nepal.

PHS97: ESTIMATED CLINICAL IMPACT OF TWO ONCOLOGIC DRUG SHORTAGES


OBJECTIVES: Drug shortages are a worldwide problem and affect all stakeholders in the pharmaceutical supply chain. The worst impact that a drug shortage can cause is afflicting patients. This study investigates the estimated clinical impact of two oncologic drug shortages: fluorouracil (5-FU) and trastuzumab. METHODS: Two Delphi-studies were set up: (i) 5-FU in the treatment of colon cancer and (ii) trastuzumab in the treatment of HER2-positive breast cancer. Questions regarding the alternative treatment, the remaining stock, effects of a shortage on the overall survival (OS) and progression free survival (PFS) and side effects were surveyed. For 5-FU, 20 gastroenterologists specialized in oncology were enrolled and for trastuzumab 18 gynecologists specialized in oncology. RESULTS: When 5-FU and its generic medicines would encounter supply problems, experts agree that capecitabine would be a valid alternative. OS and PFS will remain about the same. The perception by patients of most side effects, such as anemia, infections, diarrhea, etc. will be the same. However, when patients are treated with capecitabine instead of 5-FU, it is more likely that they will suffer from the hand-foot syndrome. When trastuzumab and its expected biosimilars would experience supply problems, no valid alternative is available. Some experts would continue the treatment without trastuzumab, others would switch to lapatinib or trastuzumab emtansine (T-DM1). It is expected that OS and PFS will decrease enormously. Patients will experience some side effects, such as diarrhea, nausea, vomiting etc. more often when lapatinib is used as alternative treatment. No differences are expected regarding cardiac toxicity. CONCLUSIONS: For most drug shortages (e.g. 5-FU), valid alternatives are available. However, manufacturers of alternative treatments might not be prepared for the increased demand.
Nevertheless, for some drugs no alternative is available (e.g. trastuzumab) and for such drugs extra measures should be considered to avoid shortages.

**PHS98: POLYPHARMACY AND INTERACTIONS - WHAT IS A PHARMACIST ROLE?**

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**OBJECTIVES:** Pharmacists have the potential to improve health system interventions, medicine therapy management and polypharmacy. There are many negative consequences associated with polypharmacy. The burden of taking multiple medications can be associated with greater health care costs and an increased clinical risk (adverse drug events, drug interactions, drug duplicity and possibly medication non-adherence). In the healthcare system of Slovakia there is not yet defined the position of a clinical pharmacist (in a community pharmacy) as a control and counseling subject. **METHODS:** Data are from patient visits to pharmacy and outpatient. We examined patients and practitioners requirements between January and March 2017 and expose a "medicines report" requiring medical interventions. The medicines report contains: type, number and clinical evidence of interaction, recommendation regarding the presence of the interaction, recommendation for future (theoretical) therapy, consideration of patient's co-payment and drug duplication. **RESULTS:** Reviewing and monitoring the use of drugs by 29 patients it was identified a presence of interactions. The analysed patients were taking from 5 to 20 medicines (average 9.17; SD=4.61; median=7 drugs/patient). There were identified together 218 interactions C (monitor therapy), D (consider therapy modification) or X (avoid combination) type (average=7.52; SD=9.35; median=7). The most clinical relevant interactions were present in group C (85.32%; average=6.41; SD=7.48; median=4). In the next group D were 14.22% interactions (average=1.07; SD=2.23; median=0) and in the group X was 1 interaction (0.46%; average=0.03; SD=0.19; median=0). **CONCLUSIONS:** The medicines report provides amendments which aimed to improve the treatment of patients and contribute to their quality of life including decreasing patient's co-payment. Need to be developed the medicines report methodology and quantify the clinical and economic value of this intervention. The condition is cooperation between stakeholders, healthcare providers and patients.

**PHS99: UNMET PHARMACEUTICAL NEEDS DURING THE ECONOMIC CRISIS IN GREECE**

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**OBJECTIVES:** The Economic Adjustment Programmes included a series of measures to restrict excess public pharmaceutical spending in Greece. Many of these statutes shifted the burden of pharmaceutical care on health consumers, who were already strained by the adverse economic environment. The aim of this study was to assess unmet pharmaceutical needs during the economic crisis in Greece. **METHODS:** A cross-sectional, observational survey was conducted in the population (aged 15 years and over) of Attika Region with a stratified quota sampling in 2014-2015. A representative sample of 2,851 individuals provided data concerning sociodemographics, health status and healthcare utilisation. Univariate associations were explored with the chi-square test and the uncertainty coefficient for nominal and ordinal independent variables, respectively. **RESULTS:** 10.1% of the sample reported at least one case of unmet pharmaceutical need during the previous year. The main reasons recorded were: wanted to wait and see if problem got better on its own (74.7%), financial inability (51.8%), negligence (48.6%), fear of side effects (34.5%), medicine ineligible for reimbursement (39.6%), and loss of health insurance (32.9%). Overall, 5.4% of the sample forfeited pharmaceutical care due to financial reasons. Lower income and educational level, unemployment, lack of health insurance (public in particular) and poorer health status were univariately associated with higher share of individuals reporting unmet pharmaceutical needs (p<0.05). **CONCLUSIONS:** The double financial burden imposed on health consumers by the economic crisis and the new cost-sharing strategies create economic barriers to pharmaceutical treatment. Special policy concern should be placed on the protection of the most vulnerable socioeconomic groups. Also, the encouragement of prescribing and dispensing generic drugs and improving the knowledge of consumers about their effectiveness, safety and efficacy may facilitate the overall access to adequate and quality pharmaceutical care.

**PHS100: THE EFFECTS OF THE ECONOMIC CRISIS ON HEALTH STATUS AND HEALTH INEQUALITIES IN GREECE**

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**OBJECTIVES:** Several studies have established the adverse effects of the economic crisis on population health in Greece. However, information on health inequalities remains scarce. The aim of this study was to investigate the impact of the economic crisis on health status and health inequalities in Greece. **METHODS:** Data were derived from
the first (2009) and second (2014) wave of the National Health Interview Survey. Health status was measured with the presence of bad self-rated health, longstanding illness, absenteeism due to health problems, and at least some limitations in usual activities. The differences of the distributions between the two waves were examined with the χ2 test. Income and education-related health inequalities were explored with the Erreygers Normalised Concentration index (C), and the overall performance with the Health Achievement index (I). **RESULTS:** The prevalence of self-rated bad health decreased from 8.1% to 6.8% (p<0.001), while it increased for long-term illness (39.7% vs. 49.3%, p<0.001), absenteeism (15.9% vs. 16.3%, p<0.001) and limitations (22.8% vs. 29.8%, p<0.001) during the crisis. Pro-rich inequalities in self-rated bad health, longstanding illness and limitations became pro-poor in 2014 (all p<0.001), while absenteeism was further concentrated in richer individuals (p=0.108). Self-rated bad health and longstanding illness was less concentrated in the less educated categories (p<0.001 and p=0.522, respectively), and absenteeism was more concentrated in more educated individuals in 2014 (p=0.039), while only the distribution changes in limitations favoured the less educated ones (p=0.070). The overall country performance improved for self-rated bad health and absenteeism, and declined for limitations and longstanding illness concerning both income and education health inequalities. **CONCLUSIONS:** In general, population health has deteriorated during the crisis in Greece, while health inequalities have dampened in favour of the lower strata, possibly due to latent health effects of downward socioeconomic mobility.

**PHS101: ASSESSING RACIAL DISPARITY IN PALLIATIVE CARE CONSULTATION AND THE IMPACT OF PALLIATIVE CARE CONSULTATION ON HOSPICE: A MULTI-HOSPITAL ANALYSIS**

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**OBJECTIVES:** The objectives were to (1) evaluate whether palliative care consultation and hospice use differed by race/ethnicity for hospitalized patients at the end of life, and (2) measure the association between palliative care consultation and use of hospice. **METHODS:** The sample included 3,980 patients admitted to three urban hospitals that had an inpatient palliative medicine service and were discharged to hospice or died during their hospital stay between 2012 and 2014. A multilevel binary logistic regression model that accounted for hospital-level clustering of patients was fit to test the association between palliative care consultation use and race/ethnicity controlling for other patient and hospital characteristics. Another multilevel binary logistic regression model was fit to the association between discharge to hospice with race/ethnicity and palliative care consultation, controlling for other patient and hospital characteristics. **RESULTS:** The sample was 45% Caucasian, 39% African American and 17% Hispanic, and 17% (n =682) had a primary diagnosis of cancer. Thirty-four percent received a palliative care consultation during their hospital stay, and 40% were discharged to hospice. In the multilevel models, race/ethnicity was not associated with receipt of a palliative care consultation or discharge to hospice. Patients with a palliative care consultation were 5.0 times as likely to be discharged to hospice as patients without a consultation (p < 0.001). **CONCLUSIONS:** Contrary to previous studies, no evidence of significant racial/ethnic disparities in the use of either palliative care or hospice at the end of life was found. However, there was significant variation across hospitals in the use of both services. Future work should focus on increasing the use of palliative medicine consultations within the hospital for patients at the end of life.

**PHS102: DETECTION AND MANAGEMENT OF DIABETES IN ENGLAND: RESULTS FROM THE HEALTH SURVEY FOR ENGLAND.**

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**OBJECTIVES:** The identification and effective management of the diabetes has the potential to reduce the economic burden associated with the disease. In this paper we examine patterns of undetected and poorly managed disease and relate our findings to current clinical advice in the UK on these issues. **METHODS:** Data were extracted from the 2013 Health Survey for England related to respondent socio-demographic characteristics and HbA1C levels. Descriptive statistics and logistic regression analyses were used to examine relationships between undetected diabetes, poorly controlled diabetes a range of covariates including, ethnicity and BMI. Concentration indices were used to examine the socio-economic gradient in disease detection and control between different ethnic groups. **RESULTS:** Asians were found to be at higher risk of undetected disease than were Whites, with a risk approximately 5 percentage points higher. While sample size did not allow us to examine differences between specific ethnicities with respect to detection, those of Bangladeshi and Pakistani descent exhibited higher risk of poor disease control, the former 28 percentage points higher than Whites, the latter 21 percentage points. These differences were evident in models that controlled for age, gender, BMI and use of GP services. Concentration indices revealed different patterns between ethnic groups. Poor disease control was more common among poor Whites and Indians and among rich Bangladeshis; no significant pattern was evident among
PHS103: UNMET HEALTHCARE NEEDS DUE TO FINANCIAL REASONS IN TIMES OF AUSTERITY

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OBJECTIVES: Financial distress affects numerous aspects of the population's economic behavior, among which is the utilization of health services. Bearing in mind that the expression of healthcare needs does not always lead to actual use of the adequate health services, purpose of the present study is the identification of factors contributing to unmet healthcare needs due to financial reasons in Greece. METHODS: Data were extracted from the "Health and Welfare" survey, a health interview survey that is conducted by the Hellenic National School of Public Health since 2002 and refer to 2016. The sample consisted of 2,003 adults. For the statistical analysis, a multiple logistic regression model was constructed, where the dependent variable was unmet healthcare needs due to financial reasons, while independent variables were: degree of urbanization, age, gender, marital status, self-rated health, educational level, income, occupation, insurance coverage, existence of chronic health problems, frequency of economic problems and degree of economic difficulties. RESULTS: According to the analysis, gender (OR=2.196), educational level, (OR=0.770) chronic health problems (OR=1.407), frequency of economic problems (OR=1.992) and degree of economic difficulties (OR=1.858) were found statistically significant. Specifically, probability to have unmet healthcare needs due to financial reasons was higher for women, respondents suffering from at least one chronic health issue, people with higher frequency of economic problems and people with higher degree of economic difficulties. Finally, higher educational level reduced the probability of unmet health care needs due to financial reasons. CONCLUSIONS: The results of the present analysis indicate the fact that utilization of health services is associated with financial factors, a finding that has even greater importance in the context of the ongoing financial and social crisis in Greece.

PHS104: COMPARISON OF COSTS AND CARE OF LUNG CANCER PATIENT AT THE END-OF-LIFE IN GERMANY DEPENDING ON THE TIME OF SURVIVAL AFTER DIAGNOSIS

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OBJECTIVES: Because of its high mortality the end-of-life phase is of high importance in lung cancer. In this observational study of claims data we aimed to investigate whether the costs and care at the end-of-life differ depending on the length of survival after diagnosis. METHODS: We analyzed 5,320 individuals with incident lung cancer in 2009 who: died until 2013, survived 6 months after diagnosis and were treated with chemotherapy and/or radiotherapy. We defined two groups depending on the median survival time (363 days). Costs for the health insurance for hospitalizations, doctor visits and medication in the last 30 days of life were modeled in generalized linear models with gamma distribution and reported as recycled predictions. Aspects of end-of-life care in the last month were modeled in logistic regression: death in hospital, intensive care treatment, unplanned hospitalization, more than one hospitalization, more than 14 days in the hospital, first palliative care treatment at least 30 days before death and chemotherapy in the last 14 days. All regression models were adjusted for age, sex, comorbidities, metastases at diagnosis and East vs. West Germany. RESULTS: We found significant differences in hospital costs (2,543€ vs. 1,828€, p-value<0.0001) and inpatient medication (82€ vs. 35€, p-value<0.0001) with lower costs in the group above Median survival. We also found significant differences between the two groups (reference above Median) in the site of death (OR=1.26 [1.12; 1.42]), chemotherapy (OR=1.30 [1.09; 1.54]), palliative treatment (OR=0.63 [0.54; 0.72]), intensive care treatment (OR=1.51 [1.33; 1.71]), hospitalizations (OR=3.30 [1.05; 10.43]) and hospital days (OR=1.47; [1.29; 1.67]). CONCLUSIONS: Patients with shorter survival are more likely to be treated with a high intensity at the end-of-life. This leads to the question whether patients should be informed even earlier about possible palliative care to avoid possibly unnecessary intense treatment shortly before death.

PHS105: MEASURING THE INTENSITY OF CARE COORDINATION FOR BLOOD CANCER PATIENTS IN FRANCE.

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OBJECTIVES: The management of blood cancers requires a patient-centered, coordinated, care program. Care coordination is the organization of patient care to deliver appropriate health care services. Understanding and measuring care coordination is of utmost importance to improve patient care. Our aim was to measure the intensity of care coordination in blood cancer patients in France. METHODS: A retrospective, monocenter study was conducted in Montpellier University Hospital, France. All adult patients with blood cancer, enrolled in the intravenous chemotherapy care coordination program in 2013-2015 and followed-up during at least 3 months were included. Data were retrieved from the electronic medical records. Coordination intensity was defined as the sum of the number of contacts and coordination actions. We considered face-to-face and phone contacts between the coordination nurses and the other stakeholders including the patient, the nurses, the general practitioner, the pharmacist, and the laboratory. Coordination actions included treatment follow-up, blood tests follow-up and other actions. The probability of having an intense coordination intensity was modeled using a logistic regression. RESULTS: We included 267 patients aged 57 (SD: 19) on average. The median follow-up was 8.4 months. The average coordination intensity was equal to 11.5 (SD: 4.1) per patient per month, among which 2.8 (SD: 1.3) contacts and 8.7 (SD: 3) actions. The coordination intensity was higher for patients with chronic lymphocytic leukemia (p<0.05). In the multivariate analysis, it was not associated with any of the following factors: age, gender, blood cancer type, driving time to the hospital, and access to the general practitioner. CONCLUSIONS: Although the care coordination intensity varied widely between blood cancer patients in France, it was not associated with their demographic and clinical characteristics.

PHS106: ASSESSING THE UTILIZATION OF DIABETIC NON-SMALL CELL LUNG CANCER PATIENTS COMPARED TO NON-SMALL CELL LUNG CANCER PATIENTS

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OBJECTIVES: The impact of type 2 diabetes (T2D) and non-small cell lung cancer (NSCLC) are mutually substantial from a public health perspective. A better understanding of the relationship between T2D and NSCLC would have significant implications for prevention and management of these diseases. The objective of this study is to assess the utilization of diabetic NSCLC patients compared to NSCLC patients. METHODS: We conducted a cohort study design utilizing Medicare claims from the SEER - Medicare linked database (2007 - 2014). Zero-inflated negative binomial models (ZINB) were used to estimate the average predicted number of visits from the index date in the T2D NSCLC cohort compared to NSCLC patients, stratified by cancer stage. The ZINB adjusted for cancer stage, geographical region, gender, age, race and comorbidities. RESULTS: Of 17,176 NSCLC patients, 5,096 patients had T2D in the pre-period. The average predicted number of visits per patient per day was higher for the NSCLC T2D patients compared to their non-diabetic peers. Non-Diabetic patients with Stage 1 NSCLC had approximately 0.37 predicted healthcare visits per day, Stage 2 had 0.47, Stage 3 had 0.62 and Stage 4 had 0.76. T2D NSCLC patients with Stage 1 NSCLC had 0.39 predicted healthcare visits per day, Stage 2 had 0.50, Stage 3 had 0.66 and Stage 4 had 0.80. CONCLUSIONS: The results of this study indicate that NSCLC patients with T2D have greater health care utilization, compared to non-diabetic NSCLC patients. Clinical strategies to better manage NSCLC T2D patients could enhance metabolic health, reduce healthcare utilization and therefore decrease costs.

PHS107: RESOURCE UTILIZATION AND DISAGGREGATED COST ANALYSIS FOR INITIAL TREATMENT OF MELANOMA

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OBJECTIVES: The incidence of melanoma is rising and accompanying treatments could form a substantial health care burden. Additionally, emerging new treatments and evolving indications for therapy lend uncertainty to the rate of changing costs. We present a contemporary microcosting analysis of initial melanoma therapy for a single-payer health system over twelve years. METHODS: Patients with invasive cutaneous melanoma were identified retrospectively from the Ontario Cancer Registry (2003–2014) and deterministically linked with administrative databases through three separate algorithms. We identified multimodal treatment received within a year of diagnosis and associated resource utilization and costs related to various aspects of the healthcare continuum. Costs were ascribed to surgery, radiation, systemic therapy, physician billings, inpatient, and outpatient hospital sources. Costs are undiscounted, unadjusted, and from the perspective of the Canadian single-payer health system. RESULTS: From 2003-2014, 28,708 patients with invasive melanoma were identified. Median age at diagnosis was 63, 46% male, and melanoma was diagnosed primarily on the extremities (44%). The most common
modality for treatment was surgery (48-62% of patients diagnosed per year) with an associated mean per-patient cost of $1849. Annual rates of systemic therapy use have remained stable over time (6-9% of patients diagnosed per year) but mean cost per-patient has increased substantially starting in 2010, reflecting use of new medications and radiation. Corresponding annual mean per-patient costs increased to maximum of $24,348 CAD for systemic therapy overall, up to $72,652 CAD for ipilimumab, and up to $10,572 CAD for radiation. The total annual burden of cost was a maximum of $46,480,586 CAD for 3082 patients diagnosed in 2014. **CONCLUSIONS:** Patterns of resource utilization and cost for treatment of melanoma are changing over time, particularly for systemic therapy. Recognition of these patterns and forecasting of future changes are critical for budgetary and policy planning for sustainable melanoma care.

**PHS108: COST OF HOSPITALIZATIONS FOR NONTUBERCULOUS MYCOBACTERIAL PULMONARY DISEASE IN FRANCE IN 2014: A PMSI DATABASE ANALYSIS**

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**OBJECTIVES:** Nontuberculous mycobacterial pulmonary disease (NTMPD) is a debilitating rare disease affecting a growing number of individuals worldwide. We evaluated hospitalizations related to NTMPD in France and assessed patient characteristics and the inpatient costs. **METHODS:** The study was performed using the 2014 French National Database on hospital care (PMSI) which covers all hospital stays in the French population. NTMPD were identified using ICD10 code A310 (Pulmonary mycobacterial infection). Patients with cystic fibrosis (EB4) were excluded. Directs costs were estimated if NTMPD was the primary diagnosis of the stays using the French National Costs study (2013 values). **RESULTS:** Overall, in 2014, 1193 stays (main diagnosis n=577) for NTMPD were identified in the database corresponding to 802 patients. 72.57% of patients were hospitalized once in the year for NTMPD (mean of 1.5 stays per patient), 50.0% were male and aged 63.3 years on average (SD 18.4). Comorbidities associated with NTMPD were mainly: infectious pneumonia (36%), COPD/asthma (29%), bronchiectasis (23%), tobacco (13%), tuberculosis (13%) and AIDS (9%). 84.5% of patients (n=1,008) had at least one associated comorbidity. The mean length of stay was 10.9 (SD 19.6) days for stays with at least one associated comorbidity vs 6.9 days (SD 8.7) (p=0.0047) without comorbidities. The mean cumulated duration of hospitalization per patient per year was 12.5 days when associated with comorbidities vs 7.1 days without comorbidities (p<0.0001) The percentage of deaths during hospitalization was 3.8% for stays with at least one associated comorbidity vs 1.6% without comorbidities (p=0.0971). The mean cost was 4,896€ (SD 4,323) for stays with at least one associated comorbidity vs 3,335€ (SD 2,840) without comorbidities (p<0.0001). **CONCLUSIONS:** The majority of hospitalized NTMPD patients had at least one associated comorbidity. NTMPD patients had long hospital stays and the presence of associated comorbidities increased the length of stay, costs and death rate.

**PHS109: DIALYSIS STATUS IN PATIENTS WITH CHRONIC KIDNEY DISEASE IN KOREA: BASED ON 12-YEARS NATIONAL SAMPEL COHORT DATABASE**

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**OBJECTIVES:** To determine overall dialysis status, healthcare utilization, and subject demographics, clinical and financial aspect of chronic kidney disease (CKD) patients with either peritoneal dialysis (PD) or hemodialysis (HD) in Korea. **METHODS:** In this retrospective, observational study, we used the Korean National Health Insurance Service-Sample Cohort Database from 2002 to 2013 (n=1,025,340). Subjects with PD or HD due to CKD (International Classification of Diseases 10th Revision code N18 or N19) were enrolled in this study. Data analysis was performed by using SAS, version 9.4. **SAS. RESULTS:** Total number of patients with dialysis was 1,481 (HD 1,311 and PD 170) in 2013. HD was the main dialysis modality (89%) rather than PD. Expected number of dialysis patients which was standardized by year 2013 population, were 143.8 and 18.6 patients per 100,000 persons for HD and PD, respectively, in 2013. These numbers were about 4-fold and 2.5-fold increases comparing to 2002. However, Percentages of patients aged less than 60 years was higher in PD than HD (67% vs. 44%), and employee subscribers for national health insurance was higher in PD than HD (55% vs. 47%). Patients of medical aid not national health insurance subscribers were highest in patients on dialysis (22%) among all patients with CKD. Annual total medical costs (median) per dialysis patient were US$23,390 for HD and US$18,945 PD in 2013 (US$1=KRW1,100). PD were treated mainly in tertiary hospitals (98%), whereas HD were both in primary clinics (51%) and tertiary hospitals (37%). Comorbid hypertension and diabetes in dialysis patients were 73% and 48%, respectively. **CONCLUSIONS:** Rapid increase of dialysis in CKD patients in recent years and higher prevalence of HD shown in this study assumed to significantly impact on the national health insurance budget continuously in the
PHS110: SOCIAL AND FINANCIAL IMPACT OF DRAVET SYNDROME

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OBJECTIVES: The objective was to develop an understanding of healthcare resource utilisation associated with the current management of Dravet syndrome (DS) in a large pan-European survey cohort of patients and their caregivers (DISCUSS) conducted in 2016. METHODS: Quality of life (family, career, leisure, childcare), disease severity (diagnosis journey, epilepsy management, comorbidities) and support (therapy, social and financial support, out of pocket expenses, healthcare system use) data were summarised statistically by age groups. Healthcare costs were based on participant only information and literature reported health service costs, personal costs on input data from participants only. RESULTS: The survey cohort consists of 584 caregivers of paediatric (93%) and adult (17%) patients with DS (<1 year – 48 years old, mean age 10 years, median 9 years), of which over 90% reside in Europe. The mean EQSD-5L index value for patients two years or older (completed in proxy by the caregiver) was very low (0.42 ±0.29, range -0.35 – 1). Most (80%) caregivers reported that caring for a child with DS had influenced their career choices. Nearly a third (30%) were unemployed. Of those in work (65%), 28% percent had missed over three working days in the past four weeks to care for the needs of their son or daughter (e.g. emergency care, routine visit to doctor). Half of patients required at least one emergency admission and 46% at least one ambulance call in the past 12 months. Although emergencies decreased with age, these remained notably high in adult patients, of which 28% reported at least one emergency admission in the last 12 months. Annual healthcare utilization costs (not including drugs) are on average $1467 per patient in the EU5 countries. CONCLUSIONS: Families caring for a member with DS must manage multiple lifelong impairments in addition to refractory epilepsy symptoms alongside considerable social and financial impacts.

PHS111: HOSPITALISATIONS AMONG A COHORT OF PATIENTS WITH HEART FAILURE VERSUS AN AGE- AND SEX-MATCHED COHORT WITHOUT HEART FAILURE IN ENGLAND: A COMPARATIVE STUDY USING CPRD DATA

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OBJECTIVES: The burden of heart failure (HF) on healthcare systems relative to the general population is not well characterised. We compared all-cause hospitalisation rates in patients with HF versus age- and sex-matched controls without HF. METHODS: This retrospective, comparative study utilised primary care electronic medical records from the Clinical Practice Research Datalink (CPRD) database, linked to secondary care Hospital Episode Statistics (HES) data. Adults with a first diagnosis of HF recorded in CPRD between 01/01/2005 and 31/12/2014 with HES linkage were age- and sex-matched in a 1:3 ratio to controls without HF with the same linkage in the same timeframe. Presence of HF and index dates were defined using Read codes (CPRD) or ICD-10 codes (HES). Patients were followed from index date to end of data collection, death or transfer out of practice, whichever came first. Age-, sex- and comorbidity-adjusted hospitalisation rate ratios (RRs) and hazard ratios (HRs) were calculated. RESULTS: Data from 28,335 patients with HF and 85,005 controls were examined (mean age 75.4 years; 45.4% women). At baseline, patients with HF had higher cardiovascular disease (CVD)-related and metabolic medication use (83.7% vs 50.2%) and a higher Charlson Comorbidity Index score (2.03 vs 1.30) than controls. CVD-related comorbidities were more common among patients with HF than controls, whereas malignancies, liver and rheumatological diseases were similarly prevalent in both groups. All-cause hospitalisation rate (RR, 1.90; 95% CI, 1.88–1.91; p<0.001) and risk of hospitalisation (HR, 1.81; 95% CI, 1.78–1.85; p<0.001) were significantly higher in individuals with HF than controls. A greater proportion of individuals with HF than controls had died or were lost to follow-up after 5 years (34.6% vs 20.4%). CONCLUSIONS: Increased hospitalisation rates and morbidity in patients with HF versus an age- and sex-matched population without HF demonstrate the burden of HF on the healthcare system in England.

PHS112: AN ECONOMIC EVALUATION OF ‘DELIVERING ASSISTED LIVING LIFESTYLES AT SCALE’ (DALLAS)

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OBJECTIVES: Running 2012-2015, ‘delivering assisted living lifestyles at scale’ (dallas) was a large-scale
intervention examining how digital health can be used for preventative care, to promote well-being, and improve people lifestyles. Using contingent valuation (CV), this study investigated general UK population value for mobile health (mHealth) lifestyle apps seeking to improve an individual’s sense of the 6Cs (connectedness, control, choice, collaboration, community and contribution) for future inclusion in the new NHS digital agenda. Specifically, can these be delivered at scale and whether they suit daily life. METHODS: A UK-wide survey was used to ask participants to report their absolute and marginal willingness-to-pay (WTP) or willingness-to-accept (WTA) the gain or loss of a new hypothetical mHealth app, ‘healthy connections’ with the aim of eliciting their direct preferences. This is regarded as an indicator and measure of the demand for the good. This provides a direct valuation for the app which could be used within a cost benefit analysis (CBA). RESULTS: In 2015, both a UK-representative sample (n=1697) and a Dallas-like sample (representative of existing, older and, in some cases, more deprived communities involved in the wider Dallas intervention) (n=302) were surveyed. This CV study revealed a positive valuation of the app across both cohorts. Absolute WTP of £196 per annum for the general UK population cohort, £162 for the Dallas-like sample and for marginal WTP, a value of £160 the UK population sample and £151 stated by the Dallas-like cohort. CONCLUSIONS: This paper highlights that there is potential value in mhealth solutions and also demonstrates that in order to reach this potential, their delivery must centre on the individual’s needs. Whilst certain traits may make some more accepting or less receptive, continual advancements and future success will be down to the adaptability of the technology to the individual and not the other way round.

**PHS113: EVIDENCE SYNTHESSES ON THE ECONOMIC VALUE OF HOSPITAL ANTIMICROBIAL STEWARDSHIP PROGRAMS [ASPS] – A CALL TO ACTION**

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OBJECTIVES: ASPs are key components of interventions addressing antimicrobial resistance (AMR). Nonetheless, a 2014 US National Healthcare Safety Network (NHSN) survey reported that only 55% of acute care hospitals had the appropriate infrastructure needed to implement a successful ASP. The case for establishing these programs requires evidence of clinical and economic value. The cost of establishing and running these programs against economic benefits are key considerations for decision makers in assessing overall value. Our objective is to describe the economic impact of ASPs based on recent evidence syntheses of primary studies. METHODS: PubMed and EMBASE searches in English were conducted to identify key review papers and meta-analyses (2011-2017) that summarized economic outcomes of hospital ASPs from a global perspective to characterize findings by country/region, healthcare systems, different perspectives, hospital type, hospital size, and ASP interventions. Only articles that measured ASP implementation and post-implementation costs were included. RESULTS: Our search identified 16 publications that synthesized the above economic costs, outcomes and impact on antimicrobial use. Although considerable heterogeneity was observed, the programs appeared to demonstrate beneficial effects on different cost perspectives, appropriate antimicrobial use and overall reduced use [defined daily doses]. The impact on length of stay (LOS) and other economic outcomes, mortality and antimicrobial resistance rate was either neutral or positive. For example, economic benefits included a 34% pooled decrease in antimicrobial costs and a 9% pooled decrease in LOS. Of the cost-savings generated within the first year, approximately 85% offset the startup costs. In subsequent years, the ASP generated cost-savings four-times the yearly maintenance costs. CONCLUSIONS: Our limited results demonstrate that costs associated with implementation of ASPs are offset by subsequent cost-savings. However, our results emphasize the need for more studies evaluating these programs to develop tailored business cases for ASPs across a range of healthcare systems and contexts.

**PHS114: USE OF HEALTHCARE RESOURCES AND ASSOCIATED COSTS OF IDIOPATHIC PULMONARY FIBROSIS IN SPAIN: A REAL-LIFE STUDY**

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OBJECTIVES: To determine the use of healthcare resources and associated costs in patients with idiopathic pulmonary fibrosis (IPF) according to their forced vital capacity (FVC) and the administered treatment in the daily clinical practice. METHODS: A longitudinal (retrospective), multicentre observational study was conducted using electronic medical records from different primary care centers (31) and specialized hospitals (4) in Catalonia. Data from patients diagnosed with IPF (incident cases) who received medical care during 2013-2015 and met certain inclusion/exclusion criteria were included. Patient follow-up was from the time of diagnosis to completing one year (2013-2016). Study groups: a) FVC=50-80% and b) FVC>80%. Main study variables: comorbidities, exacerbations,
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The expenditure healthcare curve of patients with neoplasms to a similar study performed at the same institution, oncology patients, and outpatient expenditures, from the first group was 64%/36%, and in the second, 94%/6%.

26%, 30% and 30%, respectively, in comparative group, was 5%, 5%, 8%, 21% and 61% (P<0.05). Hospitalization expenses.

Proportion of total expenses with neoplasms and other pathologies; inpatient and outpatient treatment is considered one of the greatest challenges of public and private health worldwide. Multiple linear regression model was included in the statistical analysis, p<0.05. RESULTS: 108 patients were recruited. 64.8% of patients had a FVC 50-80% (N=70) and 35.2% a FVC<80% (N=38). COPD/emphysema (67.6%), hypertension (61.1%) and dyslipidaemia (57.4%) were the most frequent comorbid conditions. After a one-year follow-up, 27.8% of patients had an exacerbation and 21.3% died (1-year survival rate: 78.7%). Patients with FVC 50-80% had a higher number of exacerbations (0.5 vs. 0.2; p=0.043), mortality (30.0% vs. 5.3%; p=0.003) and costs (average/unit cost: €27,965 vs. €11,846; p<0.001). Specific treatments administered (FVC 50-80%): N-acetylcysteine (N=21, 30.0%), pirfenidone (N=31, 44.3%), nintedanib (N=10, 14.3%) and immunosuppressants/sildenafil (N=8, 11.4%). 61.9% of NAC patients had exacerbations and 38.1% died, none of the pirfenidone patients had exacerbations or died, 30% had exacerbations and 20% died with nintedanib, 62.5% and 100% of those treated with immunosuppressants/sildenafil (worse prognosis) had exacerbations and died, respectively. Associated healthcare costs: €6,206, €24,734, €27,657, and €27,481, respectively, p<0.001. CONCLUSIONS: Use of healthcare resources and associated costs of IPF were mainly related to age, exacerbations and FVC. Pirfenidone could be associated with lower exacerbations and higher overall survival.

PHS115: HEALTH CARE CONSUMPTION AND HRQOL IN SEVERE ASTHMA IN SWEDEN

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OBJECTIVES: Severe asthma is a disabling and costly disease, often poorly controlled despite high-dosage controller medications. The objectives of this analysis were to estimate health care consumption and to investigate health-related quality of life (HRQOL) in a severe asthma cohort, derived from a large-scale population survey in northern Sweden. METHODS: Severe asthma was defined by US SARP criteria; high-dosage inhaled corticosteroids (ICS) by GINA 2014 criteria. In total, 32 patients with severe asthma were invited to a clinical examination and structured interview. Retrospective data of all asthma-related direct and indirect resource consumption during the last year were collected following a defined protocol. HRQOL was assessed by four patient-reported outcome measures: two general measures (SF-36; EQ-5D) and two disease-specific measures (SGRQ; ACT). The cohort was divided into two groups —patients with (OCS) or without maintenance oral corticosteroid (non-OCS) treatment. RESULTS: Health care resource utilization was greater in the OCS-group compared with the non-OCS group. Mean annual number of visits to specialist care was 2.0 in the OCS group vs. 0.5 visits in the non-OCS group. Four patients in the OCS group had early retirement vs. none in the non-OCS group. HRQOL was worse in the OCS group, both when measured with general and disease-specific instruments. The Mental and Physical Component Summary scores of the SF-36 in the OCS vs. non-OCS group were 50.1 vs. 40.7 and 55.8 vs. 44.4, respectively. Similarly, the total SGRQ scores indicated worse HRQOL for the OCS-group compared with the non-OCS group (37.0 vs. 27.0). CONCLUSIONS: In this severe asthma population, patients treated with maintenance OCS consumed more health care resources, were more frequently early retired, and had worse HRQOL compared with those not receiving maintenance OCS. The results indicate a need for improved treatment for patients with severe asthma on maintenance OCS. Sponsor: AstraZeneca

PHS116: ANALYSIS OF THE BEHAVIOR OF THE EXPENDITURE CURVE IN ONCOLOGY AND OTHER CAUSES OF DEATH IN THE LAST 5 YEARS OF LIFE – BRAZIL REAL-WORLD HEALTH CARE DATA

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The combination of the increase in the number of new cases of neoplasms as well as the high cost related to its treatment is considered one of the greatest challenges of public and private health worldwide. OBJECTIVES: To compare healthcare expenditure distribution in the last 5 years of life of oncology and patients with other pathologies. METHODS: Design: Retrospective analysis of the healthcare spending during the last 5 years of life. Population: 1,030 healthcare beneficiaries who died in 2015. Source data: Healthcare expenditures electronic records. Variables: a) Categories: neoplasms of any site in the year of death (n = 289, 28.0%) and individuals without diagnosis of cancer (n = 741, 72.0%); B) Expenses: grouped in 5 of 12 months’s period, before the month of death; C) Beneficiaries: age and sex. Simple descriptive statistics of numbers, percentages, averages and standard deviation. Comparative analysis between groups (t-test and Wilcoxon) using SS Statistics©2017 (p <0.05; 95% CI). Proportion of total expenses with neoplasms and other pathologies, inpatient and outpatient expenses. RESULTS: The distribution of expenditures with neoplasms during periods before death was 4%, 11%, 26%, 30% and 30%, respectively, in comparative group, was 5%, 5%, 8%, 21% and 61% (P<0.05). Hospitalization and outpatient expenditures, from the first group was 64%-36%, and in the second, 94%-6%. CONCLUSIONS: In oncology patients, we observed a different distribution of expenses in the last years of life. Comparing results from the expenditure healthcare curve of patients with neoplasms to a similar study performed at the same institution, presented at the ISPOR 19th Annual European Congress, we observe another standard that the current one,
suggesting that oral chemotherapy access and increased patient's survival may have contributed to justify the results. More discussions and studies are needed to evaluate the impact of this modification on the health system.

**PHS117: HEALTH CARE UTILIZATION ASSOCIATED WITH POLYPHARMACY IN PATIENTS WITH MULTIPLE SCLEROSIS**

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**OBJECTIVES:** Patients with multiple sclerosis (MS) are prone to polypharmacy because they often require multi-drug regimens to manage symptoms and slow disease progression. Polypharmacy is associated with poor adherence and greater risk of adverse drug events, potentially resulting in higher health care utilization. This study assessed whether polypharmacy is associated with increased health care utilization among patients with MS. **METHODS:** Pooled data from 2002–2014 in the Medical Expenditure Panel Survey (MEPS), a nationally representative survey of the U.S. households, was used to obtain a sufficient sample size. MS patients aged at least 18 years old were included and classified into a polypharmacy group if they concurrently acquired at least 5 prescription drugs, a commonly used definition in the literature. Health care utilization was determined as the total number of all cause-outpatient visits, emergency department visits, and hospitalizations. The negative binomial generalized linear regression model with log-link was employed to estimate the relationship between polypharmacy and health care utilization accounting for explanatory variables as identified by Andersen’s Behavioral Model of health services use. **RESULTS:** Of the 297 patients with MS, 14% (n=41) had polypharmacy reflecting 453,234 MS individuals during 2002–2014. The average health care utilization of patients with polypharmacy was significantly higher than those without polypharmacy (5.0 vs. 2.3, p=0.0001). Compared to MS patients without polypharmacy, MS patients with polypharmacy had 2.4 times higher health care utilization after adjusting for the explanatory variables that included demographics, socioeconomics, health insurance coverage, and common co-occurring disorders (95% CI: 1.3 to 4.5, p=0.0049). **CONCLUSIONS:** Polypharmacy among patients with MS is positively associated with greater health care utilization. The finding provides evidence that multiple prescription medications may increase utilization of outpatient, emergency department and inpatient hospital services and poses a challenge in addressing polypharmacy to optimize drug therapy management among patients with MS.

**PHS118: BUDGET IMPACT OF COMPUTER-BASED PSYCHOTHERAPY IN GERMANY**

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**OBJECTIVES:** Depressive disorders show a high prevalence and lead to substantial direct and indirect costs. In many countries the increasing demand for psychiatric and psychotherapeutic care often is not sufficiently supplied with the consequence of waiting lists and progression of the disease. Computer-based psychotherapy (CPT) of depressive disorders is discussed as a possible solution to close this gap. Scope of this analysis was to estimate the budget impact of a CPT scheme in Germany. **METHODS:** The budget impact of CPT was estimated based on data derived from clinical studies and administrative sources for costs for the German healthcare system in 2015. For the base case scenario a CPT population of 9.2% of all patients with depressive disorder was assumed. The cost of CPT was calculated with €250 per patient. Several sensitivity analyses were performed e.g. for the type and the price of CPT and the frequency of inpatient care. **RESULTS:** The base case analysis resulted in slightly reduced annual expected costs of €3,876 including CPT compared to €3,884 for standard ambulatory and inpatient care alone. The additional costs of CPT are overcompensated by the reduced costs for inpatient and outpatient care. Sensitivity analyses showed that the model is robust to variations in CPT price and the proportion of patients treated with CPT whereas it was sensitive to the frequency of inpatient treatment and the cost of inpatient and outpatient treatment. **CONCLUSIONS:** Regardless of the proportion of patients treated with CPT and also the different costs of the programs, CPT itself appears to have relatively small impact on the overall costs of depressed patients. The highest potential of cost savings were reached within a stepped-care approach including CPT because this regime leads to a substantial reduction of high-cost inpatient treatments.

**PHS119: HEALTH SERVICE IMPLICATIONS OF THE IMPLEMENTATION OF AN EARLY DISCHARGE STRATEGY FOR PATIENTS ADMITTED IN INFECTIOUS DISEASES DEPARTMENTS IN SOUTHERN EUROPE**

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**OBJECTIVES:** Among the strategies to ensure the sustainability of National Health Services, we investigated the
organizational implications of an early discharge strategy vs standard hospitalization for patients admitted to infectious diseases departments in Italy and Spain. **METHODS:** Based on experts' opinion and literature review, Skin and Soft Tissues Infections and Osteomyelitis were identified as appropriate pathologies to consider for an early discharge strategy. A further scenario considered also DRGs related to endocarditis. The total number of hospitalizations of the above mentioned pathologies was performed through the analysis of online databases of National Ministries of Health (2015) based on correspondent DRGs. We calculated the likely differential number of annual inpatient days in two scenarios: standard hospitalization vs early discharge. Considering the national annual bed occupancy rate in the two national contexts, we calculated the possible reduction in terms of number of beds at a national level and, based on literature review, the likely reduction of hospital acquired infections considering hospital's length of stay. **RESULTS:** The estimated annual number of cases eligible for early discharge is 5,508 in Italy and 5,685 in Spain. The possible reduction of number of beds accredited with National Health Services would be between -138 and -58 in Italy; and -85 and -27 in Spain. The likely yearly hospital acquired infections avoided due to the early discharge strategy are between -263 and -111 in Italy; and -159 and -51 in Spain. **CONCLUSIONS:** An early discharge strategy for patients admitted in Infectious Diseases departments in Italy and Spain is expected to allow an improvement of the efficiency of National Health Services, without affecting the clinical effectiveness, resulting in additional benefits due to a reduction in the incidence of hospital acquired infections.

**PHS120: SPATIAL DYNAMICS OF PSYCHIATRIC DISEASE HOSPITALIZED PATIENTS - REHOSPITALIZATION SIMULATION FOCUSING ON DIABETES COMORBIDITY AND REGIONAL HEALTH SERVICES IN THREE EUROPEAN REGIONS OVER THE NEXT DECADES**

**OBJECTIVES:** The development of the burden of psychiatric diseases is essential for planning purposes of health policy makers. In the CEPHOS-LINK (FP7-project: No-603264), several strategies were incorporated to analyse psychiatric re-hospitalisations. Three research questions were defined: 1) Change of re-hospitalisations in the future, 2) Theoretical improvement of structure of care on a NUTS3-level, 3) Possible impact of rising diabetes prevalence. **METHODS:** We used an agent-based approach from the Generic Population Concept (GEPOC), developed in DEXHELPP (FGF, No-843550). The implemented Python framework was extended by several modules for each question. The modules for the other two questions are exchangeable or used together. The parameterization for AT/SL/Veneto was calibrated by pooled claims. **RESULTS:** The results represents an average values out of ten simulation runs to minimize stochastic effects. Pathways of simulated patients are available on microscopic level, meaning that they can be followed over time. For the macroscopic evaluations events of the patients are aggregated up to year 2039 for different patient characteristics. The outcomes show an increase in both index- and re-hospitalisation rates, especially for females and patients with psychotic diagnoses. Looking at NUTS3 regions with highest average driving time to hospitals a change to optimised care can lower the re-hospitalisation rate by nearly 39% in AT, about 20% in SL and in Veneto with actual lowest distance to service only 7.5%. In case of diabetes it has to be noticed that the demographic changes are effecting especially prognosis for AT. **CONCLUSIONS:** All three scenarios show that psychiatric hospitalizations are rising, especially in Austria and Veneto region. The most drastic changes can be assumed to come in the timeframe of the next 10 years for non-psychotic diagnosis. Changing diabetes prevalence also has an impact on psychiatric patients' re-hospitalisation and shows that comorbidities should not be neglected when analysing future development of re-hospitalisation rates.

**PHS121: QUANTIFYING STANDARD OF CARE (SOC) HOSPITAL-RELATED RESOURCE UTILISATION FOR METASTATIC UVEAL MELANOMA (MUM) PATIENTS IN NHS ENGLAND (NHSE) USING THE HOSPITAL EPISODES STATISTICS (HES) DATASET**


**OBJECTIVES:** UM is an ultra-rare disease, with an inherently variable treatment pathway. Despite radical ocular intervention(s), ~50% of patients experience metastatic recurrence. With limited therapeutic options available, 1-year survival for mUM is 10-15%. Consequently, there is sparse data on the disease burden of mUM to NHSE. This study assessed a cohort of mUM patients within HES to evaluate their patterns of care and medical resource use. **METHODS:** A cohort of UM (ICD-10 codes C693 or C694) patients that developed a subsequent cancer code (indicating metastasis), were identified within HES (observational period: Apr2012-Jun2016, follow-up until Jan2017). Clinical diagnoses, medical procedures and tariff costs for all NHSE inpatient, day-case and A&E admissions were analysed. To specifically assess mUM resource utilisation, admissions prior to metastasis were omitted. This analysis
excluded costs not captured within HES (e.g. High Cost Drugs, Specialised Services, non-hospital palliative care). RESULTS: In our cohort (n=450), 80% of inpatient admissions for primary UM occurred at the three specialist supra-regional ocular oncolgical centres (London, Liverpool and Sheffield). "Ophthalmology" was the most frequent (77%) speciality treating patients; and 63% of patients were treated ≥40 km from home. For metastatic patients, 31% of inpatient admissions were at the three supra-regional centres, the rest at local or regional hospitals. "Medical oncology" was the most frequent (40%) treatment speciality. 28% of patients were treated ≥40 km from home; and chemo-/immunotherapy was the most frequent medical procedure delivered (112 patients, 25%). Over the observed period, the cost to NHSE for mUM inpatient admissions was £2.5 million (mean: £6,084 per patient; range: £224-58,854). The cohort attended 3,618 outpatient appointments and had 669 A&E visits. CONCLUSIONS: mUM was identified in >80% of our UM cohort whilst under surveillance at specialist centres. Large variations in mUM medical resource utilisation were observed, reflecting the heterogeneity in: disease progression, local-regional care pathways and treatment effectiveness.

PHS122: DESCRIPTION OF THE CHINESE HEALTH CARE SYSTEM AFTER THE HEALTH CARE REFORM

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OBJECTIVES: Assessing the characteristics of Chinese healthcare reform and introducing health financing structures. METHODS: A quantitative descriptive study was performed. Our study was based on document and database analysis. The indicators were obtained from WHO (World Health Organization) databases and Chinese Statistical Yearbook 2003 and 2013. RESULTS: The health insurance coverage of the Chinese population is 96%, 62% of the hospitals are state-run, 38% are private, from which 88% of the hospital beds are public and 12% are private. 51% of local institutions are public and 49% are private. The four basic pillars of Chinese healthcare are state budget tax revenue, social security, direct pay and private insurance. The new, most important forms of insurance that are currently in use are: the New Cooperative Rural Medical Scheme (NCRMS), Urban Residence Basic Medical Insurance (URBMI), Urban Employee Basic Medical Insurance (UEBMI) and the Medical Assistant Funds (MAF). In 2009, 94% of rural areas had the population NCRMS health insurance. The public health insurance coverage of the population has been increasing ever since 2010 from outpatient care. However, the insured are obligated to pay co-payment. 50% of the patient's care costs, approximately 60-70% of outpatient care costs should be reimbursed by the insured. The use of healthcare services between 2003 and 2013 has changed considerably. The un-visit rate decreased by nearly half in rural (22%) and urban (32,9%) areas. The rate of outpatient's visit decreased in rural (12.8%) areas and increased in cities (13.3 %). Un-hospitalization rate in rural areas went also downward among the urban population. The rate of hospitalization increased considerably among both rural and urban residents. CONCLUSIONS: The eleven-year health reform set up by China is to balance the differences between population and market needs. It is important to evaluate the reform's success in the future.

PHS123: SCHOOL COMMUNITIES’ PARTICIPATION IN HEALTH PROMOTION PROCESS IN LITHUANIA

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OBJECTIVES: The school is the best place for children health promotion process. Information about school community participation in health promotion process is a key when planning measures to improve the situation. The shortage of this information leads to the aim of this study – to determine the participation of school community members in children’s health promotion. METHODS: Cross-sectional study was performed in 2015. A total of 1209 schoolchildren, 1150 parents and 684 teachers from 28 Lithuanian schools were surveyed by anonymous questionnaire with response rate 68.4%. Logistic regression models with 95% of confidence intervals were used for the data analysis. RESULTS: 34.4% (95% CI: 31.6; 36.9) of students, 69.0% (95% CI: 65.4; 72.4) of teachers and 30.4% (95% CI: 27.8; 33.2) of parents participated in health promotion process. Chances of participation in health promotion increased if children attended health promoting school (HPS) (OR=3.01 (95% CI: 2.32; 3.91)), lived in the countryside (OR=1.40 (95% CI: 1.26; 2.13)), and if parents lived in the countryside (OR=2.01 (95% CI: 1.53; 2.63)) and chose a HPS (OR=1.47 (95% CI: 1.13; 1.92)). Teachers’ participation was significantly related to work at HPS 4.06 (95% CI: 2.84; 5.81)) and teaching subject such as art, music or physical education (OR=2.21 (95% CI: 1.44; 3.38)). The majority of students and their parents (70.6% (95% CI: 67.9; 73.1) and 78.3% (95% CI: 75.6; 80.5), respectively) wanted to know more about health promotion. CONCLUSIONS: Only one third of students and their parents, and the majority of teachers participated in health promotion process. School community members from HPS had higher chances of participation in health promotion activities.

PHS125: INVESTING IN SKILLED SPECIALISTS TO GROW HOSPITAL INFRASTRUCTURE AND IMPROVE QUALITY
OBJECTIVES: Hospitals cut costs by reducing staff not providing bedside care. Yet, Weinstein and Skinner (2010) claim having insufficient infrastructure, such as skilled specialists not at bedside, such as board-certified nurses and therapists can evaluate and redesign health systems to address needs of complex patients, and paradoxically reduce costs. Our objective was to validate this theory by evaluating the impact of increased skilled specialists on patient outcomes by supporting infrastructure, using an example of correlation between nurses and a hospital quality indicator. METHODS: We analyzed a retrospective cohort of patients diagnosed with hospital-acquired pressure injuries defined by AHRQ PSI03 (stage 3, 4 and unstageable pressure injuries not present-on-admission). Ratios of board-certified nurses per 1,000 hospital beds were compared to pressure injury rates in 55 U.S. academic hospitals between 2007-2012 using UHC data. Productivity functions of labor efficiency versus pressure injury rate were plotted across hospital quintiles and fitted to smoothed curves. Mixed-effects negative binomial regression validated the statistical significance of pressure injury rate improvements relative to skilled specialist efficiency, controlling for case-mix and policy changes over time. RESULTS: High performing hospitals invested in prevention infrastructure with skilled specialists based on pressure injury rate reductions. By adding 1.0 board-certified nurses per 1,000 beds, a hospital decreased pressure injury rates 17.7% per quarter. The highest performers actually supplied fewer skilled specialists per 1,000 beds and sustained improved pressure injury rates. CONCLUSIONS: Skilled specialists bring important value to health systems as a representation of investment in infrastructure. The proportion of these specialists is formulaic relative to hospital capacity. The UK King’s Fund is investing £22 billion in NHS England infrastructure to improve quality – other health systems in North America and Europe should emulate this policy to support hospitals to make investments in infrastructure to drive down patient costs and improve quality.

PHS126: EFFECTS OF AVAILABILITY OF ESSENTIAL MEDICINES LIST ON SELECTED DOMAINS OF PHARMACY SERVICES IN A NATIONAL HEALTH INSURANCE SCHEME (NHIS) ACCREDITED PHARMACY OF A UNIVERSITY TEACHING HOSPITAL IN NIGERIA: AN INTERVENTION STUDY

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OBJECTIVES: Good drug supply management is an essential component of an efficient healthcare delivery system. Essential medicine list helps to promote rational use of drugs and services. This study assessed the effects of availability of essential medicines list on selected domains of pharmacy services in an accredited health insurance pharmacy. METHODS: The study was a pre-post test intervention study involving patients who accessed services at the hospital pharmacy. Standardized and validated questionnaire was self administered to the patients before and 6 months after provision of essential medicines list to the pharmacy based on selected domains on a 5-point Likert scale: 1- very satisfied; 2- satisfied; 3- neutral; 4- dissatisfied; and 5- very dissatisfied. Data were analyzed using descriptive and inferential statistics. A P-value of P<0.05 was considered significant. Data were analyzed using descriptive and inferential statistics. RESULTS: 354 systematically selected patients participated in the study. Scores after 6 months of provision of essential medicines list were statistically significant at these mean values. Courtesy and respect shown to patients by pharmacy staff: 3.15±0.68, availability of pharmacist to fill prescription for patients promptly: 3.31±0.69, counseling provided by pharmacist: 3.52±0.61, waiting time to collect medication: 2.44±0.81, and availability of medication: 2.27±0.91 which all had values below P<0.001. However, the value was insignificant for medication charges: 2.80±0.91 which had a value of 0.219. The overall pharmacy services score before provision of medicine list was 57.20 (13.06) and after provision of essential medicine list was 74.02 (11.05) at P<0.001. CONCLUSION: Overall, provision of essential medicines list improved pharmacy services scores in all domains except in medication charges, which is subject to external forces like inflation and government policies.

PHS127: PALLIATIVE CARE SERVICES IN ROMANIA- ANALYSIS OF UTILIZATION, FUNDING AND COVERAGE

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OBJECTIVES: to describe the current use of palliative services in Romania, both inpatient care and home care, the reimbursement and coverage in territory in Romania METHODS: analysis of large administrative database (all cases reported by hospitals 2014-2016, for DRG reimbursement purpose), literature review and critical review of current legislation on the topic RESULTS: during the studied period, the number of hospital palliative care suppliers increased by 62% (40% of them being privately held). Still the coverage of population with palliative care services varies intensely from a territorial perspective, with a number of counties lacking suppliers of such services having contracts with the respective health insurance fund, while only two counties account for 40% of hospitalization
OBJECTIVES: To recognize and map the hospital drugs and medical devices supply chain process. METHODS: In
order to collect qualitative and quantitative data, ad hoc internet-based survey has been designed and submitted by Italian Association of Hospitals (FIASO) to its associates. The quantitative part of the survey (made up of 61 questions) gathered organizational and managerial information about hospitals and warehouses. The second part (29 questions) explored the qualitative aspects of the supply chain process as appropriateness, critical issues and satisfaction with respect to the managerial action. RESULTS: Both qualitative data from 56 hospitals (21 University Hospitals UH, 33 Local Health Authorities LHA, 2 Broad Intraregional Areas* BIA) and quantitative from 39 hospitals (15 UH, 22 LHA, 2 BIA) have been collected in 15 and 13 regions, respectively. UH and LHA have been split into 3 clusters based on annual medicines and medical devices revenue: cluster 1 (0-50 million €) 10 UH,16 LHA; Cluster 2 (50-100 million €) 5 UH, 12 LHA; Cluster 3 (> 100 million €) 6 UH, 5 LHA. A more conspicuous purchase value of 65 million € characterized BIA. The responding personnel are mainly technical operators (72%) and administrative staff (18%). A half of hospital facilities experienced a drug theft in the last 5 years and 70% of them possesses insurance against theft. The survey pointed out that the higher the revenue of the facility, the higher the productivity (KPI - key performance indicators). On half of the responders, the level of satisfaction towards the managers’ action is medium and on a third is high. CONCLUSIONS: In the first phase of this wide and ambitious project come out that the main weaknesses of Italian supply chain is related to infrastructures, human resources, IT, dedicated staff. The study enables to recognize supply chain process and critical issues. *centralized organization structure

PHS131: IMPROPER MEDICATION USE BY THE AGED POPULATION IN BAHRIA TOWN, LAHORE, PUNJAB, PAKISTAN

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OBJECTIVES: To estimate the improper medication use among the aged hospitalized patients in Bahria town, Lahore, Punjab, Pakistan. METHODS: An explanatory, non-experimental, cross-sectional study was accomplished from December 2016 to March 2017 in five health-care hospitals of the Lahore, Punjab province of Pakistan. The population under study was patients aged ≥60 years and being hospitalized in the selected health-care hospitals. In this study, data was collected from 500 aged patients (100 patients per hospital). All medicines prescribed in each in-patient chart were noted on a pre-designed Performa and were estimated according to the 2015 American Geriatrics Society Beers Criteria. Statistical Package for Social Sciences (SPSS) was used to analyze the data. RESULTS: In 500 hospitalized in-patient (male 52.7% and female 47.3%) charts, 3,179 medicines were prescribed. The most usually prescribed drug classes were: alimentary tract and metabolism 80%, nervous system 66.3%, anti-infectives for systemic use 62.2% and cardiovascular system 48.3%. The most usually prescribed improper medications were: omeprazole 51.3%, metoclopramide 14.3%, aspirin 9%, diphenhydramine 7.7%, ibuprofen 4%, famotidine 3.3% and chlorpheniramine 1.8%. CONCLUSIONS: The rational use of medicines is of greatest importance, most particularly in the aged population. It is highly recommended that more thoughts should be given to the aged patients.

PHS132: MUNICIPAL HEALTH CONFERENCES IN THE STATE OF BADEN-WUERTTEMBERG, GERMANY – READY FOR INITIATING AND STEERING PRIMARY HEALTH CARE PROVISIONS AT COMMUNITY LEVEL?


OBJECTIVES: Health care - as an elementary component of the community - ranks high in the value of citizens. States and municipalities therefore exercise to identify the future regional and municipal challenges in the health sector. In the state of Baden-Wuerttemberg (B-W) therefore, municipal health conferences (MHC) were introduced in 2013 by the state government and became compulsory in 2015. Key questions remain: What are the factors that promote and inhibit the establishment? And how can results be measured? METHODS: The 37 counties were examined with regard to their implementation and realization status. The implementation processes have been analyzed and problem areas were identified through internet searches, interviews and through participation as guests. RESULTS: Overall in B-W, the degree to which MHCs have been actually implemented differs but for the majority (84.09 %) this has succeeded, 4.55 % are in development, 11.36 % do not yet have a conference established. In terms of implementation of the field of actions it differs even more. MCHs usually work on recommended principles and instruments, especially the Public Health Action Cycle, which should give a smooth cyclic execution of different actions. However, the process needs expert guidance at every step and particular instruments and quality measures in order to be successful. This often is lacking on municipal level. CONCLUSIONS: On the whole, MCHs as a driver and designer of regional health care, which is to actively advise and decide on a future-oriented, needs-based health care provisions, remain behind their possibilities. Clear guidelines for action and best-practice examples are encouraging processes which are only available in some already well functioning health conferences. Policy processes indicate that legislative changes will lead to a further transfer of
OBJECTIVES: analyze the appropriateness of reimbursement of the Brazilian public health system in relation to the effective costs of the procedures for infusion of immunobiological drugs in patients. METHODS: This study was carried out at the federal university public hospital of Salvador, Brazil. The reimbursement data were obtained through the DATASUS and SIGTAP systems, which provide respectively the amounts invoiced by the hospital and the prices of the procedures paid by the health system. The method used to calculate costs was ABC (Activity Based Costing) based on the criterion of reciprocal or matrix allocation. A relationship map was created between the cost centers involved in calculating the final cost, respecting the principle of reciprocity between the non-productive cost centers before making the final apportionment to the productive cost center. Cost drivers were defined based on the most cost-involved resources and expenses expressed in direct and indirect costs, based on the month of November 2016. RESULTS: The direct cost per infusion was 77,69€. Personnel and consumer expenditures accounted for 62,7% and 24,7%, respectively, while drug and food expenses reached 10,2% and 2,3% respectively. The indirect costs involved expenses with support services, service contracts and depreciation of movable and immovable property, and summed to 2,99€. Thus, the total cost per infusion reached 80,68€. In contrast, the reimbursement value passed through the system was 13,14€ per infusion. Therefore, revenue covered only 16.3% of the procedure’s cost, generating a deficit of 67,54€ per patient to the institution and a percentage change from revenue of -514,0%. CONCLUSIONS: We verified that the reimbursement value from) the health system was insufficient to cover the costs of the infusion procedures, significantly compromising the hospital budget for patients treated with immunobiological (immunobiologics ou immunobiological agents/drugs).

OBJECTIVES: Efficient allocation of public resources require identification, measurement and quantification of costs and benefits of alternative programs. Patient reported outcomes are now routinely incorporated into economic evaluations of health technologies, but patient experience is often overlooked. The aim of this study is to develop a descriptive system for patient experience that can be valued and used to inform decision making. METHODS: Analyses were conducted in a patient dataset, the Inpatient survey (2014), which collected information about healthcare delivery from over 62,000 NHS users across England. Statistical approaches were used to identify dimensions and items using data from patients who had an operation or procedure. In the first two approaches, dimensions based on latent construct were derived using exploratory factor analysis (EFA). Item selection for each dimension was conducted using structural equation modelling (SEM) and item response theory (IRT). For comparison logistic regression analyses were applied with respondents’ rating of overall patient experience specified as dependent variable. RESULTS: EFA identified different factor models for patients with A&E and planned admissions respectively and factors contained 1 to 7 items. Bifactor models were fitted to assess unidimensionality before item selection using SEM and IRT. The two techniques identified different item as most significant variable in each factor. The 11 and 8 items identified for the two group of patients broadly related to trust and dignity, comfort and cleanliness, and clear communication to patients. Regression analyses identified a large number of independent items that were correlated with each other. CONCLUSIONS: A measure that is amenable to valuation consists of items that are distinct yet related to each other. The measurement model identified from the dataset for patients that underwent an operation or procedure was different for those with planned admission compared to emergency admission. Different methods of item selection yielded different measurement models.

OBJECTIVES: Community-based health insurance has increasingly been integrated into health systems in rural Uganda. The aim of this study was to assess whether community-based health insurance reduces child stunting. METHODS: We conducted a cross-sectional survey in rural Uganda, recruiting a total of 1,200 households with children aged 0-5 years. Child stunting was defined as height-for-age z-score (HAZ) < -2. RESULTS: Community-based health insurance was associated with a reduced risk of child stunting (adjusted odds ratio [aOR] = 0.68, 95% confidence interval [CI] = 0.49-0.95). CONCLUSIONS: Community-based health insurance may be an effective strategy to reduce child stunting in rural Uganda.
developing countries. However, there is limited evidence on its probable health outcome impacts beyond the conventional health financing and facilitating services access functions. This research aims to explore about the possible impact of community-based health insurance on child health, using stunting indicator. METHODS: Using a cross-sectional survey covering 464 households from south-western Uganda, we apply a novel instrumental variables technique, the two-stage residual inclusion which not only measures the effect of insurance but also the effect of insurance duration on child stunting. RESULTS: Our results indicate that in a consistently linear relationship, each year of insurance contributes to about 15.4% less probability of being stunted. Moreover, these results further indicate that children in households that had consecutively been in insurance for 7 years had a probability of stunting of only 0.329 compared to 0.518 for children in households that had not have insurance. CONCLUSIONS: This study contributes to the still small but growing body of literature that concludes that community health insurance can have broader outcomes, extending beyond the conventional functions of financial protection and health services utilisation. Our study, therefore, recommends that developing countries, in absence and or limited capacity of larger tax-financed social health insurance schemes, should support and facilitate the expansion of community health insurance scheme not only for their contribution to health financing but even more for mortality and morbidity aversion.

PHS136: EMERGENCY DEPARTMENT USE AMONG AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE PATIENTS IN THE US

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OBJECTIVES: Autosomal dominant polycystic kidney disease (ADPKD) is the most common heritable renal disease, characterized by fluid-filled cyst development and variable total kidney volume (TKV) progression. Healthcare utilization (e.g., emergency department [ED] visits) reflect incident cardiovascular and renal events related to ADPKD complications (e.g., hypertension, hematuria and hemorrhaging, acute and chronic pain, urinary tract infections, and renal failure). Recent research has looked at the course of inpatient care for ADPKD patients, however very little is known about their use of EDs, treatment, and progression to the inpatient setting. METHODS: A cross-sectional study using the 2010 Nationwide Emergency Department Sample (NEDS) was performed. ADPKD patients were selected using ICD-9-CM: 753.12 and 753.13. Patients were stratified using disposition from ED via transfer to short-term hospital and/or admitted as an inpatient from the ED. CPT/HCPCS and ICD-9-CM code sets were used to identify procedure and diagnosis frequencies among ADPKD patients in the ED setting. RESULTS: The study contained a sample of 8,871 ED visits. More females were hospitalized after an ED visit compared to males (51.34% vs. 48.66%, p<0.0001). The hospitalized group was significantly older than their non-hospitalized counterparts (57.86 vs. 42.85, p<0.0001). Mean total charge for ED services were significantly higher in the non-hospitalized group ($4,662.9, SD=$5,968.5) compared to the hospitalized group ($1,703.7, SD=$1,317.2, p<0.0001). Hospitalized visits most frequently occurred due to device complications, implantation, or graft and infections. Among non-hospitalized patients, 30.80% experienced abdominal pain, genitourinary congenital anomalies, and urinary tract infections. CONCLUSIONS: ED-based hospitalized patients were mostly admitted due to complications from surgery, whereas non-hospitalized patients appear to be seeking symptom control. A high proportion of patients with ADPKD appear to be readmitted to an inpatient setting through an ED as a result of surgical care. Further research to explore readmission rates post-surgery is needed.

PHS137: ALTERNATIVE SOURCES FOR HEALTH CARE FUNDING: PUBLIC HEALTH TAXES IN HUNGARY BETWEEN 2011-2016

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OBJECTIVES: Imposing taxes upon harmful products, such as tobacco, alcohol, unhealthy foods and beverages are getting more common around the world. Their aim is to create revenue for health care and to change the population’s health awareness and health status. The aim of our study is to assess these dues in Hungary between 2011-2016. METHODS: A quantitative, retrospective study was carried out. We assessed changes of the public health product tax (unhealthy foods, beverages, alcohol) and the health contribution of tobacco industry businesses. Data derived from the National Tax and Customs Administration and the National Health Insurance Fund Administration of Hungary. RESULTS: Public health tax income and number of taxable products increased over the years. The Act’s extension to alcoholic beverages resulted in a >24% increase of the tax income since 2015, while the sales of taxable alcoholic beverages decreased by 16.92% in 2016. Most of all tax income came from prepacked sweetened products (36.8%, $38.659 million) and alcoholic beverages (24.15%, $25.370 million) in 2016. Prepacked sweetened products (72.83%) and salty snacks (13.78%, $14.069 million) were the biggest tax bases (in kilogram), increasing continuously over the years. Sugary drinks were the main product of tax bases (in liter) (81.02%), although only
17.54% of income can be linked to this item. Tobacco industry’s contribution was supposed to bring $41.573 million to the Fund since 2015, however the income was only $1.948 million that year, and it had to be paid back in 2016. **CONCLUSIONS:** Public health tax on unhealthy foods and beverages was established successfully, it created a small but stable income source for the Health Insurance Fund, and was able to change the population’s consumption habits positively in some cases (energy drinks, alcoholic drinks). Contribution of tobacco industry could not remain a revenue source and was repealed after one year.

**PHS138: COMPARISON OF WOMEN’S HEALTH CARE IN GERMANY, AUSTRIA AND SWITZERLAND REGARDING SURGICAL THERAPY OPTIONS FOR PATIENTS WITH ABNORMAL UTERINE BLEEDING**

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**OBJECTIVES:** The study aimed to assess differences in the current medical care situation of women with abnormal uterine bleeding (AUB) in Germany (D), Austria (A) and Switzerland (CH) (DACH). The study focused on describing the availability of and access to surgical therapy options of the respective health care systems, in order to compare the countries regarding structural data and evidence requirements in women’s health care. **METHODS:** Data were obtained through official databases, medical associations and governmental institutions (G-BA, AGES, Swissmedic, etc.) of the respective countries. Additionally, internet searches were conducted to identify recent country-specific information. Key figures used for analyzing differences between the DACH countries were: Structural data: Variables describing the health care situation regarding the indication AUB, e.g. prevalence of AUB, doctors/1000 women, hospitals/1000 women, financing framework, setting of care/procedures, number of procedures/1000 women. Requirements: Clinical and health economic evidence, e.g. requirement standard rating based on evidence level according to the GRADE scheme (1= high; 2=medium; >2= low). Searches were performed in 2017. For every country, the latest available figures were used. **RESULTS:** The hysterectomy rates per 1000 women differ between the three countries, with Germany having the highest rate. Differences were also found in ablation techniques, these procedures are most frequently done in Switzerland, which is explained by the higher fee of material expenses (Sachkostenpauschale). Clinical and HEOR evidence requirements vary, depending on the setting. Compared to the other two countries, the inpatient access requirements are lowest in Germany. **CONCLUSIONS:** The difference in procedure rates is assumed to be influenced by the different financial frameworks of reimbursement in the countries. Cross-border standards for the treatment of AUB should be implemented to ensure equal access to uterus-preserving therapies. Furthermore, real world evidence is needed to explain the differences especially in hysterectomy rates between the three countries.

**PHS139: STRUCTURAL CHANGE IN THE HUNGARIAN HEALTH CARE SYSTEM**

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**BACKGROUNDS AND OBJECTIVES:** In the last decade many challenges have appeared against the modern health care system. The society is aging, the elderly people have growing need for long-term, the number of chronic illnesses is increasing continuously, the pharmaceutical, surgical and diagnostic technologies are developing rapidly. The effective management of these problems will require structural changes in the health care system. **METHODS:** At macro level the study focuses on the dimensions of capacity N of patients, activities, financing, technology content and HR of care. At regional-county level it examines the procedures of competence and task distribution among hospitals and other health provider institutions and level of integration. At the level of institutions further dimensions are examined as the institutional physical infrastructure, such as the number of sites and pavilions, block-structure. **RESULTS:** The capacity of acute and chronic care has decreased (has been reduced by ca. 28% from 2004 to 2014). The number of one-day surgical procedures is increasing (from 5% to 20% of all surgical interventions from 2005- to 2015). Prevention plays an important role in the government’s communication and measure like smoking cessation. Also the group praxis model has been launched in the primary care GP services. The regional profile change is part of the concentration of active capacities in the county and the integration of hospitals. At institutional level block structure of hospitals and new profession have been created (emergency care units). **CONCLUSIONS:** The structural change is in progress, but it is still there are potential efficiency gain in the better organization and management of the health services. We are lagging in the development of outpatient care, home care and ICT based services. Strategic, well-planned health policy professional programs (like cancer control program), restructuring and integration of the delivery system based on efficiency and quality are highly needed.

**PHS140:** **PERCEIVED SERVICE QUALITY AND PATIENT SATISFACTION AT PHARMACY DEPARTMENT IN YOGYAKARTA, INDONESIA**
OBJECTIVES: to measure the gap between patients’ expectations and perceptions about services delivered in pharmacy department. METHODS: A questionnaire concerning the perceived quality of health care sent to out-patients in pharmacy department, in a government hospital in Siemen district, Yogyakarta Province, Indonesia, during a period of 2016. Participants were two hundred patients aged 18 or older responded to the survey and provided their own ratings of the care. The SERVQUAL model was employed, consisting five main dimensions of service, are tangibles, reliability, responsiveness, assurance, and empathy. Description of respondent’s characteristics, quality dimensions and patient satisfaction was examined. RESULTS: In our survey, 54% of patients were female and 46% male. Thirty-one percent of patients were 45-54 years old. Using servqual model we found a gap -0.487 with service quality mean score 2.938; (SD 1.16) and patient satisfaction mean score 3.425 (SD 0.54). Patients with less education were more satisfied than those with more education. Gaps existed between all five expectation categories and ‘overall perception’ of quality. The direction of the gaps indicated higher perceived quality than expected (all statistically significant) with responsiveness domain demonstrating the largest unfavourable gaps. CONCLUSIONS: We found the SERVQUAL model to be useful in revealing differences between patients’ preferences and their actual experience in health care service quality.

PHS141: ANALYSIS OF EPIDEMIOLOGICAL DATA ON BURDEN DISEASE IN EUROPE

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Today, depression is considered as one of the most common diseases. According to WHO, the beginning of the XXI century depressive disorders accounted about 40% in total mental pathology. Annually in the world about 200 million people suffer from depression, and this figure is actively growing. In this regard, the priority of health systems is an effective work aimed at the prevention and treatment of this disease. The aim of our study was to analyze the epidemiological data on the burden disease, depressive disorders caused by the results of the analytical data on network internet survey. As a result of the search, it is revealed that over the past few decades, the problem of depressive disorders is of particular relevance for the system of medical care. In the process of the project’s realization of «European research epidemiology of mental disorders» almost 13% respondents showed the signs of psychotic depression at definite time in their lives and 4% – in the last 12 months. The total number of people with psychotic depression has reached over 21 million in Europe. According to WHO «epidemic threshold» of suicides – 9 people per 100,000 population, but in our country, this figure ranges 40. All this leads to major economic losses to society and negative socio-economic effects that create the «burden of disease». Thus, the above data indicate that in terms of the economic burden of depression’s prevalence in our country has negative consequences on the necessity of the introduction of effective medical technologies for prevention and treatment of diseases. The burden of depression’s prevalence in our country has negative consequences on the necessity of the introduction of effective medical technologies for prevention and treatment of diseases.

PHS142: CHARACTERIZATION OF LOW DENSITY LIPOPROTEIN (LDL) LEVELS IN PATIENTS DIAGNOSED WITH ARTERIAL HYPERTENSION IN COLOMBIAN POPULATION IN THE YEAR 2016

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OBJECTIVES: This study aimed to describe the parameters of Low-density lipoprotein cholesterol (LDL-c) in patients diagnosed with Arterial Hypertension in Colombian health system in 2016. METHODS: Based on secondary analysis of the database of the high cost account which is an organization created by the Ministry of Health and the ministry of finance of the country, we describe people with confirmed diagnosis of arterial hypertension, reported by the insurers of the national territory during 2016, results were obtained from the 32 departments and the totality of the country insurers. This database has 1,151,247 records that have a diagnosis of hypertension. The analysis was descriptive through measures of central tendency and dispersion depending on the nature of each variable. RESULTS: 96.7% of the population study consisted of adults between 40 and 70 years of age or older. On average, 28 out of 100 individuals over the age of 50 maintained their optimal LDL-C levels (<100mg/dl) or close to optimal levels (100-129mg/dl), which was slightly higher for the group of 60-69 years old. For the values of high and very high LDL-C, adults between 60 and 69 years old presented the highest percentages of these results. Among the hypertensive patients for whom BMI data were available, approximately 70% had some degree of overweight or obesity. The
highest LDL-C percentages were obtained in the population with systolic blood pressure between 120–139 mmHg and/or for those with a diastolic blood pressure between 80–89 mmHg. **CONCLUSIONS:** In this study, the prevalence of high LDL-C for individuals diagnosed with hypertension was estimated at 11.2% in the Colombian population and is low compared to other countries. It was established that as the literature says, in the country the increase in age also increases the levels of LDL-C.

**PHS143: CHARACTERIZATION OF LOW DENSITY LIPOPROTEIN (LDL) LEVELS IN PATIENTS DIAGNOSED WITH DIABETES MELLITUS IN COLOMBIAN POPULATION IN THE YEAR 2016**

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**OBJECTIVES:** This study aimed to describe the levels of low-density lipoprotein cholesterol (LDL-c) in patients diagnosed with Diabetes Mellitus (DM) in Colombian Health System in 2016. **METHODS:** The group made an analysis of a database of the High Cost Account which is an organization created by the Ministry of Health and the Ministry of Finance of the country, the population was described with confirmed diagnosis of DM, reported by the insurers of Colombia during the year 2016, results were obtained from all departments and the totality of the country insurers. 99,837 records were found whose have diagnosis of DM confirmed. The analysis was descriptive through measures of central tendency and dispersion depending on the nature of each variable. **RESULTS:** Less than 1% of the population with DM was between 18 and 39 years old. The highest levels of LDL-C (≥190 mg/dl) were within the overweight population and in those whose Systolic and Diastolic Blood Pressure (BP) was between 120 - 139 (60%) and <80 (48.4%) respectively. Extreme values of systolic (≥160mmHg) and diastolic (≥100mmHg) BP represented the lowest incidence within this risk group (less than 2%). **CONCLUSIONS:** In this study, the prevalence of high LDL-C for individuals diagnosed with DM was estimated at 5% in the Colombian population. These results agree with studies that show that diabetic dyslipidemia is characterized by normal or slightly increased LDL-C. It is necessary to evaluate the behavior of small and dense LDL-C particles in the development of DM.

**PHS144: CHARACTERIZATION OF LOW DENSITY LIPOPROTEIN (LDL) LEVELS IN PATIENTS DIAGNOSED WITH CRONIC KIDNEY DISEASE IN COLOMBIAN POPULATION IN THE YEAR 2016**

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**OBJECTIVES:** This study aimed to describe the parameters of Low-density lipoprotein cholesterol (LDL-c) in patients with Chronic Kidney Disease (CKD) in Colombian Health System in 2016. **METHODS:** Based on secondary analysis of the database of the High Cost Account, an organization created by the Ministry of Health and the Ministry of Finance of the country, we describe people with confirmed diagnosis of CKD, reported by the insurers of the national territory during 2016. Results were obtained from the 32 departments and the totality of the country insurers. This database has 980,393 whit diagnostic of CKD, records that have 9-year CKD registry and 3-year lipid profile data. The analysis was descriptive through measures of central tendency and dispersion depending on the nature of each variable. **RESULTS:** From the study population, about 46 out of 100 individuals aged 70 years or older had high (160-189mg/dl) and very high (≥190mg/dl) LDL-C levels, almost twice compared whit the group of 60-69 years old (28%) in the same categories. Among overweight patients, about 39% had LDL-C levels within the optimal (<100mg/dl) and near optimal (100-129mg/dl) categories, while for the high and very high categories, the percentages were 40.2 and 38.9% respectively. Regarding blood pressure, the population with systolic Blood Pressure levels between 120-139 mmHg, on average, 50% of the individuals presented very high values of LDL-C. Optimal LDL-C levels were found in almost half of the patients with a GFR between 30-59 (CKD Stage 3). **CONCLUSIONS:** In this study, the prevalence of high LDL-C in the Colombian population diagnosed with CKD was estimated at 9.6%, and is low compared to other countries. Our findings are in line with previous reports in which LDL-C levels are normal or slightly elevated in patients with early-stage CKD.

**PHS145: CLOSING THE EVIDENCE GAP FOR ORPHAN DRUGS: DO GERMAN REGULATORY REQUIREMENTS GIVE INCENTIVES FOR HIGH LEVEL EVIDENCE GENERATION?**

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OBJECTIVES: Medicines granted with an Orphan Drug (OD) designation by the European Commission are offered a range of incentives beyond access to the centralized authorization procedure and inevitably receive reimbursement within the German health technology assessment. This analysis investigated whether German regulatory requirements give incentives for high level evidence generation for ODs. METHODS: Medicines with an OD designation were graduated in two evidence groups evaluated by the German Federal Joint Committee (GBA): a non-quantifiable benefit or a quantifiable benefit. Trials of both groups were compared regarding study design and patient relevant endpoints. Furthermore, the reimbursement price was analyzed (launch price vs reimbursement price after one year). RESULTS: 52 dossiers with OD designation were evaluated by the GBA since implementation of the Act on the Reform of the Market for Medicinal Products (German: Arzneimittelmarktneuordnungsgesetz, AMNOG) in 2011. 60% (n=31) of the dossiers received the statutory non-quantifiable additional benefit. 40% (n=21) acquired a quantifiable additional benefit. Almost all assessments resulting in a quantifiable benefit were based on at least one RCT (91%, n=20). This subgroup succeeded in demonstrating a statistically significant advantage in a mortality endpoint in 23% (n=7), a morbidity endpoint in 43% (n=13) or a morbidity endpoint in 23% (n=7) of the cases. 63% (n=19) of the dossiers with a non-quantifiable benefit also presented RCTs. Even though some endpoints were significant, they were not acknowledged. Major reasons for not acknowledging these RCTs were the lack of patient relevant data, the usage of surrogate or combined endpoints and a high bias potential. CONCLUSIONS: German regulatory requirements give incentives for high level evidence generation. ODs presenting significant and patient relevant data from RCTs have a higher chance to achieve a quantifiable benefit that leads to a better positioning in price negotiations. Patient relevance of endpoints and effect sizes are key success factors.

PHS147: TITLE: MULTI-DISCIPLINARY DECISION MAKING IN GENERAL PRACTICE- A CASE STUDY OF SWITCHING BETWEEN ORAL ANTICOAGULANTS

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OBJECTIVES: As the prevalence of chronic conditions and co-morbidities increase complex long-term conditions, management responses are required. Such responses require an integrated approach to care. This necessitates a multi-disciplinary approach to decision making when treating patients with Atrial Fibrillation (AF). While the European Society of Cardiology guidelines (Kirchhof, 2017) advocate a structured integrated approach to care, that is patient-centred with multidisciplinary teams, the collaboration needs to be meaningful and appropriate. It is important to determine if General Practitioners (GPs) are collaborating in the multidisciplinary decision making when switching between oral anticoagulants (OACs) for AF patients. This paper explores Irish GPs’ experience of switching between OACs, the prevalence of multi-disciplinary decision making and determines what GP characteristics influence the likelihood of multi-disciplinary decision making in the community. METHODS: Primary data was used and a probit and multinomial logit applied to determine the factors influencing the likelihood of multi-disciplinary decision-making for OAC switching decisions. RESULTS: While 88% of GPs in the survey indicated they had AF patients whose OAC was switched, only 64% of GPs indicated the decisions involved more than one decision maker, i.e. were multidisciplinary. Female GPs and GPs who initially prescribed OACs were more likely to engage in multidisciplinary decision-making surrounding switching OACs amongst AF patients. The latter characteristic suggests a greater sense of appreciation of the complexities and pharmacokinetic/pharmacodynamic characteristics of OACs, which is unsurprising. CONCLUSIONS: This case study reveals that some multidisciplinary decision-making is occurring, but it is not standard practice. Moreover there is a lack of patient participation in the decision making process. As indicated by Kirchhof (2017) integrated care, with coordinated multidisciplinary decision-making, has the potential to provide continued care in the community. Knowledge of these prescribing decisions is necessary to promote optimal use of OACs and in particular costly NOACs and to ensuring patient-centred care.

PHS148: IMPACT OF LIFESTYLE EDUCATION AND PHARMACIST INTERVENTION OF DRUG-RELATED PROBLEMS ON ELDERS AT HIGH RISK OF HAVING DEMENTIA

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OBJECTIVES: This study evaluated effectiveness of lifestyle education and pharmacist counselling on elders at high risk of dementia. We also investigated the risk factors and feasibility of memory screening held in community pharmacy of Hong Kong. METHODS: Subjects who were 60 years old or above and not diagnosed with dementia were recruited in this study. Participants were invited to join follow-up sessions if they were classified to have “possible cognitive impairment” by memory impairment screen (MIS). Cognitive-beneficial lifestyle education and pharmacist counselling were provided to subjects in the first follow-up session. The effects of lifestyle education were evaluated by comparing the knowledge quiz performance before education and after education (i.e. in the second follow-up session three months later) while the effects of pharmacist counselling were assessed by the proportion of drug-related problems (DRPs) totally solved by interventions proposed by pharmacists. RESULTS: Among 1842
participants who were eligible and completed MIS, 183 elders were invited and 97 of them attended both follow-up sessions. The lifestyle knowledge quiz score was found to significantly increase by 16.6% after intervention (p<0.001). 24 (50%) of DRPs were totally solved after pharmacist counselling in the second follow-up session. NNT to identify a subject with DRP was 2.03 and NNT to totally solve DRP in one subject is 3.95. Older age especially after 70 years old, impaired mobility and higher anticholinergic cognitive burden (ACB) score were found to be associated with worse performance in MIS, which implied that pharmacists may have a role in minimizing anticholinergic cognitive burden in these elders. CONCLUSIONS: Lifestyle education and pharmacist counselling were found to be effective in transferring cognitive-beneficial lifestyle knowledge and solving DRPs of elders at high risk of dementia. Demographic factors associated with MIS score included age, ACB score and impaired mobility.

**PHS149: PROSPECTIVE EVALUATION OF PATIENT-CENTERED CARE IN SHORT-TERM CANCER SURVIVORS, AT ONE AND TWO YEARS POST TREATMENT, THROUGH THE PATIENT ASSESSMENT OF CHRONIC ILLNESS CARE QUESTIONNAIRE.**

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**OBJECTIVES:** The Chronic Care Model (CCM) is an accepted framework for delivering care to patients with chronic illnesses. The Patient Assessment of Chronic Illness Care (PACIC) is a questionnaire designed to assess the CCM from the patient’s perspective. Our aim was to document if patient’s assessment of chronic illness care changed at two time points. PACIC has been validated in Spanish **METHODS:**: This prospective study included patients with colorectal (CCR), breast or prostate cancer. PACIC was administered by mail at 1-year and 2-years after finishing treatment. Questionnaire has 5 subscales, patient activation (PA), delivery system design (DSD), goal setting (GS), problem solving (PS) and follow-up coordination (FU). In addition there is a global score (G). Each subscale and the global are scored from 1 to 5 with higher scores indicating patient’s perception of greater involvement in self-management and receipt of chronic care counseling. Data are expressed as mean change (standard deviation of change). Comparison amongst two times was performed through non-parametric Wilcoxon test. **RESULTS:**: There were 477 patients included, 106 prostate, 251 breast and 120 with CCR. 1-year scores were: PA: 3.3 (1.3), DSD: 3.6 (1.2), GS: 2.8 (1.3), PS: 3.0 (1.5), FU: 2.3 (1.3) and G: 2.9 (1.1). The mean change (SD) by dimensions were: PA: 0.1 (1.3), DSD: 0.11 (1.2), GS: 0.1 (1.1), PS: 0.09 (1.3), FU: 0.01 (1.1) and global: 0.07 (0.9). There were no statistically significant differences amongst both follow-up periods in any dimension, but DSD. However the effect size of this change was as small as 0.09 (mean change divided by SD of change). **CONCLUSIONS:**: Based on these data the patient’s assessment of chronic illness care in these short-term cancer survivors does not change along the first two years of follow-up.

**PHS150: FAST-TRACK MEDICATION REFILL (FTMR) SERVICE COULD BE MORE COST-EFFECTIVE THAN THE CURRENT MODEL OF CARE IN HONG KONG**

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**OBJECTIVES:** This study compared the cost-effectiveness of the hypothetical FTMR service, where cardiovascular disease patients not requiring any medication change from a follow-up visit could obtain their refill medications from pharmacists directly, with the current model of care in Special Out-Patient Clinics under the Hospital Authority in Hong Kong. **METHODS:** The ten-year costs per person, including hospitalization and running costs, and the quality-adjusted life-years (QALY) associated with the proposed FTMR model with a follow-up frequency of either every 3 or 6 months and the current model of care as the base case were estimated by a Markov model. Model inputs were derived from characteristics of patients attending the Hypertension Clinic in Prince of Wales Hospital from April 2016 to March 2017 and from clinical trials published in the literature. The outcome measure was incremental cost per QALY gained (ICER). **RESULTS:** Using the Gross Domestic Product (GDP) per capita of Hong Kong (USD 43496.54) as the willingness-to-pay per QALY, an every-3-month FTMR was more cost-effective than the current model, with an average follow-up duration of 22.77 weeks with an ICER of United States Dollar (USD) 28,300 and a QALY gain of 0.07 year while an every-6-month FTMR dominated over the current model by offering both cost savings of USD 289 and QALY gain of 0.009 year. An every-3-month FTMR was more cost-effective than an every-6-month FTMR with an ICER of USD 37,200 and a QALY gain of 0.06 year. **CONCLUSIONS:** The hypothetical FTMR service was shown to be a cost-effective choice for stable patients to have their chronic medications refilled compared with the current model of care in Special Out-Patient Clinics in Hong Kong. The implementation of an every-3-month FTMR also fosters a closer therapeutic monitoring in this patient population.
PHS151: A PILOT STUDY ABOUT THE APPROPRIATENESS OF THE BREAST CANCER CARE PATHWAY IN A LOCAL HEALTH AUTHORITY ASL CN2 (PIEDMONT, ALBA BRA-ITALY) BASED ON E.PIC.A. (ECONOMIC APPROPRIATENESS OF AN INTEGRATED CARE PATHWAY) PROTOCOL

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OBJECTIVES: Identifying replicable mechanisms that can govern the expenditure and appropriateness of Healthcare System is important to guarantee the sustainability. A pilot study was performed in ASL CN2 to evaluate performance in breast cancer diagnosis and treatment, using the methodology E.Pic.A. proposed by Massa et al.(1). METHODS: A board of professionals identified 7 Key Performance Indicators (KPIs) on the basis of the current guidelines from the Italian Association Oncology. Data were gathered from real-word sources. Stage of breast cancer was defined through the tumor, node, metastasis [TNM] staging of the pathology report obtained at surgery. RESULTS: A cohort of 95 patients underwent surgery of breast cancer at ASL CN2 in 2015 was included in this study. Respectively, 4% (KPI1) and 44% (KPI2) of patients with tumor stage I and II performed one diagnostic examinations within 2 months before and after surgery; In KPI3 none of the patients received subsequent axillary dissection and/or breast reconstruction within 3 months after mastectomy; In KPI4 20% of patients received surgical re-intervention with a mean time of 79 days; In KPI5 58% of patients received adjuvant chemotherapy within 60 days after surgery; In KPI6 57% of patients performed radiotherapy within 90 days after surgery (who did not receive adjuvant chemotherapy) and 69% within 180 days after surgery (who received adjuvant chemotherapy); In KPI7 74% of the patients with tumor stage I and II performed one diagnostic examinations within 365 months after surgery. CONCLUSIONS: This study sustains the replicability of E.Pic.A. in different realities, the use of the KPIs to measure the performance is a way to guarantee a homogenous level of care regardless where the treatment is performed. Potentially, the improvement of these KPIs could lead to cost savings coming from inefficiencies that could be relocated to higher-value interventions for patients. References: 1.Massa et al., The Breast 34 (2017) 103-107

DISEASE-SPECIFIC STUDIES

INDIVIDUAL’S HEALTH - Clinical Outcomes Studies

PIH1: COMPARING THE EFFECT OF PROGRESSIVE RELAXATION AND PERINEAL STRENGTHENING INTERVAL EXERCISES AMONG WOMEN WITH PRIMAER DYSMENORRHOEA TO REDUCE MENSTRUAL CRAMPS

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OBJECTIVES: Primaer dysmenorrhea is one of the most common gynecological complaints, although women who suffer from menstrual cramps often take pain killers and antispasmodics only. The aim of this study is to assess the effect of Jacobson’s progressive relaxation therapy (PR) and Kegel’s perineal muscle exercises (PME) on reducing menstrual cramps during primaer dysmenorrhea, to evaluate the questionnaires filled before and after treatments, and to determine the effectiveness of a 5-week therapy. METHODS: A prospective, longitudinal study was carried out with non-probability targeted sampling. Our sample consisted of 12 young QE-s suffering from primaer dysmenorrhea. They were randomly divided into two groups: one got PR while the other got PME therapy twice a week for five weeks. Our study was carried out at the University of Pécs, Zalaegerszeg, Hungary. During data collection questionnaires were filled out before and after treatments (socio-demographic and anthropometric data, Visual Analogue Scale=VAS, EQ-5D, Menstrual Symptom Questionnaire=MSQ). FemisScan was used for measuring perineal muscle strength. We calculated descriptive statistics and paired samples t-test (significance level: p<0.05) with MS Office Excel 2016. RESULTS: VAS points showed a significant decrease in both groups (PR: p=0.001; PME: p=0.03), as well as EQ-5D (PR: p=0.0008; PME: p=0.0029), and MSQ points (PR: p<0.001; GIT: p=0.001). Data of perineal muscle measurement also changed significantly, except for speed (p=0.078098). CONCLUSIONS: We can conclude after seeing the results of 12 treated QE-s that progressive relaxation and perineal muscle exercises can be effective in treating primaer dysmenorrhea.

PIH2: OFF-LABEL DRUG USE IN HOSPITALIZED CHILDREN: A PROSPECTIVE OBSERVATIONAL STUDY AT GONDAR UNIVERSITY REFERRAL HOSPITAL, NORTHWESTERN ETHIOPIA
**PIH3: A COST-EFFECTIVENESS MODELING EVALUATION COMPARING ORIGINATOR FOLLITROPIN ALFA TO A BIOSIMILAR FOR THE TREATMENT OF INFERTILITY IN GERMANY, ITALY AND SPAIN**

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**OBJECTIVES:** Biosimilars for infertility treatment typically cost less than or the same as originator products; however, biosimilars may not be cost-effective when all costs to achieve a desired clinical outcome are considered. The aim of this study was to estimate the cost-effectiveness per live birth of the originator follitropin alfa preparation (GONAL-f®) and a biosimilar (Ovaleap®) for three countries: Germany and Italy (where the drug costs differ) and Spain (where the drug costs are similar). **METHODS:** Patient and treatment data from Strowitzki et al. (DOI:10.1186/s12958-015-0135-8) were used. The respective DRG 359 tariffs for assisted reproductive technology plus additional tariffs for gonadotropins, follow-up visits and costs related to adverse events were used in Italy and Spain. In Germany, treatment costs were used from per-intervention outpatient tariffs plus ovarian hyperstimulation (OHSS) costs. The mean cost per live birth in each treatment arm was calculated from the sum of all costs divided by the live-birth rate (LBR). The incremental cost-effectiveness ratio (ICER) was calculated as the difference in costs divided by the difference in LBR. Univariate sensitivity analyses were also performed. **RESULTS:** Per-patient costs were higher with the originator than the biosimilar in Germany and Italy (difference €158 and €142, respectively) but were more aligned in Spain (difference €23). LBRs were 0.32 for the originator and 0.27 for the biosimilar. Overall costs per live birth were higher for the biosimilar in Spain (£14856 [originator] and £17765 [biosimilar]), in Germany (£8135 and £9185) and in Italy (£68543 and £9736). Compared with the biosimilar, the originator generated ICERs of €415, €2918 and €2620 for Spain, Germany and Italy, respectively. Sensitivity analyses had no strong effect on the ICERs. **CONCLUSIONS:** Treatment with the originator was more cost-effective per live birth than treatment with the biosimilar, even when incremental costs and/or reimbursement frameworks differed.

**PIH4: FORECASTING THE POTENTIAL PUBLIC HEALTH IMPACT OF HERPES ZOSTER VACCINATION IN ITALY**

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**OBJECTIVES:** Herpes Zoster (HZ) and its complications such as postherpetic neuralgia (PHN) impose a considerable disease and economic burden in Italy. In February 2017, the updated National Immunization Plan (NIP) was approved, this includes HZ vaccination for everyone aged 65 years old. This study estimates the potential public health impact of introducing a two-dose candidate HZ adjuvanted subunit vaccine (HZ/su), submitted for approval, or a Zoster Vaccine Live-attenuated (ZVL). **METHODS:** The ZOster ecoNomic Analyses (ZONA) model is a static, multi-cohort Markov model that followed all 65-year-old subjects over their remaining lifetime from the year of vaccination. To adapt the model to the Italian setting, a literature review was conducted to identify the inputs. Population statistics were derived from the national bureau for statistics and epidemiological inputs came from peer-reviewed articles. Vaccine characteristics were estimated from the respective clinical trials. To forecast the impact of vaccination in 2018, 20% coverage was assumed for both vaccines, as per the NIP, with a second-dose compliance of 70% for
HZ/su. Scenario analyses will be performed around second-dose compliance. **RESULTS:** Vaccinating 20% of the 726,337 individuals aged 65 years, HZ/su would prevent 11,948 HZ cases, 1,775 PHN cases and 1,004 of other complications compared to 4,677 HZ cases, 697 PHN cases and 393 of other complications avoided with ZVL over the population lifetime. The number needed to vaccinate (NNV) to prevent 1 HZ case for HZ/su was 13 compared to 32 for ZVL. The NNV to prevent 1 PHN case was 82 for HZ/su and 209 for ZVL, respectively. **CONCLUSIONS:** This study predicts that the introduction of a HZ vaccination program in Italy could substantially reduce the burden of disease related to HZ. Introducing HZ/su to the 65-year-old population in Italy would avoid a greater number of HZ cases and its complications compared to ZVL.

**PIH5: PRESCRIPTION ANALYSIS ON OFF-LABEL DRUGS IN PEDIATRIC PATIENTS USING THE CLAIMS DATA OF THE NATIONAL HEALTH INSURANCE IN KOREA**

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**OBJECTIVES:** Among the pediatric patients under 19 years old, clinical trials are restricted and have many obstacles in performing research prospectively. Thus, lots of drugs are prescribed as off-labeled in the real practices for this age group. The purpose of this study is to investigate the off-label usages in pediatric patients using some real-world data in Korea. **METHODS:** Seventeen off-label drugs mainly used in the pediatric clinical practices were chosen, and prescriptions from November 2010 to October 2015 for those drugs were examined using the Korea Health Insurance Review and Assessment Service database. Frequency of prescriptions for each drug use in the patients under 19 years old and the proportion of off-label prescriptions among them were analyzed. Prescription patterns were investigated according to the types of medical institutions, inpatient or outpatient, medical departments, prescription years, regions, and primary disease codes. **RESULTS:** Among the 17 off-label drugs considered, Mosapride Citrate Hydrate (13,439,742 prescriptions) was the most frequently used off-label drug, followed by Domperidone Maleate (8,746,901 prescriptions) and Levofloxacin (2,612,328 prescriptions) in pediatric patients. The proportions of off-label use ranged between 84% and 100% except for 5 out of 17 medications. Those drugs as off-labeled were most frequently prescribed in outpatient settings, in the department of pediatric medicine, and in the Seoul metropolitan area. **CONCLUSIONS:** A large number of prescriptions for off-label drug uses in the pediatric patients were found through the health insurance claims data in Korea. There could be some limitations on such analysis since the claims data may not cover all off-label uses. Nevertheless, the study results bring some important attention to the current state of off-label drug use in those children without appropriate insurance policy.

**PIH6: RACIAL DIFFERENCES IN THE PREVALENCE OF COGNITIVE IMPAIRMENTS AND DEMENTIA, UTILIZATION OF CHEMO-IMMUNOTHERAPY AND MORTALITY IN ELDERLY DIFFUSE LARGE B-CELL LYMPHOMA PATIENTS**

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**OBJECTIVES:** The objective of this study was to describe racial differences in the prevalence of a cognitive impairment or dementia diagnosis, likelihood of chemo-immunotherapy utilization and subsequent survival in elderly diffuse large B-cell lymphoma (DLBCL) patients. **METHODS:** We conducted a retrospective cohort study using cancer data from the Surveillance, Epidemiology, and End Results (SEER)–Medicare linked database. We identified Medicare beneficiaries with a first primary DLBCL diagnosis between 2001 and 2011. A validated algorithm for use with administrative claims data was used to determine presence of neurocognitive impairment or dementia diagnosis at baseline and throughout the study period based on International Classification of Diseases, Ninth Revision (ICD-9) and procedural codes. **RESULTS:** Of the 10,626 Medicare beneficiaries identified with a DLBCL diagnosis, 410 (3.9%) patients also had evidence of a neurocognitive impairment or dementia diagnosis during the study period. The proportion of patients with comorbid neurocognitive impairment or dementia with DLBCL diagnosis was slightly higher among Non-Hispanic Black (6.1%) and Hispanic (4.6%) patients compared to non-Hispanic White (3.7%) and Asian/Pacific Islander (3.3%) patients. In multivariable models, patients with neurocognitive impairment or dementia had significantly lower odds of systemic treatment with chemo-immunotherapy (OR: 0.43; 95% CI: 0.34–0.54) with even lower odds of treatment among Black (OR: 0.16; 95% CI: 0.04–0.48) and Hispanic patients (OR: 0.17; 95% CI: 0.06–0.46). Poorer cancer-specific survival was observed among DLBCL patients with documented neurocognitive impairment or dementia (HR: 1.61; 95% CI: 1.43, 1.81), but this association was attenuated when adjusting for differences in curative treatment received (HR: 1.39, 95% CI: 1.24, 1.57). **CONCLUSIONS:** There are racial differences in neurocognitive impairment and dementia and chemo-immunotherapy utilization among elderly DLBCL patients. Further research is needed to understand patient, caregiver and provider preferences in the care of lymphoma patients with these conditions.
PIH7: A STUDY ON EVALUATION OF FALL RISK AMONG GERIATRIC PATIENTS AT A TERTIARY CARE PUBLIC TEACHING HOSPITAL

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Falls in older people are a major concern in terms of disability, institutionalization, mortality and socioeconomic burden and are considered as one of the “Geriatric Giants”. OBJECTIVES: To evaluate fall risk among geriatric patients at a tertiary care public teaching hospital. METHODS: This questionnaire based study utilized the “John Hopkins Fall Risk Assessment Tool” to assess the risk of falls among geriatric patients. The tool is a prevalidated tool and consists of parameters like age, history of fall, elimination of bowel/urine, high fall risk medications, patient care equipments, cognition and mobility. Based upon the these parameters a well determined score was obtained and on the basis of scores obtained the patients were categorized into moderate fall risk (6-13 points) and high fall risk (>13 points). The data was obtained from patients reporting at the medicine department. RESULTS: Based on age, the patients were classified into three categories; elderly (60-69 yrs), middle aged old (70-79 yrs) and oldest old (≥80 yrs). The average age of the patients was found to be 68.3±0.4 years. The studied sample (260 patients) had a high frequency of moderate fall risk (65%) and high fall risk (18.5%). Only 9.2% patients have experienced a fall event before hospitalization. Based on the evaluated scores of JHFRA-tool, this study also confirms that the mobility functions, high fall risk drugs and cognitive functions are major contributing fall risk factors. A positive correlation between high fall risk drugs (HFRDs) and average fall risk score was observed. Anti hypertensives, diuretics and laxatives were frequently dispensed HFRDs. CONCLUSIONS: In India falls are an emerging public health problem and a hurdle to active ageing. There is a strong need for coordinated and collaborative efforts of health professionals, researchers, policy makers and health care delivery systems to develop prevention strategies, to avoid economic burden and promote active ageing.

INDIVIDUAL’S HEALTH - Cost Studies

PIH8: COST-COMPARISON BETWEEN THE ETONOGESTREL IMPLANT AND THE MEDROXYPROGESTERONE ACETATE INJECTABLE: NUMBER OF UNINTENDED PREGNANCIES AND FINANCIAL IMPACT

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OBJECTIVES: The Long-Acting Reversible Contraceptive (LARC) methods are recognised for their high efficacy rates and are widely prescribed throughout the UK. Despite their high upfront costs for treatment initiation, NICE deemed LARC methods to be more cost-effective than oral contraceptive pills even at one year of use (NICE CG30 2005). Further research is needed to assess the implications on unintended pregnancies and financial impact between two of the most commonly prescribed LARC methods, the etonogestrel implant and the medroxyprogesterone acetate injectable. METHODS: A 3 year time-horizon cost-comparison analysis was developed to assess the budgetary impact of using the implant compared to the injectable. The outcomes estimated are the difference in the number of unintended pregnancies and the associated financial impact. To facilitate comparison of the outcomes between these contraceptives, it is assumed that women are equally using the implant and the injectable. The calculation of the number of unintended pregnancies was based on typical failure rate for both methods. RESULTS: Using 2016 data, approximately 685,075 women aged 16-49 in the UK received either the implant or the injectable. Based on typical failure rates and equal usage of method, it is expected that over a three year period 52 and 1,028 unintended pregnancies will occur in women using the implant and the injectable respectively. Use of the implant versus the injectable resulted in 976 fewer unintended pregnancies and realised financial savings of £57,276,103; of which £55,680,715 is attributable to treatment costs (ingredient, consultations, removal/insertion costs) and £1,595,388 to the cost of unintended pregnancies (live birth, miscarriage, abortion, ectopic pregnancy). CONCLUSIONS: Although assuming equal shares between the implant and the injectable may not accurately reflect clinical practice; these results support the implementation of policies to increase the number of women on implants versus injectable to further prevent unintended pregnancies and realise associated cost savings.

PIH9: HOSPITAL BURDEN 18 MONTHS AFTER SURGICAL TREATMENT OF FUNCTIONAL MENORRHAGIA IN FRANCE

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OBJECTIVES: To assess the current hospital burden of functional menorrhagia surgically treated in France. METHODS: A retrospective database analysis was performed using the French exhaustive national hospital discharge database (PMSI). All hospital stays from 2009 to 2015 with 4 types of menorrhagia surgery identified by CCAM codes associated with ICC-10 codes were extracted. 2nd generation (2G), 1st generation (1G), curettage, hysterectomy. Only incident 35-55 year-old women were analyzed (no surgery since 2006). An algorithm was completed with the medical input of experts in order to exclude any patient identified as presenting comorbidities that would introduce bias in the results (breast or colorectal cancer, myoma, endometriosis...). Patients operated on before 2014/06/30 were followed at least 18 months from their surgery. Another algorithm and a medical review identified rehospitalizations related to surgery failure or complication. Hospital costs associated with these patients were estimated using the French official tariffs expressed in 2017 Euro. RESULTS: 7,863 patients with 2G (7%), 39,935 with 1G (36%), 38,923 with curettage (35%), 23,163 with hysterectomy (21%) were included. Whereas the global evolution was -13% from 2009 to 2015, it was +80% for 2G and +5% for 1G, and -37% for curettage and -15% for hysterectomy. The 18-month failure rate ran from 2.8% for hysterectomy to 9.9% for 2G, 12.7% for 1G and 20.6% for curettage, whereas the 18-month complication rate was 1.4% for curettage, 1.5% for 1G, 1.9% for 2G and 5.3% for hysterectomy. The trend was similar at 24 and 60 months. The 18-month median cost per patient varied from €782 [Q1 741-Q3 2,732] for curettage to €1,059 [913-2,075] for 1G, €1,173 [1,002-2,231] for 2G, €3,090 [2,909-4,189] for hysterectomy. CONCLUSIONS: This study shows that mini-invasive 1G and 2G techniques low complication rates and costs are in line with their recommended use at first stage.

PIH10: AGEING OF THE WORKING POPULATION AND DISABILITY INSURANCE: AN ECONOMIC AND DEMOGRAPHIC ANALYSIS ON THE DISABILITY BENEFIT IN ITALY

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OBJECTIVES: The aim of the study is to estimate the number of beneficiaries of disability benefits and the relative costs for chronic-degenerative pathologies (CDP). Furthermore, we analyze the demographic structure of the people who receiving for the first time a disability benefit as well as the association between the number of disability insurance awards (DIA) and the aging working population. METHODS: We analysed the database about the DIA and the mean cost for benefit of the National Institute of Social Security (INPS) for three types of social security benefits: incapacity pensions (for people without work ability), disability pensions and disability benefits (for people with reduced work ability). Also, we collected data for sex and age for the main groups of chronic-degenerative diseases. RESULTS: The model estimated for CDP a mean yearly cost for disability pensions from 2009 to 2015 of €4.7 billion with a decrease from 2009 to 2015 of 41.2%; a mean yearly cost of €2.4 billion with an increase of 34.1% for disability benefits and a mean cost of €856 million with an increase of 25.4% for incapacity pension. Age-specific rates of the older ages shows significant increases in all the period.A comparison of standardized rates reveals that demographic changes in the considered period have had a strong impact on the trend of the DIA, particularly for musculoskeletal disorders and cancer (CA). CONCLUSIONS: The most important indirect costs in Italy from 2009 to 2015 was represented by disability pensions (59% of the total cost), followed by disability benefits (29% of total indirect cost). Analysis and elaborations show a general tendency to increase the number of DIA between 1995 and 2015, particularly for CA. Both groups include highly disabling diseases that may continue to grow due to the population aging and absorb a growing amount of economic resources from the social security system.

PIH11: ANALYSIS OF REAL DATA FOR TREATMENT OF PRETERM BIRTH IN PREGNANT IN UKRAINE

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OBJECTIVES: In the world about 36% of infant deaths were due to preterm-related causes in 2013. In Ukraine, 7-9% pregnant women have a risk of preterm birth. We analyzed a real data from 102 medical records of pregnant women diagnosed with preterm birth. These patients were treated at the Lviv Regional Clinical Hospital during January-June 2016. METHODS: ABC/VEN analysis of prescribed drugs, analysis of direct cost on real schemes. RESULTS: It was established that for treatment of preterm birth 75 trade names of drugs and 2 supplements were prescribed. Generally, gynecologists prescribed 689 drugs in dosage forms for treatment of preterm birth. The direct costs for treatment of 102 women amounted to 75354.3 UAH (2571.8 Euros, 1 Euro=29.3 UAH), the average cost per patient was 738.8 UAH (25.3 EUR). The highest costs for treatment were on hormonal drugs. Direct costs for scheme by progesterone in dose 200 mg/day during 12 weeks ranged from 1415.7 UAH to 5006.7 UAH (48.32-170.87 EUR depending on trade name of drug per one pregnant woman. Average costs for drugs included in the recommendations were 6517.4 UAH (222.4 euro) and depending on the state of pregnancy. In Ukraine, the costs per
treatment are paid by pregnant women out of pocket, when the average salary is currently 4281.66 UAH (146.1 EUR). **CONCLUSIONS:** Analysis showed that the number of prescribed medications per 1 woman on average was 7 drugs, it is polypragmasy and risk for interactions and side effects for newborn. Real data confirmed the need to reduce the number of prescriptions for pregnant women and, accordingly, reduce the cost of treatment for preterm births. Necessary is a state funding for the costs on care for pregnant women.

### PIH12: PRESCRIPTION COSTS ASSOCIATED WITH A PEDIATRICIAN-LED CARE MODEL SERVING CHILDREN WITH MEDICAL COMPLEXITIES (CMC)

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**OBJECTIVES:** Children with medical complexities pose a unique challenge to systems, payers and providers because of the range of complexities they present with and the personnel, resource use, and cost attributed to their care. Innovative systems of care delivery may increase the quality of care for medically complex children, yet managing prescription costs remains a challenge due to rare disease states, lack of therapy options, and long-term therapy. Prescription cost patterns and expenditures for children with medical complexities were examined. **METHODS:** This was a retrospective secondary analysis of prescription drug claims using Texas Medicaid administrative claims data for patients with medical complexities (N=222) who were enrolled in the Specialty for Children pilot study. Patients were randomly assigned to receive care in a pediatrician-led care coordination system (treatment) or usual, current care (control) for a 2-year period. Average prescription costs were analyzed. **RESULTS:** A total of 222 patients with 16,398 drug claims over a 2-year period were included in the study. Average per member per month (PMPM) prescription costs of were $1,390 (SD= $265.88). When claims for the 96 (< 1 %) most costly prescriptions were removed, average PMPM costs were $726 (SD= $90.30) These costly medications were prescribed for 6 of the 222 children (2 Hemophilia, 2 Genetic Disorder, 2 Infantile Spasms). **CONCLUSIONS:** Medications for children with complex chronic conditions were high, with less than one percent of prescriptions making almost up half of the total prescription costs. Future research initiatives and policy decisions should carefully consider utilization patterns and costs for these patients.

### PIH13: COST-EFFECTIVENESS ANALYSIS OF LONG-ACTING RECOMBINANT FSH (CORIFOLLITROPIN ALFA) VERSUS RECOMBINANT FSH (FOLLITROPIN ALFA) IN ASSISTED REPRODUCTION TECHNIQUES IN THE MANAGEMENT OF INFERTILITY IN IRAN

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**OBJECTIVES:** Assisted reproductive technologies (ARTs) are well-established treatments for many types of subfertility representing substantial economic and healthcare implications for patients, healthcare providers and society as a whole. To help inform healthcare treatment practices and funding decisions an economic evaluation was conducted to compare the long-acting recombinant FSH (LA-FSH) and recombinant FSH (rFSH) in ARTs in the Iranian National Health Service in terms of cost-effectiveness. **METHODS:** A markov decision-analytic model was used to estimate cost-effectiveness ratios for ‘the incremental cost per additional live birth rate’ for women entering into in-vitro fertilization (IVF) treatment involving fresh and frozen cycles in any sequence (after the first fresh embryo transfer cycle) for a maximum of three cycles. The mean values of transition probabilities were derived from randomized controlled clinical trials and published reports. Cost data for procedures and drugs were derived and validated according to the perspectives of the National Health Service in Iran. A probabilistic sensitivity analysis was performed to deal with uncertainty and to construct a cost-effectiveness acceptability curve. **RESULTS:** The model predicted a live birth rate after three cycles of 27.3% for LA-FSH and 26.4% for rFSH. The cost of IVF treatment was $1868 for LA-FSH and $1882 for rFSH. As a result, treatment with LA-FSH was found to be the dominant treatment strategy in IVF because of improved live birth rates and lower costs. However, performing a probabilistic sensitivity analysis, the average costs per live birth of LA-FSH and rFSH were found not to be significantly different. Furthermore, deterministic sensitivity analysis indicated that the model is most sensitive to the LA-FSH drug acquisition cost. **CONCLUSIONS:** LA-FSH may represent a cost-effective choice compared with rFSH when used for ovarian stimulation in an Iranian National Health Service point of view.

### PIH14: TESTOSTERONE REPLACEMENT THERAPY AS AN ANTI-AGEING TREATMENT FOR MEN: A LITERATURE REVIEW AND ECONOMIC EVALUATION

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**OBJECTIVES:** Testosterone replacement therapy (TRT) is not yet approved for the treatment of low testosterone due to ageing alone. Despite this, a rapid growth of TRT use in older men has been reported, particularly in the
United States, aiming to improve bone mineral density, diabetes mellitus, sexual function, body composition and quality of life. This research aims to explore whether TRT is an effective anti-ageing treatment in men. Specific objectives include: to explore the impact of TRT on various morbidities associated with ageing men; to examine treatment factors of TRT (such as dose, treatment length) on its effectiveness; and to conduct an economic evaluation to assess the cost-effectiveness of TRT as an anti-fracture agent. METHODS: A comprehensive search of MEDLINE, PsycINFO and EMBASE was undertaken in October 2015 which identified 224 studies; studies were classified by the morbidity and clinical area investigated and categorised by evidence level. Randomised controlled trials were primarily used to assess treatment effectiveness. The economic evaluation compared intramuscular testosterone undecanoate to no treatment. Direct treatment costs were calculated and fracture risk reduction estimates (using FRAX® tool) made for a series of example patients with differing characteristics using an economic model. RESULTS: Treatment length, dose and administration route of TRT were important factors in bone mineral density changes. However, studies measuring changes in metabolic parameters of men with diabetes reported conflicting findings and there was little evidence of effectiveness regarding the other morbidities associated with ageing. Safety concerns regarding cardiovascular risk remain uncertain. TRT was not found to be a cost-effective anti-fracture treatment, with calculated costs per hip fracture avoided estimates ranging from £75,000-£600,000. CONCLUSIONS: The evidence base remains insufficient for TRT via any route to be confirmed as an effective anti-ageing treatment and so its use for this purpose should be limited at this time.

PIH15: A COST-EFFECTIVENESS ANALYSIS COMPARING THE ORIGINATOR RECOMBINANT HUMAN ALFA TO THEIR BIOSIMILARS FOLLITROPIN ALFA FOR THE TREATMENT OF INFERTILITY

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OBJECTIVES: Bioequivalence of the two recent Biosimilars of recombinant human FSH (r-hFSH) has been demonstrated on the number of oocytes retrieved but not on the final outcome of interest for women concerned, the number of live births. Objective of this analysis is to assess the cost-effectiveness (CE) of the originator r-hFSH compared to the two biosimilars available in producing live births in patients undergoing a medically assisted reproduction program from a French perspective. METHODS: An Excel-based decision-tree model depicting the different relevant outcomes of fertility treatment with r-hFSH over the 1st cycle was developed (including ovarian hyperstimulation syndrome, OHSS). Clinical and safety outcomes were derived from head-to-head clinical trials evidence provided for the 2 new Biosimilars of r-hFSH European registrations. Resources considered were based on French Health Insurance data; on French comprehensive national hospital database analysis and on French clinical experts opinions through a management questionnaire. A National Health Insurance perspective using official French tariffs (£2017) were considered. In order to test the robustness of results, deterministic sensitivity analyses were carried out on the main variables. RESULTS: Treating 100 women with originator r-hFSH resulted in 5 to 9 additional live births compared to the two biosimilars (6 if pooled data are considered). The additional total cost per woman treated with originator r-hFSH ranged from +£259 (for one biosimilar and pooled) to +£279 (for the other biosimilar). The incremental CE ratio (£ per additional live birth) ranged from 3275, 4352 to 4804 (versus 1st biosimilar, pooled and 2nd biosimilar respectively). Analysis included OHSS. All sensitivity analyses carried out support these results. CONCLUSIONS: Originator r-hFSH is a cost-effective strategy compared to biosimilars whatever the consideration or not of OHSS. This present CE model is based on clinical trials evidence. It would be of interest to carry out further investigations using French real world evidence (RWE) to confirm these results.

PIH16: THE COST-EFFECTIVENESS OF IVF TREATMENTS GONAL-F® VERSUS HP-HMG IN THE UNITED ARAB EMIRATES (UAE)

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OBJECTIVES: In the UAE, infertility rate is about 2.2%, with growing incidence. In-vitro fertilization (IVF) is one of the commonly used techniques in the UAE for the management of infertility. This study assessed the cost-effectiveness of recombinant human follicle-stimulating hormone (rFSH, Gonal-f®) with highly purified human menopausal gonadotrophin (HP-HMG) for ovarian stimulation in IVF treatment in the UAE. METHODS: A decision tree combined with a Markov model was developed, simulating each step in the IVF protocol from the start of therapy until either live born, new IVF treatment cycle, or stopping IVF (ovum pickup, fertilization, embryo transfer and life born). Differentiation between Gonal-f and HP-HMG was based on a published meta-analysis. Three settings were
considered that included 1) fresh transfer only, 2) combined fresh transfer and freeze oocytes, and 3) combined fresh transfer and freeze embryos. Costs are listed as 2016 AED. The model was validated by expert gynecologists from the UAE RESULTS: Gonal-f® was cost-effective over HP-hMG with lower average treatment costs and higher live births per patient in all three settings. In setting 1 average treatment cost was estimated at 51,935 for Gonal-f® and AED 52,371 for HP-hMG. The probability of live born per patient with Gonal-f® was 0.235 versus 0.233 with HP-hMG. In setting 2, these costs were AED 55,715 and AED 56,142, for Gonal-f® and HP-hMG, along with increased probability of live born (0.243 and 0.241, respectively). Setting 3 had lowest average treatment cost of AED 48,080 and AED 48,822 and highest probability of live born, 0.307 and 0.303, for Gonal-f® and HP-hMG, respectively. Sensitivity analysis showed the robustness of the results. CONCLUSIONS: Gonal-f® may represent a cost-effective option compared with HP-hMG for ovarian stimulation for IVF treatment in the UAE.

PIH17: COST-EFFECTIVENESS ANALYSIS OF FOUR SURGICAL STRATEGIES FOR THE TREATMENT OF FUNCTIONAL MENORRHAGIA IN FRANCE

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OBJECTIVES: Functional menorrhagia is responsive of significant economic burden, as its initial management is based on surgical strategies and implies hospitalization in case of failure or severe complications. The objective of this study is to compare 4 surgical strategies used for the treatment of functional menorrhagia in terms of costs and failure or complication avoided. METHODS: A retrospective database analysis was performed using the French exhaustive national hospital discharge database (PMSI). All hospital stays from 2009 to 2015 with 4 types of menorrhagia surgery identified by CCAM codes associated with ICD-10 codes were extracted: 2nd generation (2G), 1st generation (1G), curettage, hysterectomy. Only incident 35-55 year-old women were analyzed (no surgery since 2006). Rehospitalizations related to surgery failure or severe complication were followed during at least 18 months. Hospital costs associated with these patients were estimated using the French official tariffs expressed in 2017 Euro. A cost-effectiveness analysis was performed comparing each surgical procedure to 2G, in terms of cost and rate of failure or severe complication avoided. RESULTS: 7,863 patients with 2G (7%), 39,935 with 1G (36%), 38,923 with curettage (35%), 23,163 with hysterectomy (21%) were included. Mean cost per patient was respectively €4,285 for curettage, €6,064 for hysterectomy, €4,182 for 2G and €3,765 for 1G. Failure or complication occurred in respectively 17.9%, 30.6%, 10.1% and 21.5% of patients treated by 2G, curettage, hysterectomy and 1G. As compared to 2G, curettage was dominated (less effective and more expensive), hysterectomy was more expensive and more effective (ICER = €24,128 per % patient with failure or complication avoided) and 1G was less effective and less expensive (ICER = €11,583 per % patient with failure or complication avoided). CONCLUSIONS: This study shows 1G and 2G techniques are cost-effective, in line with their recommended use at first stage in France.

PIH18: PROBABILISTIC COST-UTILITY ANALYSIS OF PERGOVERIS IN WOMEN PATIENTS UNDERGOING IVF

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OBJECTIVES: the aim of this analysis is to compare the effectiveness of recombinant FSH (rFSH) + recombinant LH (rLH) and human menopausal gonadotropin (hMG) controlled ovarian stimulation protocols in a well-defined subgroup of patients that underwent IVF in Italy. METHODS: a probabilistic decision tree was developed to simulate the therapeutic path of a cohort of patients undergoing IVF, according to a rFSH + rLH or hMG controlled ovarian stimulation protocol. The model considers National Health System (NHS) perspective and a time horizon equal to two years with simulations of biannual cycles and a maximum of 3 therapy cycles. A one-way sensitivity analysis and a Probabilistic Sensitivity Analysis (PSA) were conducted to take into account the variability of the results based on the parameters considered in the analysis. RESULTS: the model estimated that patients undertaking therapeutic protocol with rFSH + rLH, have advantages than the women undertaking a protocol with hMG, both in terms of waiting time (13.2 months vs 13.5 months for pregnancy and 7.2 months vs 7.5 months for the test positivity respectively) and in terms of general success rate (23.6% vs. 17.0% - P < 0.001 for pregnancy and 28.2% vs. 20.6% - P < 0.001 for positive tests respectively). The model estimated that, at the end of the analysed period, the ICER per QALY values are below a willingness to pay of €20 – €40,000. The simulations showed, for patients with ≥ 10 and ≤ 15 retrieved oocytes, that with a willingness to pay of €15,000/QALY the probability that rFSH + rLH therapeutic protocol is cost-effective respect to therapeutic protocol hMG is higher than 80%. CONCLUSIONS: the cost-utility analysis demonstrated that the rFSH + hMG combination in controlled ovarian stimulation protocol in the IVF patients may be an opportunity from both economic and quality of life perspective.
**PIH19: FACTORS ASSOCIATED WITH MEDICATION ADHERENCE IN KOREAN POSTMENOPAUSAL OSTEOPOROSIS(PMO): RESULTS FROM PMO OUTCOMES RESEARCH(OR)**

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**OBJECTIVES:** This analysis was proposed to investigate factors associated with medication adherence in PMO patients of Korea. **METHODS:** Data in this analysis were from PMO OR, a cross-sectional study from March 2013~July 2014 with 29 participating general-hospitals. Patients’ demographic, clinical characteristics, and treatment patterns were collected from medical chart review, and patient-reported outcomes on treatment satisfaction and medication adherence were measured by 14-item Treatment Satisfaction Questionnaire for Medication(TSQM) and Osteoporosis-Specific Morisky Medication Adherence Scale(OS-MMAS), respectively. Multiple logistic regression analysis was conducted to investigate factors associated with adherence(Low-adherence; OS-MMAS score<8, high-adherence; score=8). **RESULTS:** Of total 1,804 patients(mean age 62.33±10.90 years) receiving PMO prevention or treatment, only 27.4% were practicing high adherence. Of total, 59.7% were using bisphosphonate(BPP) with majority taking drug usage of ‘Once a week’(718 patients, 67.2%). Remaining 27.7% were taking hormone-therapy(HT) with drug usage of ‘Once a day’(495 patients, 100.0%) and 12.6% taking selective-estrogen receptor modulator(SERM) with drug usage of ‘Once a day’(495 patients, 100.0%). As a result of multivariable analysis, family history of osteoporosis(OR=0.607, 95%CI:0.424-0.870), longer treatment duration(OR=0.998, 95%CI:0.997-0.999), experience of GI symptom(OR=0.666, 95%CI:0.496-0.896), drug usage of ‘once a week’(OR=0.367, 95%CI:0.242-0.556) and ‘once a day’(OR=0.485, 95%CI:0.284-0.829) compared to ‘once a month’, were negatively associated with adherence, while higher convenience score from TSQM was positively associated with adherence(OR=1.034, 95%CI:1.022-1.046). Per treatment pattern, use of HT(OR=0.732, 95%CI:0.198-0.730) compared to BPP was negatively associated with adherence. There was no significant difference in adherence between SERM and BPP. **CONCLUSIONS:** Among the identified factors associated with medication adherence from this study, choice of treatment agent, frequency of drug usage, and considerations for patients’ GI symptoms are adjustable during the course of treatment. Such strategic adjustments are critical for providing effective PMO treatment.

**PIH20: CROSS BORDER REPRODUCTIVE CARE: PROFILE AND INCENTIVES OF WOMEN TRAVELLING TO GREECE FOR IVF TREATMENT**

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**OBJECTIVES:** To map the profile of travellers for IVF treatment from the UK to Greece, to investigate the incentives that forced them to seek IVF treatment abroad and to understand the reasons for the selection of Greece. **METHODS:** The study sample consisted of 91 women from the UK who visited Greece during 2010-2015 in order to receive IVF treatment. A cross-sectional study was carried out using an anonymous electronic questionnaire developed by the researchers, which was personally e-mailed to each participant and included 24 close-ended questions. **RESULTS:** The study population consisted mostly of white women (81.3%), heterosexual (92.3%), married (64.8%), of higher educational and economical status and a mean age of ~40 years old. Overall, 67 women had eventually a positive pregnancy test, while the multiple pregnancy rate was 20.9%. The most predominant motivations for seeking treatment abroad was the high cost of treatment at home country (69.2%), dissatisfaction of previous treatment at the home country (62.2%), high cross-border success rates (60.4%) and the desire for multiple embryo transfer (47.3%). 59.3% of the women reported that they chose Greece due to the clinic’s high success rates, 51.6% due to economic costs and 50.5% due to the quality of care, with a statistically significant correlation between the choice of donor treatment and anonymity (p=0.002) and availability (p <0.001). 89.9% of the women would recommend Greece for IVF treatment, while 74% stated that treatment in Greece was better suited to their needs. **CONCLUSIONS:** The cost and the quality of treatment are raised as crucial reasons for medical tourism and choosing Greece for IVF treatment, although incentives are personalized for every woman according to their socio-demographic and medical background. Alongside with the globalization of IVF, the need for a framework of effective cooperation between countries has become even more evident.
PIH21: PATIENTS’ PREFERENCES RELATED TO TREATMENTS FOR ENDOMETRIOSIS-RELATED PAIN: RESULTS OF A DISCRETE CHOICE EXPERIMENT IN THE UK

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OBJECTIVES: To generate evidence on patient preferences concerning medication attributes among UK patients with endometriosis-related pain. METHODS: An online discrete choice experiment among endometriosis patients diagnosed 0.5-10 years ago and without confounding pain conditions. Attributes and levels were defined from literature search, expert and patient interviews. The design included 12 choice sets, each consisting of two alternative fictitious treatments and a No treatment option. A pilot study was conducted and a subset did a cognitive-debriefing interview. A D-efficient design was used for the full study. Analyses included a conditional logit model with interactions. RESULTS: The attributes following qualitative research were: mode of administration, ability to conceive, worst level of (i) pelvic pain, (ii) period pain, (iii) pain during intercourse, need for pain medication (days/month), fracture risk and out-of-pocket costs. Following pilot analysis (n=30) and patient interviews (n=10), minor wording and format changes were made. The full study included 200 participants. Participants’ average age was 32.5 (19-42), 58.5% used hormonal contraceptives, 71% wanted (more) children, and 45% were dissatisfied with current pain treatment; 78% of patients always took pain treatment during their periods, 78% reported a period pain-level of 7-10. Of pain types, period pain had the most influence; patients’ WTP was £36.39 for a period pain-level of 4-6. “Ability to conceive” was valued at £20.51/month and participants preferred options without fracture risk (£13.51/month). Both of these are limitations with current treatments. Treatment at a lower cost was preferred, as were oral tablets over vaginal rings and weekly injections. CONCLUSIONS: The most important pain type was period pain, perhaps influenced by the fact that 75% of participants experienced severe period pain. Overall lack of preference for vaginal rings should be interpreted with caution as interviews highlighted patients’ lack of awareness of this device. A treatment allowing patients to conceive was appreciated.

PIH22: DEVELOPMENT OF A SCREENING QUESTIONNAIRE TO DETECT HEAVY MENSTRUAL BLEEDING IN WOMEN OF CHILD-BEARING AGE

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OBJECTIVES: Heavy menstrual bleeding (HMB) affects up to 30% of women at some point in their lives, having an important impact on their HRQoL. Nevertheless, the complexity of its management, due to the inconvenience of the techniques to assess the real blood loss and the poor correlation between blood loss and women perception, is currently a problem for both women and HCPs. This study aims to develop a screening questionnaire to easily identify HMB in women of reproductive age. METHODS: This study consists of two phases: the conceptual development of a set of items candidates to discriminate those women with HMB (current abstract) and the assessment of their sensitivity and specificity to detect HMB. An extensive literature research was done to find scales and items previously used to detect abnormal uterine bleeding or impact of HMB in HRQoL. Then, a workshop session was conducted with a committee of 12 gynecologist experts in HMB, in order to elicit new items, select from available items or redefine them. Cognitive interviews were held with 10 women with HMB and results were presented and discussed with the expert committee to develop a final revised version of the questionnaire. RESULTS: Literature review identified 46 different items of which the scientific committee selected 27 questions. Following the results of the cognitive interviews, 9 questions were erased, 8 questions were redefined and 3 new questions were added. At the end, a questionnaire of 21 items was developed: 7 of the items are related with quantity of bleeding and 14 items are related with the impact of HMB in their daily activities. CONCLUSIONS: A questionnaire of 21 items has been developed to screen women with HMB. This questionnaire is currently under psychometric validation to assess its sensitivity and specificity to detect HMB, as a second phase of this study.

PIH23: PATIENT-REPORTED OUTCOME MEASURES FOR WOMEN WITH VULVODYNIA

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OBJECTIVES: Vulvodynia has a profound effect on several domains of women’s quality of life (QoL). This study compared vulvodynia-specific patient-reported outcome measures (PROMs) for use in clinical studies. METHODS: Semi-structured interviews with 27 stakeholders including clinicians and payers from France, Germany, Spain, UK, Italy, and USA were conducted to identify important QoL domains to assess impact of vulvodynia in clinical studies. Subsequently, a narrative synthesis was conducted to appraise the vulvodynia-specific
PROMs extracted from a narrow review of literature. The PubMed was the primary source of the search. Manual search on reference lists was then used to identify additional PROMs. RESULTS: A desired vulvodynia-specific PROM from stakeholders’ perspectives should measure vulvar pain’s impact on patient’s life in several aspects such as sexual functioning, daily activities (ability to use tampon, wear tight pants), social functioning, and mental health. Six PROMs were included including Vulvar functional Status Questionnaire (VQ); vulvar-specific Skindex-29; Vulvovaginal Symptoms Questionnaire (Vsq); Vulvar Pain Assessment Questionnaire inventory (VPaq); PROMIS SexFS v2 vulvar discomfort scales (PROMIS SexFS VDS); and Pelvic Pain Impact Questionnaire (PPIQ). The VPaq inventory is the most comprehensive PROM that offers 5 scales for use in screening, measuring quality of pain, coping, and partner factors. All PROMs are self-administered with a number of items from 4 (PROMIS SexFS VDS) to 63 items (VPaqFull). While the VPaq inventory is the most comprehensive PROMs, it is considerably long (VPaqScreen-33 items). The PROMIS SexFS VDS is the shortest but focuses on discomfort and sexual functioning. The PPIQ is short (8 items) and covers important Qol domains impacted by vulvodynia. While validity and reliability were established, responsiveness data were lacking for these PROMs. CONCLUSIONS: Although several vulvodynia-specific PROMs are available, clinical responsiveness information has been lacking. Researchers should test these instruments in clinical trials before adopting them in clinical practice environment.

PIH24: MEDICATION RELATED QUALITY OF LIFE AMONG ETHIOPIAN ELDERLY PATIENTS WITH POLYPHARMACY: THE CASE OF NORTH GONDAR ZONE

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OBJECTIVES: We aimed to assess medication related quality of life (MRQOL) among elderly patients with polypharmacy at Gondar University Hospital, Gondar, Ethiopia. METHODS: A prospective cross sectional study was carried out among 150 elderly patients in internal medicine and ambulatory wards of Gondar University hospital from March 25 to May 15 2017 using validated scale, Medication-Related Quality of Life Scale version 1.0 (MRQoLS-v1.0). RESULTS: A total of 150 elderly patients with poly pharmacy participated in the study with a mean age 70.06 5.12 and two third of the participants (67.3%) were female. Overall prevalence of poor quality of life due to polypharmacy in the current study was found to be 75.3% of the participants. Regarding severity of impairment in MRQoL, Univariate analysis revealed that frequency of hospital visits (COR=1.34, 95% CI, 1.02-1.77) and number of medications (COR =1.94, 95% CI, 1.33, 2.8) had statistically significant positive association with the likelihood of having severe impairment. The multivariate analysis also showed that one unit increase in the number of hospital visits (AOR =1.45, 95% CI, 1.040-2.024) and medications greater than 5 (AOR =1.91, 95% CI, 1.29, 2.84) increases 1.45 and 1.91 times the likely hood of posing severe impairment of MRQoL, respectively. As far as poor MRQoL quality of life is concerned multivariate analysis didn’t show any significant association between the poor MRQoL, and Sociodemographic and clinical data of patients. CONCLUSIONS: The overall prevalence of poor quality of life due to polypharmacy was 75.3% that implies polypharmacy results poor quality of life in elderly patients. Frequency of hospital visit and number of medication was the independent predictors for severe impairment in MRQoL. This study needs further investigation to see the correlation between independent variables and dependent outcomes. Deprescribing aiming at minimizing inappropriate poly pharmacy should be sought by physicians in elderly patients.

PIH25: PATIENT AND CAREGIVER BURDEN IN CONGENITAL ADRENAL HYPERPLASIA (CAH) IN CHILDREN: RESULTS OF A STRUCTURED LITERATURE REVIEW

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OBJECTIVES: CAH are rare autosomal-recessive disorders affecting cortisol biosynthesis, and characterised by elevated androgen levels and ambiguous genitalia in affected females. In infancy, CAH can cause adrenal insufficiency (AI), a life-threatening condition potentially leading to adrenal crisis. We performed a literature review to identify the burden of CAH and AI of CAH origin, focusing on humanistic and caregiver burden for children. METHODS: A structured, comprehensive literature review was conducted to identify articles describing the burden and treatment landscape of CAH. Literature databases, websites and conference proceedings were searched. Eligible articles reported CAH or AI of CAH origin, and provided data on ≥1 topic of interest (epidemiology; natural history; clinical characteristics; humanistic, caregiver and economic burden; treatment options; or clinical guidelines). RESULTS: A total of 2,204 citations were identified, and 226 included in the final review, of which 17 reported humanistic (n=10) or caregiver burden (n=7) for children with CAH (aged 0-18 years; focus on 0-6 years, where reported). None reported humanistic/caregiver burden for children with AI. Children with CAH had significantly (p<0.05) lower quality of life than healthy children, when self- and parent-reported in three studies. CAH was associated with significantly (p≤0.01) higher rates of anxious/depressive, withdrawn/depressive, and aggressive behaviours. Four studies reported issues with sexuality and gender identity. Several studies reported substantial
caregiver burden associated with paediatric CAH. Key findings were: caregivers experienced depression (59%); and 61-79% of parents reported concerns over their child’s development. For children aged <6 years, key findings were: caregivers experienced "latent anxiety", and disruption to daily routines and work life; 61% of parents reported social out-casting as their biggest concern for their child; and 46% of parents interviewed described their own/families’ time as severely affected by having a child with CAH. CONCLUSIONS: This comprehensive review highlights that paediatric CAH is associated with substantial patient and caregiver burden.

**PIH26: EUROPEAN STUDY ON ACUTE COUGH IN CHILDREN: RESULTS OF POLAND**

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**OBJECTIVES:** Cough represents the first reason of a viral infection of upper airways for consulting a general practitioner (GP) for pre-school children. Although it is a benign symptom, cough can have a significant impact on children’s and parent’s life. This research aimed to investigate the personal, familial and social impact of acute irritative or mixed cough in infant and children. **METHODS:** A prospective, multicenter, observational study with a one week follow-up was conducted in children and infants suffering from common upper respiratory infections, consulting pediatricians or GPs in Poland. Impact of cough on children’s and parent’s sleep and on children’s scholastic and sport activities was assessed using the Paediatric Cough Questionnaire (PCQ). Parents’ satisfaction of cough management was evaluated using the Client Satisfaction Questionnaire (CSQ). **RESULTS:** 474 patients were included and fully followed until Day 7. 51.1% were boys and mean age was 3.0 (±1.5) years. Recurrent ear-nose-throat infections were reported for 39.7% of patients, respiratory disease for 34.4% and allergies for 20.9%. Child regularly in contact with the following known risk factors: smokers, pets and carpets were respectively 26.7%, 42.2%, 69.2%. At D0, 33.6% of parents declared having interrupted child care arrangement for 2.8 (±2.0) days and 21.7% declared having been absent of work for 3.1 (±2.2) days since the onset of cough. The impact of cough decreased significantly from 23.5% to 2.7% (grouped answers “Moderately or A lot” to the 4 questions of the PCQ, p<0.0001). The distribution of intensity of cough, respectively “Mild/Moderate/Severe", improved from 24.5%/52.6%/22.8% at D0 to 88.7%/8.5%/2.8% at D7. CSQ score was 28.3 (±2.9) out of a maximum of 32 at D7. **CONCLUSIONS:** The study has shown that cough in infant and children has a heavy impact on patients and their parents life and has to be recognized as a major family burden.

**PIH27: QUALITY OF LIFE OF PREGNANT WOMEN IN RUSSIAN FEDERATION**

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**OBJECTIVES:** to evaluate the quality of life (QOL) of pregnant women with general questionnaire EQ-5D. **METHODS:** Base - perinatal center of City Clinical Hospital E.O. Mukhina Moscow. Study period: September 2016 - January 2017. Design:anonymous retrospective questioning of pregnant women. The questionnaire included questions about age, place of residence, term of labor, number of previous pregnancies and EQ-5D part. Mathematical, statistical and analytical methods were used **RESULTS:** 235 patients aged from 18 to 43 years (av.age 29.4 ± 4.6 years) were questioned/ Most of them 188 (80%) live in Moscow, 47 (20%) - in the Moscow region. The average term of labor was 39 ± 2 weeks. 99 (42%) had first pregnancy, 82 (35%) - the second, 31 (13%) - the third, in 24 (20%) - 4 or more pregnancies. 160 patients (68%) had no problems with movements, moderate difficulties were noted in the remaining 75 (32%) of the respondents. Also, the majority - 193 (82%) didn’t experience difficulties with self-service, 42 (18%) experienced moderate difficulties. Daily activity wasn’t impaired in 153 (65%) patients, and 82 (35%) had some problems with the daily routine. 60 respondents (25.5%) didn’t complain about pain and discomfort during pregnancy, more than half: 155 (66%) experienced moderate pain and discomfort. 20 (8%) of the women surveyed experienced severe pain and discomfort. Only 49 respondents (20%) didn’t experience anxiety and depression, 136 (57%) noted a slight anxiety, in 30 women (13%) these feelings were strongly pronounced. The average score of QOL measured with the visual analogue scale (VAS) was 0.76 ± 0.15. Data of QOL were higher in patients attened special group for physical exercises during pregnancy (p<0.05). **CONCLUSIONS:** in most cases there were no changes in physical activity of patients, psycho-emotional changes, such as anxiety and depression, pain and discomfort were noted. It can be improved by physical activity.

**INDIVIDUAL’S HEALTH - Health Care Use & Policy Studies**

**PIH28: TRADITIONAL AND COMPLEMENTARY MEDICINE IN PREGNANCY AND POSTPARTUM: REASONS AND PERCEPTIONS**
OBJECTIVES: The use of traditional and complementary medicine (T&CM) has been drastically increased among Malaysians. This study aims to determine the reasons of and perceptions on T&CM use during pregnancy and postpartum period. METHODS: A cross-sectional study was conducted using self-administered, close-ended questionnaires and open-ended questions for additional comment(s) or suggestion(s). Data of 374 women were analysed and represented via descriptive statistics. RESULTS: Participants with history of complication(s) during or after delivery were more likely to use T&CM (n=62, 87.3%). The most popular reason for T&CM use was to aid postpartum recovery (n=226, 79.3%). Majority of the participants agreed that T&CM is safe because it is derived from natural sources (n=186, 49.7%), they would try T&CM as a result of convincing testimonies (n=180, 48.1%), support other women who want to use T&CM (n=185, 49.5%), and consult with healthcare providers before practicing T&CM (n=190, 50.8%). Almost half of the participants were unsure about using T&CM due to the lack of clinical evidence (n=187, 50.0%) and strongly agreed that the government should ensure the quality and a safe use of T&CM (n=166, 44.4%). CONCLUSIONS: Many women are practising T&CM although they are aware that there are insufficient evidences on its benefits. Therefore, it is pivotal to have more studies to be done on the safety and efficacy of T&CM in Malaysia.

PIH29: BARRIERS TO THE INTRODUCTION OF ACTUAL TECHNOLOGIES FOR INDUCTION OF LABOR MANAGEMENT

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OBJECTIVES: Taking into account the fact that in the world, including Ukraine, the frequency of weakness of labor activity tends to increase (from 8% to 17% of the total number of births), and the frequency of emergency abdominal delivery due to abnormality of labor is also increasing, it is necessary to implement effective preventive obstetric technologies. One of such technologies is induction of labor activity, the main purpose of which is to prepare cervix before delivery. Prostaglandins remain the single most effective method for achieving ‘maturity’ of cervix and induction of labor in combination with timely amniotomy and provide positive clinical effects and patient satisfaction. METHODS: A multidisciplinary working group of specialists in the field of obstetrics and gynecology, as well as WHO experts in the field of reproductive health, take part in the development of medical and technological documents on ‘Induction of labor’. The method of synthesis of scientific sources (randomized controlled trials, systematic reviews, meta-analysis) of the international database for the applying of high-quality technologies was used in the work. RESULTS: As a result, it was considered appropriate to use misoprostol and mifepristone for cervix ripening and induction of labor as a modern technologies with proven efficacy. It should be noted that misoprostol and mifepristone are included in the Essential Medicines WHO Model List for use in delivery. However, in Ukraine these agents are not licensed for induction of labor, therefore can’t be implemented in practice. CONCLUSIONS: Existing methods of induction of labor do not always give the desired result. One of the barriers is the discrepancy between the instructions of the medicinal product of one manufacturer, licensed in different countries. This requires coordination and harmonization of regulations and standards with the best world practice for improving the quality of medical care for patients during delivery.

PIH30: EFFECTS OF PROPOFOL VERSUS OTHER GENERAL ANESTHESIA IN CHILDREN YOUNGER THAN 3 YEARS OF AGE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: The use of propofol in general anesthesia in children less than 3 years of age remain off-label in many countries because its safety and effectiveness have not been established. We performed a systematic review to evaluate propofol anesthesia in young children. METHODS: A comprehensive literature search was conducted in three databases to find all randomized clinical trials of propofol versus any other agents for general anesthesia conducted with children under 3 years old. RESULTS: A total of 14 papers from 12 unique randomized controlled trials were included. Induction of anesthesia with propofol was compared to thiopentone, sevoflurane, and halothane in eight articles and maintenance of anesthesia with propofol was compared to sevoflurane and dexmedetomidine in four articles. Two studies compared propofol to dexmedetomide for both induction and maintenance. Achievement of adequate intubation condition was significantly lower in the propofol treated group (RR 0.82, 95% CI 0.48 – 0.81). Regarding hemodynamic responses after the induction, treatment effects differed by control. The propofol group...
showed higher mean blood pressures compared to sevoflurane, but yielded lower blood pressures than thiopentone and dexmedetomidine. It also demonstrated higher heart rates than the dexmedetomidine, while showing lower heart rates than thiopentone and sevoflurane. In overall, there were tendencies to lower minimum mean arterial pressures and heart rates after the induction in propofol group than controls (MBPs: -3.00, 95% CI -7.84 ~ 1.85; HRs: -6.91, 95% CI -17.21 ~ 3.39). Adverse events including desaturation, apnoea, postoperative nausea and vomiting, and emergence agitation, did not differ significantly. Recovery times including time to extubation, eye opening, and emergence also did not differ significantly. CONCLUSIONS: A meta-analysis showed that propofol did not significantly lower hemodynamic responses than other general anesthetic agents. Profiles of adverse events and times to recovery of propofol group were not significantly different from those of the controls.

### PIH31: MEDICATION USE DURING PREGNANCY IN THE NETHERLANDS: A POPULATION-BASED STUDY

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**OBJECTIVES:** The objective of this study was to assess medication use during pregnancy in a population-based setting in the Netherlands. **METHODS:** A cross-sectional analysis was conducted using pharmacy dispensing records linked to pregnancy records. Community pharmacy dispensing records were obtained from the Out-patient Pharmacy Database of the PHARMO Database Network (PHARMO) – a population-based network of electronic healthcare databases combining data from different healthcare settings in the Netherlands. Pregnancy records were obtained from the Perinatal Registry of the Netherlands (Perined) – a nationwide registry containing maternal and neonatal characteristics and data on perinatal care. Pregnancies between 1999 and 2015 of women registered in Perined as well as PHARMO were included in the study. Use of unsafe medication was defined according to 5 categories of the Dutch classification of medication in pregnancy: A) medication with pharmacological effects that (A1) should be monitored when used or (A2) should be (temporarily) avoided: B) medication with teratogenic effects that (B1) should be monitored when used or (B2) should be (temporarily) avoided and C) medication with unknown risks due to insufficient experience. **RESULTS:** The PHARMO-Perined cohort included 475,332 pregnancies of 343,783 women (mean (±SD) age at delivery 30.3 (±4.8) years, 81% with Dutch ethnicity). A total of 335,017 (70%) pregnancies were identified during which women were dispensed medication at least once. Among all pregnancies, 137,893 (29%) were exposed to unsafe medication with the highest use for medication in category C (79,416 pregnancies, 58%) followed by category A2 (48,584 pregnancies, 35%), category A1 (38,084 pregnancies, 28%), category B2 (13,094 pregnancies, 9%) and category B1 (1,952 pregnancies, 1%). **CONCLUSIONS:** Nearly one third of all pregnancies were exposed to medication not indicated as safe. Future interventions in the Netherlands should focus on the prevention of unsafe medication use during pregnancy.

### PIH32: VERY LOW COMPLIANCE FOR VULVOVAGINAL ATROPHY (VVA) TREATMENT: A RETROSPECTIVE U.S. HEALTHCARE CLAIMS DATABASE ANALYSIS

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**OBJECTIVES:** Vulvovaginal atrophy (VVA) or genitourinary syndrome of menopause (GSM) is a highly prevalent and underreported condition in post-menopausal women. Symptoms classically include pain at sexual activity, vaginal dryness, irritation, and urinary symptoms. The study objective is to characterize compliance to current VVA treatments. **METHODS:** VVA women (ICD9: 627.3, 625.0), aged 45+, and continuously enrolled 365 days before (baseline period) as well as after first VVA diagnosis with no VVA treatment during the baseline period were selected from the Truven Health MarketScan® Databases (01/2010-06/2015). VVA treatments included intravaginal estradiol cream (EC), conjugated estrogens (CE), estradiol tablet (ET), and estradiol ring (ER), as well as oral ospemifene (OS – introduced 2013). Compliance and treatment rates were assessed during the first year following initial VVA diagnosis. Treatment discontinuation was assessed using Kaplan-Meier from initial dispensing to discontinuation (60 untreated days), switch, or end of data availability. A switch was defined as the start of a different treatment anytime from initial dispensing and up to 60 days following discontinuation. **RESULTS:** From 203,310 VVA women, 69,066 (34.0%) had ≥1 treatment during the one-year following initial VVA diagnosis: EC(42.3%), CE(34.0%), ET(19.2%), ER(3.4%), and OS(1.1%). On average, treatment was initiated 29 days after VVA diagnosis (SD=69.9 days, median=0 day). 74.3% of women received only one dispensing anytime after VVA: CE(82.1%), EC(80.8%), ER(53.2%), ET(51.9%), and OS(41.5%). Discontinuation at 3, 6, and 12 months was 86.8%, 89.7%, and 95.1%, respectively. Only 3.7% switched to another treatment. All results are similar when stratified by year of VVA diagnosis or age. **CONCLUSIONS:** This study shows that about only one third of women initiated therapy in the year following first VVA diagnosis and that close to 75% abandoned treatment after their first dispensing and 95% of them within one year. These results highlight the serious unmet need in the treatment of VVA.
PIH33: DISCLOSURE OF TRADITIONAL AND COMPLEMENTARY MEDICINE USED DURING PREGNANCY AND THE POSTPARTUM PERIOD TO HEALTHCARE PROVIDERS

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OBJECTIVES: Although the high prevalence of traditional and complementary medicine (T&CM) used during pregnancy and the postpartum period has been well documented, not a single study in Malaysia has been carried out to evaluate the communication between these women and their healthcare providers regarding T&CM use. Therefore, this study aims to identify the disclosure of T&CM use by pregnant and postpartum Malaysian women to their healthcare providers. METHODS: In-depth qualitative interviews were carried out on all three major Malaysian ethnic groups: Malays, Chinese and Indians until the saturation point for this study was achieved. Framework analysis observed three themes in this study: disclosure rate among participants, reasons for T&CM use disclosure, and reasons for T&CM use non-disclosure. RESULTS: A majority of the participants disclosed their T&CM use and agreed that disclosure of T&CM use to healthcare providers is important to avoid any complications during pregnancy and postpartum from happening or worsening. The lack of concern by healthcare providers towards T&CM use, the perception that T&CM will not disrupt conventional medicines and the assumption that T&CM is safe to use due to its practice which has been passed down from generation to generation were the most popular reasons for non-disclosure of T&CM use. CONCLUSIONS: This study reveals that communication between T&CM users and healthcare providers about the integration of traditional and conventional practices is crucial due to the interactions which might occur. Hence, awareness studies regarding T&CM use is urgently needed in Malaysia to bridge the gap between T&CM users and healthcare providers.

PIH34: A MULTI-DIMENSIONAL ASSESSMENT OF THE CONSERVATIVE TECHNOLOGIES USED FOR THE TREATMENT OF UTERINE FIBROIDS IN ITALY

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OBJECTIVES: An innovative diagnostic procedure (MRgFUS) is used for the treatment of uterine fibroids (UF), a disease affecting 13.80% of all ages Italian women. The study aim was a multi-dimensional evaluation of the benefits concerning the introduction of MRgFUS, in comparison with conservative procedures: myomectomy, and uterine artery embolization (UAE). METHODS: In 2017, a Health Technology Assessment was conducted at the Lombardy Region perspective. Data were gathered using specific questionnaires, self-reported interviews and systematically searching medical literature, considering the 9 EUnetHTA dimensions and the MCDA approach. RESULTS: MRgFUS introduction would lead to: i) a decrease in the adverse events incidence (p-value<0.001); ii) an effectiveness improvement (symptoms’ relief); iii) a best cost-effectiveness trade-off; iv) a significant decrease in the length of hospital stay (p-value<0.001), with the possibility to perform a day-hospital procedure; v) a generation of health migration phenomena; vi) a significant decrease in patients’ productivity loss, reporting a saving of -54.60% compared with surgical procedures (p-value<0.001) and -20.37% compared with UAE (p-value=0.024); vii) an improvement in the quality of life for both patients and caregivers, with a shorter recovery-time period. While the new equipment introduction, in the short term, requires training courses productivity losses, in the long run, there would be a reduction in the areas described above, thus making it the preferred technology, with an average organisational value of 0.32, followed by UAE (0.12). Lombardy Region could benefit from economic and organizational advantages with the adoption of MRgFUS into the clinical practice (-6.29%), thus being able to perform, on average, 57,181 additional DRGs, within three years. CONCLUSIONS: The results suggested that MRgFUS could be considered an advantageous technological alternative in the UF target population, providing a potential overall benefit with its acquisition, thus supporting the definition of a future dedicated national reimbursement tariff.

MUSCULAR-SKELETAL DISORDERS - Clinical Outcomes Studies
PMS1: TRANSFUSION TRENDS IN PRIMARY AND REVISION TOTAL JOINT ARTHROPLASTY: ARE RECENT DECLINES SHARED EQUALLY?

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OBJECTIVES: Advances in total joint arthroplasty (TJA) blood management protocols over the past decade have resulted in a precipitous decline in the incidence of transfusion. However, these advances may not be proportionate – with certain institutions still having higher incidence of transfusion relative to their peers. This study examined whether these declines varied by procedure, patient, or hospitalization characteristics. METHODS: This retrospective study used the Premier Perspective® hospital database (2010-2015). Patients selection criteria included: inpatient visit for primary total hip arthroplasty (P-THA), primary total knee arthroplasty (P-TKA), revision THA (R-THA) or revision TKA (R-TKA); aged 18+; no history of fracture; and no concurrent hip and knee procedures. Significance of time trends within cohorts were analyzed with the Cochran-Armitage Test. RESULTS: A total of 314,779 P-THA patients, 605,702 P-TKA patients, 38,399 R-THA patients, and 54,144 R-TKA patients met selection criteria. Overall incidence of transfusion declined significantly between 2010 and 2015, from 22.1% to 7.1% for P-THA, 18.1% to 3.2% for P-TKA, 30.6% to 18.5% for R-THA, and 19.8% to 9.8% for R-TKA (all P<.001). The percent reduction from 2010 to 2015 varied by hospital size; larger hospitals (400+ beds) demonstrated greater improvements vs. small hospitals (0-199 beds). Percent reduction for large vs. small hospitals was 73.5% vs. 60.3% for P-THA; P-TKA: 85.0% vs. 80.5%; R-THA: 40.2% vs. 23.4%; and R-TKA: 54.3% vs. 37.5%, respectively. Transfusion incidence reductions observed in community hospitals were greater than academic centers for P-THA (70.4% vs. 64.1%), R-THA (45.4% vs. 33.2%), and R-TKA (51.1% vs. 49.6%); P-TKA was nearly equal (82.1% vs. 82.3%). CONCLUSIONS: This study demonstrates that there was a considerable decline in TJA transfusion incidence between 2010 and 2015. However, these declines were not shared equally by procedure type, facility size, or academic status. While significant advances have been made, there remains a large opportunity for improvement.

PMS2: LIFETIME RISK OF REVISION FOLLOWING JOINT REPLACEMENT: EVIDENCE FROM ROUTINELY-COLLECTED DATA

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OBJECTIVES: To estimate the effect of age, gender and diagnosis (osteoarthritis, OA, or rheumatoid arthritis, RA) on the lifetime risk of revision following total knee and hip replacement (TKR and THR). METHODS: Individuals who received TKR or THR were identified using primary care linked to hospital records in England (CPRD-HES). Based on ten-year follow-up, parametric survival models were specified with age, gender and diagnosis included as explanatory variables and distributions chosen on the basis of AIC. While risk of revision was extrapolated, risk of mortality was assumed to revert to population lifetables after ten years. These competing risks were combined using a Markov model to estimate lifetime risk of revision. RESULTS: 10,260 and 10,961 individuals received TKR and THR respectively. Lifetime risk of revision following TKR for 50-year-olds was: female, OA: 21% (95% CI: 17% to 25%); male, OA: 25% (22% to 30%); female, RA: 14% (10% to 20%); and male, RA: 16% (11% to 20%). For 85-year-olds these fell to: female, OA: 2% (2% to 3%); male, OA: 2% (2% to 3%); female, RA: 1% (1% to 2%); and male, RA: 1% (1% to 2%). Lifetime risk of revision following THR for 50-year-olds was: female, OA: 11% (10% to 14%); male, OA: 11% (10% to 16%); female, RA: 15% (8% to 20%); and male, RA: 15% (10% to 24%). For 85-year-olds these fell to: female, OA: 3% (2% to 4%); male, OA: 2% (2% to 3%); female, RA: 3% (2% to 4%); and male, RA: 3% (2% to 3%). CONCLUSIONS: Lower age at surgery and being male is associated with a higher lifetime risk of revision following both TKR and THR. Risks for OA and RA were not significantly different. These findings will help inform shared decision making.

PMS3: EARLY RESPONSE TO CERTOLIZUMAB PEGOL IN RHEUMATOID ARTHRITIS PREDICTS OUTCOME: DATA FROM A PROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: To evaluate the performance of clinical markers of early treatment failure as predictors of late treatment failure in patients with rheumatoid arthritis (RA) in everyday clinical practice. METHODS: Data from a 1-year interim analysis of the ECLAIR study, which followed patients with RA starting treatment with certolizumab pegol...
(CZP) in France, were used. Patients were evaluated at study entry and at 3-monthly routine consultations thereafter. Disease activity was assessed at each visit using CDAI, DAS28(ESR) and HAQ-DI. Early treatment response was measured at Week 12, at which point patients with missing data or no longer taking CZP were excluded from the analysis. Late treatment response was measured at 1 year, at which point linear interpolation, LOCF or NRI were used to impute missing data. Non-response at Week 12 was defined as CDAI>10, ΔDAS28(ESR)<1.2, or ΔHAQ-DI<0.22; and at 1 year as CDAI=22, DAS28(ESR)>3.2, or HAQ-DI>0.5. Positive predictive value (PPV; proportion of treatment failures at 1 year in Week 12 non-responders), sensitivity and specificity were used to evaluate the predictive performance of each tool. RESULTS: Overall, 792 patients were enrolled, of whom 730 were analyzed. The PPV for CDAI (assessed in 532 patients) was 88.8%, indicating that most patients identified as non-responders at Week 12 failed to respond at 1 year. Specificity was also high (96.0%), indicating that <5% of patients who achieved CDAI response at 1 year were non-responders at Week 12. Similar analyses performed for DAS28(ESR) and HAQ-DI produced PPVs of 69.0% and 75.4%, respectively. CONCLUSIONS: This study was the first conducted under real-life conditions in France to demonstrate a strong relationship between early and late treatment failure. Simple tools such as CDAI, assessed during routine consultations, may be reliable markers to predict treatment failure without the need for complementary biological tests.

PMS4: EFFECT OF ANTI-DIABETIC DRUGS ON RISK OF FRACTURE IN TYPE 2 DIABETES MELLITUS PATIENTS: A NETWORK META-ANALYTIC SYNTHESIS OF RANDOMIZED CONTROLLED TRIALS OF THIAZOLIDINEDIONES

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OBJECTIVES: Fracture risk is higher in older adults with type 2 diabetes mellitus (T2DM). Anti-diabetic drugs have different effects on bone metabolism. We performed a pairwise and network meta-analysis (NMA) including randomized controlled trials (RCTs) to study the risk of bone fractures associated with thiazolidinediones (TZDs), compared to placebo or active drugs and rank anti-diabetic drugs for fracture risk in T2DM patients. METHODS: We searched PubMed/Medline and clinical trial registration websites from inception to May 2, 2017, for published or unpublished RCTs comparing the effects of TZDs with comparators on fracture risk in T2DM patients. Pairwise meta-analyses within DerSimonian-Laird random effects model and NMA within a Bayesian framework were performed to calculate odds ratios (OR) to compare effect of anti-diabetic drugs on fracture risk. Treatment ranking was estimated using surface under the cumulative ranking curve (SUCRA) statistic for the outcome. RESULTS: We identified 17 RCTs examining 7 treatments, including 22,437 T2DM patients with 968 events. Pairwise meta-analysis showed significant association between risk of fracture and TZDs use vs. comparators (OR 1.33, 95% CI 1.09-1.64, P = 0.006). Subgroup analysis of TZDs vs. metformin use also showed significant association (OR 1.57, 95% CI 1.13-2.18, P = 0.007), while no significant association was found with TZDs vs. placebo, TZDs vs. sulfonylureas, and TZDs vs. other anti-diabetic drugs (OADs) (OR 1.26, 95% CI 0.90-1.76; OR 1.53, 95% CI 0.92-2.56 and OR 1.10, 95% CI 0.77-1.56, respectively). According to SUCRA, sulfonylureas ranked best (0.72) drug followed by metformin+sulfonylureas (0.67), metformin (0.62), placebo (0.52), TZDs+metformin (0.43), OADs (0.35), and TZDs ranked worst (0.19) drug for the T2DM patients with fracture risk. CONCLUSIONS: TZDs associated with risk of fracture in T2DM patients. From NMA, TZDs seems least effective drug for the T2DM patients with fracture risk. The current findings need to be confirmed by future well-designed RCT studies.

PMS5: ACCESS AND SECONDARY USE OF DATA COLLECTED IN AN ELECTRONIC MEDICAL CHART: RESULTS OF THE REAL WORLD ROSWITCH STUDY.

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OBJECTIVES: Secondary use of data to describe in real life the efficacy and the characteristics of Rheumatoid arthritis (RA) patients switching from Intravenous (IV) to Subcutaneous (SC) Tocilizumab (TCZ) formulation. METHODS: RIC Nord de France, a French rheumatologist network, set up an electronic medical chart (eMC) to enhance communication and data sharing during RA patients’ course. Individual patient’s data fulfilling inclusion criteria were extracted from the eMC, and provided to Roche-Chugai for analyses. Patients switching or not from IV to SC TCZ between April 30th 2015 (date of available SC formulation) and January 15th 2016 were included. The Primary Efficacy Endpoint (PEE) was the proportion of patients remaining in their DAS28-ESR category remission/ADA or moving to an inferior DAS28-ESR category at 24 weeks (W24) and permanent discontinuation of
drug persistence was of 31.79 with adalimumab, 32.2 (45.67%) etanercept, 100 (14.18%) golimumab and 98 (13.90%) with infliximab. The average patients were included, with a mean age of 52.5 years (±13.3); 50.8% (n=358) female. 185 patients (26.24%) treated disease activity (DAS, ACR, PsARC, BASDAI, ASDAS, MDA) and functional (analyzed at 0, 3, 6, 12, 24, 36 and 48 months after starting a first TNFi. Response was measured by composite patients registered at the Rheumatic for TNFi discontinuation, in PsA patients.

OBJECTIVES: To assess the relative efficacy of abaloparatide compared with osteoporosis treatment options (alendronate, denosumab, ibandronate, raloxifene, risedronate, romosozumab, strontium ranelate, teriparatide, zoledronic acid). METHODS: PubMed®, Embase® and Cochrane Central Register of Controlled Trials were searched for all randomized controlled trials published prior to December 12, 2016 including postmenopausal osteoporotic women with and without prior fractures. Selection of trials for inclusion in the Network meta-analysis (NMA) were based on populations (inclusion/exclusion criteria), interventions (dose/frequency) and outcomes (fracture assessment). NMA were conducted by fracture sites with relative risk (RR) of fractures as the main clinical endpoint. RESULTS: For vertebral fractures (VF) and nonvertebral fractures (NVF), 17 studies informed a network of 11 treatments, and 20 studies informed a network of 10 treatments, respectively. For VF, abaloparatide had the greatest effect relative to placebo (RR 0.13; 95% CrI: 0.04-0.34), with estimates ranging from 0.27 for romosozumab to 0.71 for strontium ranelate. For NVF, abaloparatide had a greater risk reduction versus placebo (RR 0.52; 95% CrI: 0.29-0.88) and was most effective (with a probability of 0.74) versus teriparatide (RR 0.67; 95% CrI: 0.48-0.93) and romosozumab (RR 0.74; 95% CrI: 0.52-1.05). In a further evaluation of specific fracture sites, 9 studies reporting wrist fractures informed a network of 7 treatments. Abaloparatide was associated with the greatest effect versus placebo (RR 0.35; CrI: 0.14-0.80) and reduced the risk of fractures versus teriparatide (RR 0.44; CrI: 0.17-1.02) and denosumab (RR 0.42; CrI: 0.16-1.0). The network meta-analyses illustrated a good level of agreement with the direct trial evidence and direct pairwise comparisons. CONCLUSIONS: Based on the current NMA, abaloparatide treatment results in a reduction in RR of both vertebral and nonvertebral fractures in women with and without prior fractures versus placebo in comparison with other treatment options. Generalizability is limited to the trial populations included in the NMA.

PMS7: EFFECTIVENESS AND PERSISTENCE OF THE FIRST TUMOR NECROSIS FACTOR INHIBITOR IN PORTUGUESE PSORIATIC ARTHRITIS PATIENTS.

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OBJECTIVES: Tumor necrosis factor inhibitors (TNFi) dramatically improved the management of psoriatic arthritis (PsA). Nevertheless, a significant proportion of patients do not respond and/or are intolerant to TNFis. The objective of this work was to assess the effectiveness, measured by response rates and drug survival, and the main reasons for TNFi discontinuation, in PsA patients. METHODS: This was a retrospective non-interventional study of PsA patients registered at the Rheumatic Diseases Portuguese Registry, with at least 1 TNFi prescription. Data was analyzed at 0, 3, 6, 12, 24, 36 and 48 months after starting a first TNFi. Response was measured by composite disease activity (DAS, ACR, PsARC, BASDAI, ASDAS, MDA) and functional (HAQ) indices. Drug survival was assessed by Kaplan-Meier survival analysis. In all analyses significance level was set at 0.05. RESULTS: 705 PsA patients were included, with a mean age of 52.5 years (±13.3); 50.8% (n=358) female. 185 patients (26.24%) treated with adalimumab, 322 (45.67%) etanercept, 100 (14.18%) golimumab and 98 (13.90%) with infliximab. The average response rates, measured by composite disease activity and functional indices, are shown in Table 1. The average drug persistence was of 31.79±17.03 months for TNFi as a group, with 205 (29.08%) of discontinuations during a
period of 4 years of follow-up. The main reasons for discontinuation of the first TNFi were: non-response/loss of response 111 (54.15%), adverse event 48 (23.41%), surgery 6 (2.93%), refusal to continue treatment, 4 (1.95%), loss to follow-up 3 (1.46%), pregnancy 4 (1.95%), death 2 (0.98%), remission 2 (0.98%), and others 10 (4.88%). CONCLUSIONS: PsA patients receiving a first TNFi will persist on treatment for an average of 2.6 years with treatment discontinuation rates of 29.08%. Non-response/loss of response constitutes the major reason for treatment discontinuation in this population.

PMS8: IMMUNOBIOLOGICAL USE PROFILE IN THE SERVICE OF RHEUMATOLOGY OF A HEALTHCARE PROVIDER.

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OBJECTIVES: Assess the profile of use of immunobiological (IMB) in the service of rheumatology of a Health Plans Operator (HPO) located in Fortaleza, Ceará, Brazil. METHODS: This is a descriptive and retrospective study. The data was collected from the medical skills performed in the rheumatology service, as well as the revision of patients’ charts in use of IMB from 2012 to 2016. RESULTS: Were analyzed 354 patients, with female predominance, 68.36% (n = 242) and the median of age was 50 years. The pathologies of higher incidence were rheumatoid arthritis with 42.37% (n = 150), ankylosing spondylitis with 39.27% (n = 139) and erythodermic arthritis with 8.76% (n = 31). 487 therapeutic schemes were used during the period. The inhibitors of the tumor necrosis factor (anti TNF) were the most used in relation to the other classes, representing 73.10% (n = 356). The other classes were interleukin-6 (12.32%) inhibitors, depletor of lymphocytes B (6.98%); T lymphocyte inhibitor (6.16%); interleukin-17 inhibitor (1.03%); interleukin inhibitor-12/23 (0.41%). The most prominent anti TNF were the infliximab, the adalimumab and the golimumab representing 21.36%, 19.51% and 11.50% of the use, respectively. CONCLUSIONS: The knowledge of the profile in the patient and patient care information is the basis for any planning strategy. The high cost of these medicines shows the need for multiprofessional auditing to evaluate the correct use and impact that the IMBs possess in the healthcare provider. This is important to plan and offer the best care of the patient and intervene when necessary.

PMS9: RETROSPECTIVE SURVEY FOR HEPATITIS B VIRUS REACTIVATION DURING IMMUNOSUPPRESSIVE THERAPIES FOR RHEUMATOID ARTHRITIS USING ADMINISTRATIVE DATA

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OBJECTIVES: Risk of hepatitis B virus (HBV) reactivation has increased because of advances in immunosuppressive therapies. People having a previously-resolved HBV infection and those with serum HBs-antigen positivity are likely to develop liver injuries after the therapies. However, the risk of HBV reactivation for rheumatoid arthritis (RA) patients is still unclear. The aim of this study was to clarify the significance of HBV reactivation in RA patients undergoing immunosuppressive treatments. METHODS: Adult patients who had been diagnosed with RA between 1 April 2011 and 31 March 2015 were extracted from the Medical Information Analysis (MIA) databank managed by the Clinical Research Center at the National Hospital Organization (NHO) Headquarters. Medical centers N and B are NHO hospitals located south in Japan. We conducted chart reviews in these hospitals to identify the cases with reactivation of HBV and to investigate the incidence of it. RESULTS: For verifying the HBV reactivation, 103 and 89 candidates were abstracted and chart reviews were conducted in the two hospitals. Among them, 47 and 71 patients underwent periodic HBV-DNA testing while receiving immunosuppressive therapies, and 35 and 46 of patients had previously-resolved HBV infections (74.5% with 95%CL: 59.7-86.1%, and 90.1% with 95%CL: 80.7%-95.9%, respectively). Incidence rates of HBV reactivation were 3.26 and 0.56 / 100 person-years in the two medical centers. CONCLUSIONS: Two medical centers had different rates of HBV reactivation. This difference is likely a result of the differences in characteristic and comorbidities of patients who used these medical centers. We plan to evaluate the incidence of HBV reactivation after an immunosuppressive therapy using an administrative database. Because information of changes in serum HBV-DNA levels after immunosuppressive therapies was unavailable in the database, we conducted a chart review. This chart review will be a good sample for our future project.

PMS10: THE STUDY ON MECHANISM OF NF-KB SIGNAL MOLECULE IN KASHIN-BECK DISEASE

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OBJECTIVES: Kashin-Beck disease (KBD) is an endemic osteoarthropathy. This study is to observe the change of NF-κB signaling in KBD patients and expression of NF-κB p65 in human C28/I2 chondrocyte for analyzing the effect of NF-κB p65 on chondrocyte apoptosis. METHODS: 161 Patients with KBD and 312 healthy controls were randomly selected from Shaanxi, China matched by age and sex. Venous blood was collected from patients and healthy controls. The model of C28/I2 chondrocyte oxidative damage was established by using tert-butyl hydroperoxide (tBHP), and cell apoptosis and reactive oxygen species (ROS) was detected by Hoechst 33342 and dichlorofluorescein methods, respectively. The proteins of whole blood and cells was extracted by Trizol method, expression level of NF-κB p65 molecule in whole blood were detected by Western blotting. RESULTS: Compared with age and sex, differences were not statistically significant between KBD group and control group (t=0.336, P=0.737, χ²=0.407, P=0.523). The protein expression level of NF-κB p65 in KBD group was 1.833 times as high as that of control group (P<0.05). In C28/I2 chondrocyte oxidative damage model, the number of cell apoptosis increased in tBHP group and level of ROS and protein expression level of NF-κB p65 were higher than that of control group (P<0.05), however, levels of ROS were lower than that of control group (P<0.05), protein levels of NF-κB p65 were down-regulated in low and middle selenium pre-protection group compared to tBHP group (P>0.05). CONCLUSIONS: The NF-κB signaling pathway is up-regulated in KBD patients, moreover, chondrocyte experiments showed cell apoptosis was mediated via up-regulation of NF-κB p65, and the expression of p65 is down-regulated by Na2SeO3 intervention, which suggest NF-κB signaling pathway play an important role in pathogenesis of KBD (This research was supported by National Natural Science Foundation in China No.81573104, 81172610, 81673117).

PMS11: ESTIMATING THE PREVALENCE OF DEPRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS IN KOREA USING NATIONAL HEALTH INSURANCE CLAIMS DATA

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OBJECTIVES: The prevalence of depression in patients with rheumatoid arthritis (RA) is estimated to be 3.5 times that of the general population and even higher than those with other chronic diseases. However, in Korea, there is still unmet needs in nation-wide data. Thus, this study aims to explore the prevalence of depression in patients with RA according to various definitions of depression and RA severity using the Health Insurance Review and Assessment service (HIRA) claims database in 2014. METHODS: RA patients were defined as adults (≥ 19 years old) who had at least one claim record with a diagnosis of RA (ICD-10 codes: M05-06) from HIRA – National Patients Sample (NPS) data in 2014. Depression was defined according to ICD-10 codes of F06.32, F31.3, F31.4, F32, F33, F34.1, F38.1 and F41.2. RESULTS: Overall, 13,462 RA patients were identified from 2014 HIRA-NPS data. By multiplying this figure by inverse sampling probability for each patient, the total number of adult RA patients in the nation was estimated to be 448,688. The prevalence of depression among RA patients ranged from 14.1% to 16.5% depending on the operational definition for depression. RA patients with at least one hospitalization had about 1.53 times higher chance of experiencing depression than those without hospitalization (25.1% vs.16.4%). Patient characteristics seemed to be associated with depression. For instance, female had a higher rate of depression (17.8%) than male patients (13.0%). Patients enrolled in Medicaid (33.7%), which is a public assistance program, tended to experience depression more than those enrolled in National Health Insurance (15.5%), which is a mandatory contributory health security program. CONCLUSIONS: The prevalence rate of depression in RA patients in Korea is high and can vary depending on patient characteristics and disease severity, suggesting that more attention to depression in RA patients is necessary.

PMS12: THE STUDY ON EXPRESSION OF AP-1 SIGNALING PATHWAY AND POLYMORPHISMS OF SEP15 AND TRXR-2 GENES IN KASHIN-BECK DISEASE

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OBJECTIVES: Kashin-Beck disease (KBD) is an endemic osteoarthropathy, and apoptosis of chondrocyte is its main pathological feature, which mainly distributed from northeastern to southwestern of China. However, the pathogenesis of KBD still remains unknown. Recent studies have found that selenoproteins SNP may influence the KBD susceptibility, and AP-1 pathway plays an important role for regulating apoptosis-related genes. Therefore, we performed this experiment to investigate the polymorphisms of Sep15 rs5859 and TrxR-2 rs1139793 as well as proteins expression of AP-1 pathway in KBD patients and controls for understanding KBD pathogenesis. METHODS: 208 KBD patients and 206 control subjects from Shaanxi in China were included in this study. PCR-Restriction Fragment Length Polymorphism and Amplification Refractory Mutation Specific-PCR were used to detect Sep15 rs5859 and TrxR-2 rs1139793, respectively. The protein expression levels of AP-1 signaling pathway in whole blood from 20 KBD patients and 20 healthy controls were detected by Western blotting.
blunting. **RESULTS:** The minor A-allele frequency of Sep15 rs5859 in KBD patients was significantly higher than that of control group (P<0.05). The cases carrying A-allele had a 2-fold increased risk of developing KBD compared with the G-allele carriers (OR 95%CI: 1.064-3.956). There was no significant difference in genotype and allele distribution of TrxR-2 rs1139793 between KBD patients and controls. The expression levels of JUB and JUD in KBD group were higher than that in control group (P<0.0001). **CONCLUSIONS:** The frequency of the minor A-allele of Sep15 rs5859 is a risk factor for KBD. AP-1 signaling pathway is up-regulated in KBD patients, which might contribute to chondrocyte apoptosis of KBD (This research was supported by National Natural Science Foundation in China No.81573104, 81172610, 81673117).

**PMS13: RISK OF MAJOR OSTEOPOROTIC FRACTURE (HIP, VERTEBRAL, RADIUS, HUMERUS [MOF]) AFTER FIRST, SECOND AND THIRD FRAILITY FRACTURE IN A SWEDISH GENERAL POPULATION COHORT**

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**OBJECTIVES:** Fracture is an established risk factor for future fracture and important for risk-assessment, economic modelling, and treatment decision-making. We estimated the risk of subsequent MOF following first, second and third fracture. **METHODS:** Women ≥50 years with ≥1 fracture between 2006-2012 (index date) were identified from national registers (1998–2015) and followed from first, second and third fracture. Women with a fracture at index were matched (1:3) with non-fracture controls, based on gender and age. Fracture risk was assessed by a parametric survival spline model with subsequent MOF as failure event, and controlled for nine known risk factors (comorbidities, treatment, demographic-related). **RESULTS:** 229,259 women (age mean=74 years) with one fracture, 36,465 (age mean=80 years) with two and 6,687 (age mean=83 years) with three were identified. Five-year cumulative incidence of subsequent MOF was 23.0% (CI95:22.7–23.4) after first fracture (index any site), 37.6% (CI95:36.1–39.1) after second, 21.2% (CI95:18.0–25.0) after third, with the majority of subsequent fractures occurring in the first 2 years post fracture. Risk of subsequent MOF was highest in the first 6 months following index fracture; the adjusted relative risk (RR) of MOF was 2.2 (CI95:2.1–2.2) following any fragility fracture, 4.5 (CI95:4.2–4.9) following a vertebral fracture and 1.9 (CI95:1.8–2.1) following a hip fracture. After a second fracture, these RRs were 2.6 (CI95:2.4–2.8), 3.8 (CI95:2.9–5.2) and 2.0 (CI95:1.9–2.1); and after the third fracture, the RR was 1.5 (CI95:1.5–1.5). **CONCLUSIONS:** Fracture risk significantly increases rapidly within 6 months following a fragility fracture, remains very elevated in the subsequent 2 years and persists over 5 years. The relative risk manifests within 6 months and gradually declines over 5 years following the fracture. A patient who has suffered any fragility fracture requires prompt intervention to minimize that risk and avoid significant personal, economic and societal burden.

**PMS14: 90-DAY MORTALITY AND ITS PREDICTORS IN MEN WITH CONTRALATERAL HIP FRACTURE AFTER FEMORAL NECK FRACTURE**

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**OBJECTIVES:** There is a high mortality with not well understood risk factors after the second hip fracture. The aim of the study was to analyse the 90-day mortality and its risk factors in men with contralateral hip fracture. **METHODS:** Men aged 60 years and over treated with primary femoral neck fractures in the year 2000 and suffered from contralateral hip fractures between 01 January 2000 and 31 December 2008 were selected from the database of the Hungarian National Health Insurance Fund. Risk factors as age, comorbidities, type of fracture and surgery, surgical complications, day of hospital admission were analyzed by multinomial logistic and Cox regression analysis (p<0.05). Statistical tests were performed using the SPSS version 19.0. **RESULTS:** 49 men met the criteria with 32.65% mortality rate at 90 day respectively. Logistic regression analysis showed significantly higher risk for mortality in men with higher age at 90 day (OR: 1.137), and pertrochanteric fracture at 90 day (pertoehanchanteric fracture vs. femoral neck fracture, OR: 5.757) after contralateral hip fracture. Cox regression identified location of second hip fracture (pertoehanchanteric fracture vs. femoral neck fracture HR: 3.865, other fractures vs. femoral neck fracture HR: 10.770) as risk factor for 90-day mortality in men. **CONCLUSIONS:** Older age and pertrochanteric fracture type proved to be risk factors for 90-day mortality after contralateral hip fracture in men over 60 years. There is a need to develop an efficacious prevention strategy for the reduction of the mortality after the second hip fractures.

**PMS15: 90-DAY MORTALITY AND ITS PREDICTORS IN WOMEN WITH CONTRALATERAL HIP FRACTURE AFTER FEMORAL NECK FRACTURE**

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**OBJECTIVES:** There is a high mortality with not well understood risk factors after the second hip fracture. The aim of the study was to analyse the 90-day mortality and its risk factors in men with contralateral hip fracture. **METHODS:** Men aged 60 years and over treated with primary femoral neck fractures in the year 2000 and suffered from contralateral hip fractures between 01 January 2000 and 31 December 2008 were selected from the database of the Hungarian National Health Insurance Fund. Risk factors as age, comorbidities, type of fracture and surgery, surgical complications, day of hospital admission were analyzed by multinomial logistic and Cox regression analysis (p<0.05). Statistical tests were performed using the SPSS version 19.0. **RESULTS:** 49 men met the criteria with 32.65% mortality rate at 90 day respectively. Logistic regression analysis showed significantly higher risk for mortality in men with higher age at 90 day (OR: 1.137), and pertrochanteric fracture at 90 day (pertoehanchanteric fracture vs. femoral neck fracture, OR: 5.757) after contralateral hip fracture. Cox regression identified location of second hip fracture (pertoehanchanteric fracture vs. femoral neck fracture HR: 3.865, other fractures vs. femoral neck fracture HR: 10.770) as risk factor for 90-day mortality in men. **CONCLUSIONS:** Older age and pertrochanteric fracture type proved to be risk factors for 90-day mortality after contralateral hip fracture in men over 60 years. There is a need to develop an efficacious prevention strategy for the reduction of the mortality after the second hip fractures.
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OBJECTIVES: There is a high mortality with not well understood risk factors after the second hip fracture. The aim of the study was to analyse the 90-day mortality and its risk factors in women with contralateral hip fracture. METHODS: Women aged 60 years and over treated with primary femoral neck fractures in the year 2000 and suffered from contralateral hip fractures between 01 January 2000 and 31 December 2008 were selected from the database of the Hungarian National Health Insurance Fund. Risk factors as age, comorbidities, type of fracture and surgery, surgical complications, day of hospital admission were analyzed by multinominal logistic and Cox regression analysis (p<0.05). Statistical tests were performed using the SPSS version 19.0. RESULTS: 263 women met the criteria with 20.15% mortality rate at 90 day respectively. Cox regression identified location of second hip fracture (pertrochanteric fracture vs. femoral neck fracture HR: 3.865) as risk factor for 90-day mortality in women. CONCLUSIONS: Pterrochanteric fracture type proved to be risk factors for 90-day mortality after contralateral hip fracture in women over 60 years. There is a need to identify further risk factors in order to develop an efficacious prevention strategy for the reduction of the mortality after the second hip fractures.

MUSCULAR-SKELETAL DISORDERS - Cost Studies

PMS16: EFFICACY-BASED BUDGET IMPACT ANALYSIS OF SECUKINUMAB VS ADALIMUMAB IN THE TREATMENT OF ANKYLosing SPONDYLITIS IN FINLAND

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OBJECTIVES: Biologic treatments have enhanced the treatment outcomes of patients with active ankylosing spondylitis (AS). Until recently, TNF-alpha-inhibitors have been the only biologics approved for the treatment of active AS. We assessed the potential budget impact of the first non-TNF-alpha biologic secukinumab (fully human IL-17A inhibitor) versus adalimumab (TNF-alpha-inhibitor) in the treatment of AS in the Finnish public health care setting. METHODS: The number of patients and current market share of different biologics were based on national reimbursement registry data. Patients were assumed to receive either adalimumab (40mg) or secukinumab (150mg) according to their approved dose. Among the included patients (n=827) 26% were estimated to begin their first biologic treatment, and rest were assumed to be on ongoing treatment. Response to treatment and subsequent switching was incorporated in order to take further treatment lines into account. Response rates were based on a previously published matching-adjusted indirect comparison (MAIC) between secukinumab and adalimumab. Patients not achieving response (ASAS20) were switched to another biologic treatment. All patients received full year treatment. Cost for second line biologic treatment was weighted with the corresponding market shares. RESULTS: According to the budget impact analysis, treating AS patients with secukinumab instead of adalimumab would lead to EUR4.8M savings within a 1-year time period. The annual total costs were EUR6.5M vs EUR71.3M with/without secukinumab, respectively. Potentially 74% more AS patients (1442 vs 827) could be treated with secukinumab instead of adalimumab under a given health care budget. The response rates for secukinumab were consistently higher compared to adalimumab, based on matching-adjusted indirect comparison. CONCLUSIONS: Considerably more patients could be treated more effectively with a biologic under rational allocation of resources. These results also suggest dominance of secukinumab compared to adalimumab as it gives higher treatment outcomes with lower costs in the treatment of patients with active AS in Finland.

PMS17: BUDGET IMPACT MODEL OF SECUKINUMAB FOR PSORIASIS, PSORIATIC ARTHRITIS AND ANKYLosing SPONDYLITIS TREATMENT IN ITALY

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OBJECTIVES: Psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are chronic, immune-mediated, inflammatory diseases associated with different comorbidities and worsening health-related QoL. In Italy approximately 35,377 PsO, PsA and AS patients are estimated to receive biological drugs in 2017. Secukinumab is a first-in-class recombinant, fully human 17A inhibitor. The objective of this study was to estimate the budget impact, up to 5-years, from the Italy National Health Service perspective, of introducing Secukinumab for the treatment of PsO, PsA and AS patients alongside major market comparators. METHODS: The 5-years budget impact model was developed, only direct medical cost were considered. Model implementation considered input data on eligible population, market shares, resource use and cost of items (drug therapy costs, administration costs, management diseases-related costs and adverse events costs) with and without the introduction of Secukinumab. Ex-factory list
prices. Italian National Tariffs and data from published literature were applied. To assess the robustness of the model’s results, a sensitivity analysis (10 % range of variables) was developed. RESULTS: Considering total direct medical costs, cumulative saving resulted in about 106 mEUR after 5 years from Secukinumab introduction. The largest cumulative cost savings was observed in AS patients with 67.7 mEUR In PsA and PsO patients saving estimates resulted in 32 mEUR and 6.3 mEUR, respectively. In the fifth-year the cost reduction per patient resulted in 2,050 EUR for AS, 609 EUR for PsA and 53 EUR for PsO. CONCLUSIONS: From the Italian NHS perspective, Secukinumab presents a cost-saving option for the treatment of PsA and AS, potentially increasing if used in biologic-naive PsA patients, while doesn’t involve any rise in costs for the treatment of PsO. With the introduction of Secukinumab more patients could be treated more effectively with biologics in Italy under a given health budget due to the cost-offsets.

PMS18: TOFACITINIB IN ADULT PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS: BUDGET IMPACT ANALYSIS

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BACKGROUND: Tofacitinib is a new drug in Russian pharmaceutical market indicated for adult patients with active rheumatoid arthritis (RA) and an inadequate response or intolerance to previous treatment with one or more traditional disease-modifying antirheumatic drugs (DMARDs). OBJECTIVES: To assess the budget impact of tofacitinib for RA treatment from Russian healthcare perspective. METHODS: The Excel-based budget impact model (BIM) compared two scenarios of RA treatment: current practice without tofacitinib (1) and new practice when tofacitinib is one of the treatment options (2). Current practice included RA treatment with traditional basic DMARDs, nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticosteroids (GCS) and biologic drugs which are recommended by guidelines and commonly prescribed in Russia (adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept, tocilizumab and rituximab). BIM considered 3-year time horizon and included direct medical costs for drugs and their administration. Costs calculations were based on the registered marginal sales prices of drugs except tofacitinib, when the proposed manufacturer’s price was used; and tariffs for medical services in Russian healthcare in 2016. The market share of tofacitinib was modeled due to manufacturer’s forecast. RESULTS: Scenario with tofacitinib is a cost saving option for Russian healthcare due to its lower price if compared with biologic drugs and possible use in outpatient setting. 8,223, 8,285 and 8,348 patients are treated in the 1-st, 2-nd and 3-rd year respectively, with the gradual increase of tofacitinib market share from 0% to 8.3%. The total costs for three years will be 22.5 billion rubles (€350.05 million) and 21.8 billion rubles (€339.34 million), for the 1st and 2nd scenarios respectively. Thus, the budget expenditures due to introduction of tofacitinib are reduced for 688.35 million rubles (€10.71 million) within 3 years. CONCLUSIONS: Introduction of tofacitinib into medical practice of active RA treatment will significantly reduce the Russian healthcare system expenses.

PMS19: ESTIMATION OF THE BUDGET SAVING POTENTIAL DUE TO THE INTRODUCTION OF AN ETANERCEPT BIOSIMILAR (SB4) FOR THE TREATMENT OF APPROVED ADULT ETANERCEPT INDICATIONS IN BELGIUM

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OBJECTIVES: Biologics are very effective medicines for the treatment of a broad spectrum of autoimmune diseases, but represent a substantial cost in the healthcare systems. Etanercept is one of the preferred biologics in the treatment of autoimmune diseases due to its well established safety and efficacy profile in the approved indications. The study objective was to assess the budget impact of introducing an etanercept biosimilar, SB4, in Belgium for approved adult etanercept indications. METHODS: A budget-impact model (BIM) was used to estimate the cost saving potential of introducing SB4 in Belgium over a three-year horizon from the payer’s perspective. Annual sales (€) of the reference product in the year prior to biosimilar entry were used assuming these to remain constant over the 3-year horizon. Three model scenarios with different SB4 adoption rates vs the reference product were developed: slow (10%; 20%; and 30% of total etanercept sales at year 1; 2; and 3), moderate (15%; 30%; 45%) and rapid (20%; 40%; 60%). Prices were obtained from published sources. RESULTS: introduction of SB4 in the biologic treatment setting over a three-year horizon resulted in projected budget-savings of: €4.97m, €7.45m and €9.93m in the slow, moderate and rapid uptake scenario, respectively. This would allow for savings equivalent to 634, 951 and 1,268 patient-years for the slow, moderate and rapid uptake scenario, respectively. CONCLUSIONS: Introduction of SB4 represents substantial cost-saving potential for the healthcare system in Belgium. Mechanisms that can support the biosimilar uptake are essential in order to achieve these savings, which are currently not in place in Belgium. These savings will contribute to healthcare system sustainability in Belgium, as these could be used to treat additional patients within the same therapeutic area, fund novel therapies for other disease areas and/or potentially fund other hospital or medical department needs.
PMS20: EVALUATION OF THE COST SAVING POTENTIAL OF INTRODUCING AN ETANERCEPT BIOSIMILAR (SB4) FOR THE TREATMENT OF APPROVED ETANERCEPT INDICATIONS IN THE REPUBLIC OF IRELAND

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OBJECTIVES: Biologics such as etanercept are considered very effective but costly treatment options. The biosimilars’ introduction as a treatment option is thought to be an opportunity to achieve cost savings within the healthcare environment. The study objective was to assess the possible budget impact of introducing an etanercept biosimilar, SB4, within the Republic of Ireland for approved adult etanercept indications. METHODS: There are two potential savings generated by: a mandatory cut of 20% of the originator price after its biosimilar entry and the biosimilar adoption. Annual sales (€) of the etanercept reference product in the year prior to biosimilar entry were used assuming these to remain constant over 3-year horizon. A budget-impact model was used to estimate the cost saving potential of introducing SB4 vs the reference product over a three-year time horizon from the regional payer’s perspective. Three scenarios with different SB4 adoption rates were developed: slow (10%, 20%, 30% at year 1, 2, 3 respectively), moderate (15%, 30%, 45%) and rapid (20%, 40%, 60%). Prices were obtained from published sources. RESULTS: The mandatory cut of the originator price resulted in €12m savings per year. Moreover, due to the SB4 uptake, further budget savings can be achieved over the three-year horizon: €2.78m, €4.16m and €5.55m in the slow, moderate and rapid uptake scenario, respectively. The total potential savings are equivalent to additional 1,731 to 2,056 patient-years. CONCLUSIONS: SB4 introduction represents substantial cost-saving opportunities for the healthcare system in the Republic of Ireland. National/regional policies toward biosimilars influence their adoption thus impacting saving potential. These savings will contribute to healthcare system sustainability in the Republic of Ireland without compromising the quality of care delivered, as these could be used to treat additional patients within the same therapeutic area, fund novel therapies for other disease areas and/or potentially fund other hospital or medical department needs.

PMS21: ESTIMATION OF THE BUDGET SAVING POTENTIAL DUE TO THE INTRODUCTION OF AN ETANERCEPT BIOSIMILAR (SB4) FOR THE TREATMENT OF APPROVED ADULT ETANERCEPT INDICATIONS IN PORTUGAL

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OBJECTIVES: Biologics are innovative drugs that changed the paradigm in the treatment of many autoimmune diseases. However, biologics represent a substantial cost in the healthcare systems. Etanercept is one of the preferred biologics in the treatment of autoimmune diseases due to its well established safety and efficacy profile in the approved indications. This study’s objective was to assess the budget impact of introducing an etanercept biosimilar, SB4, in Portugal for approved adult etanercept indications. METHODS: A budget-impact model (BIM) was used to estimate the cost saving potential of introducing SB4 in Portugal over a three-year horizon from the payer’s perspective. Annual sales (€) of the reference product, in the year prior to biosimilar entry were used assuming these to remain constant over the 3-year horizon. Three model scenarios with different adoption rates of SB4 vs the reference product were developed: slow (10%; 20%; and 30% of total etanercept sales at year 1; 2; and 3), moderate (15%; 30%; 45%) and rapid (20%; 40%; 60%). Prices were obtained from published sources. RESULTS: Introduction of SB4 in the biologic treatment setting over a three-year horizon resulted in projected accumulated budget-savings of: €1.52m, €2.27m and €3.03m in the slow, moderate and rapid uptake scenario, respectively. This would allow for savings equivalent to 167-333 patient-years for the three uptake scenarios. CONCLUSIONS: The introduction of SB4 represents substantial cost-saving potential for the healthcare system in Portugal. The budget impact was sensitive to SB4 market uptake rates. Mechanisms in place that can support the biosimilar uptake are essential in order to achieve these savings. These savings will contribute to healthcare system sustainability in Portugal, as these could be used to treat additional patients within the same therapeutic area, fund novel therapies for other disease areas and/or potentially fund other hospital or medical department needs.

PMS22: ESTIMATION OF THE ADDITIONAL BUDGET SAVING POTENTIAL DUE TO THE RAPID ADOPTION OF AN ETANERCEPT BIOSIMILAR (SB4) FOR THE TREATMENT OF APPROVED ADULT ETANERCEPT INDICATIONS IN SPAIN

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OBJECTIVES: Biologics such as etanercept are considered effective but costly treatment options. SB4, an etanercept biosimilar, is available in Spain since July 2016 and its adoption has been until now slow generating minor savings for the Spanish healthcare system. This study’s objective was to assess the additional budget savings of introducing SB4 that can be achieved with a rapid biosimilar adoption in Spain. METHODS: The cost saving potential
of introducing SB4 in Spain was estimated over a two-year horizon from the payer’s perspective. Annual sales (€) of the reference product in the year prior to biosimilar entry were used assuming these to remain constant over the 2-year horizon. Two model scenarios with different adoption rates vs the current SB4 adoption trend were compared. For the current adoption rate, the actual market share of first 5 months was used to extrapolate for year 1 (2%) and 2 (4%). Two further adoption rates were modeled based on rates seen in Germany and UK using the actual market share in year 1 and extrapolate for year 2: Germany (moderate: 20% and 50%) and UK (rapid: 50% and 80%). Prices were obtained from published sources. RESULTS: Introduction of SB4 resulted in potential savings of €0.17m and €0.48m based on current biosimilar adoption rate in year 1 and 2, respectively. If adoption rate was increased, additional savings of €1.52m & €5.18m for the moderate and €4.06m & €9.66m for the rapid scenario could be achieved in year 1 & 2. CONCLUSIONS: The SB4 introduction represents substantial cost-saving potential for the healthcare system in Spain. However, the slow adoption rate will generate savings of only €0.65m over a two-year horizon. Additional savings up to €13.92m could be achieved, if mechanisms are implemented, as those in UK and some regions in Germany, to support the biosimilar uptake.

PMS23: THE BUDGET IMPACT OF INTRODUCING DEMINERALISED BONE MATRIX COMBINED WITH LOCAL BONE TO REPLACE CURRENTLY AVAILABLE TREATMENTS FOR LUMBAR SPINAL FUSION PROCEDURES IN SPAIN

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OBJECTIVES: Estimate the budget impact (BI) of introducing demineralised bone matrix (DBM) combined with local bone (LB) in lumbar spinal fusion to treat lumbar degenerative disk disease in Spain. METHODS: A decision tree model was developed to evaluate the 4-year BI associated with introducing LB combined with DBM putty (LB+DBM) to replace currently available treatment options including iliac crest bone graft (ICBG), LB alone, and LB combined with ceramic bone graft extenders (LB+ceramic). The market shares of the currently available treatments were 30% ICBG, 40% LB, and 30% LB+ceramic respectively. The analysis was conducted for 100 patients assuming LB+DBM would replace the currently administered treatment mix. Patients receiving DBM were administered 5cc and those receiving ceramics were administered 10cc beta-tricalcium phosphate. The model structure was based on previously published models identified through a structured literature search. The cost of DBM, ceramic, surgical procedures, adverse events, treatment failure, and reoperations were included in the base-case analysis, and productivity loss was analysed in sensitivity analysis. Costs were sourced for Spain in €2017 and no discounting was applied. The model’s inputs and assumptions were validated by two Spanish clinical experts. RESULTS: Over 4 years, replacing currently available treatments with LB+DBM spinal fusions resulted in an additional cost of €12,330 (€123/patient) and an additional 14 successful fusions, implying a cost of €88 per additional successful fusion. Initial procedure costs were higher for LB+DBM, but result in subsequent cost savings in terms of reoperations and adverse events. When including costs of productivity loss, the introduction of LB+DBM resulted in cost savings of €70,294 (€703/patient). CONCLUSIONS: For patients eligible for lumbar spinal fusion in Spain, replacing currently available treatments with LB+DBM results in increased costs for the payer but cost savings for society, while providing more successful fusions in both cases.

PMS24: ECONOMIC EVALUATIONS OF ETANERCEPT IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS IN SPAIN: A SYSTEMATIC REVIEW

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OBJECTIVES: To perform a systematic review on pharmacoeconomic studies associated with psoriasis (PsO) and psoriatic arthritis (PsA) treated with etanercept (ETN) in Spain. METHODS: A systematic review was carried out in PubMed, Embase, Cochrane Library, conference abstracts, Health Technology Assessment reports and grey literature from January 2004 to January 2017. The methodological quality of the studies identified was evaluated using the Consolidated Health Economic Evaluation Reporting Standards checklist. Inclusion criteria were: economic evaluations (full or partial), and dose optimization studies published in English or Spanish language, on PsO and PsA for ETN in Spain. RESULTS: A total of 376 references were identified, of which 28 were selected; 79% analyzed PsO (8 full economic evaluations, 8 cost-analysis and 6 dose optimization studies) and 21% PsA (5 dose optimization studies and 1 cost-analysis study). Most of them used only pharmacological costs. Different time- horizons were adopted (12 weeks-4 years). In PsO, total annual cost (direct and indirect costs) per patient ranged from €9,445 to €17,436/PASI75-year. It increased when dose escalation (switching from 50 mg/week to 100 mg/week) lasted longer than 26 weeks (€17,768/patient-year), reaching the maximum at 52 weeks (€23,772/patient-year). Differences were found in studies including induction cost (€10,302-€15,268/patient-year) comparing to those including drug
maintenance cost (€4,987-€14,420/patient-year). Full economic evaluations in PsO show an incremental-cost ranging from €9,110 to €14,337/PASI75-year. Only one incremental cost-utility analysis (€29,430 and €52,367/QALY gained, 25 mg and 50 mg, respectively; no dose regime specified) was identified. The total annual cost of ETN in PsO ranged from €8,585 to €11,480/patient-year, which includes average cost before and after dose optimization programs at hospital setting. CONCLUSIONS: Economic evaluations of ETN undertaken in Spain were highly heterogeneous in the study design (ie; dose regime, time horizon) so findings need to be interpreted with caution due to very broad interval costs.

PMS25: COMPARISON OF SECUKINUMAB VS INFLIXIMAB IN A COST PER RESPONDER ANALYSIS BASED ON A MATCHING-ADJUSTED INDIRECT COMPARISON OF EFFICACY DATA FOR THE TREATMENT OF PSORIATIC ARTHRITIS AT 48 WEEKS FROM A MOROCCAN PERSPECTIVE

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OBJECTIVES: The objective of this analysis was to estimate and compare the long-term cost per responder (CPR) based on the American College of Rheumatology outcomes (ACR 20/50/70) following 48 weeks of psoriatic arthritis (PsA) treatment with secukinumab (SEC, anti-IL-17A) and 54 weeks with infliximab (INF, anti-TNF). METHODS: The CPR for each treatment was estimated by dividing the drug acquisition cost by its response rate. Drug costs were estimated on the basis of the official Agence nationale de l’Assurance Maladie website (currency in MAD) and the number of doses required for one year (week 52 for SEC; week 54 for INF). The long-term response rates were derived from a previous matching-adjusted indirect comparison (MAIC) based on the data from FUTURE 2 (SEC) and IMPACT 2 (INF) clinical trials. MAIC analysis matched the populations on key baseline characteristics. RESULTS: MAIC analysis showed higher ACR (20/50/70) response rates for SEC 150mg and 300mg (week 52) compared to INF (week 54) for biologic-naïve patients. ACR 20 response rates were 88%, 77% and 59% whereas ACR 50 response rates were 45%, 68% and 37%, and ACR 70 response rates were 22%, 31% and 22% for SEC 150mg, 300mg and INF respectively. Among PsA patients, cost per ACR20 responder were MAD 408,670.00, MAD 262,048.00 and MAD 228,740.00 and MAD 288,469.00, cost per ACR50 responder were MAD 408,616.00, MAD 567,361.00 and MAD 228,740.00 and MAD 288,469.00, cost per ACR70 responder were MAD 463,298.00, whereas costs per ACR70 responder were MAD 408,616.00, MAD 567,361.00 and MAD 764,442.00 for SEC 150mg, SEC 300mg and INF respectively. CONCLUSIONS: ACR (20/50/70) response rates were higher for SEC 150mg and 300mg compared to INF at one year (SEC:week 52; INF:week54). The cost per response for all ACR response rates at 48 weeks were consistently lower for SEC vs. INF. PsA patients could be treated more efficient and effectively with SEC versus INF in Morocco.

PMS26: DIRECT ORAL ANTICOAGULANTS VERSUS LOW-MOLECULAR-WEIGHT HEPARINS FOR VENOUS THROMBOEMBOLISM PREVENTION FOLLOWING TOTAL KNEE REPLACEMENT: COMPARATIVE EFFECTIVENESS AND MEDICAL COSTS FROM A FRENCH NATIONWIDE COHORT STUDY OF AROUND 60,000 PATIENTS

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OBJECTIVES: The aim of the study was to assess effectiveness, risk and medical costs of Direct Oral Anticoagulants (DOAC) versus Low-Molecular-Weight Heparin (LMWH) for venous thromboembolism (VTE) prevention following total knee replacement (TKR) in real-life setting, with a focus on apixaban. METHODS: All patients with TKR performed in France between 2013 Jan-1st and 2014 Sept-30th, and home return after discharge, were identified and followed-up for 3 months in the SNIIRAM nationwide claims database. Patients treated with DOAC (dabigatran, rivaroxaban, and apixaban) were 1:1 matched on gender, age and propensity score with patients receiving LMWH. Relative risk (RR) of hospitalized VTE and bleeding during drug exposure was estimated using quasi Poisson model. Medical costs were calculated according to the collective perspective for the same period. RESULTS: Among the 60,901 patients identified, 15,720 treated with DOAC and 1,752 with apixaban (i.e. almost all DOAC patients) were matched to the same number of patients receiving LMWH. The risk of VTE was lower, but non-significantly, with DOAC than LMWH (RR: 0.89, 95%CI [0.42 to 1.16]) with less bleeding (RR: 0.64, [0.43 to 0.97]). The mean cost per patient was lower with DOAC compared to LMWH for drugs (€330 vs €439), medical visits (€204 vs €208), nursing procedures (€81 vs 2646), lab tests (€33 vs €82), hospitalisations (€316 vs €342), transports (€281 vs €333), and total medical costs (€1,492 vs €1,934). Results for apixaban vs LMWH were
very similar (e.g. €1,489 vs. €1,935 for total medical costs). **CONCLUSIONS:** The study confirms a better benefit-risk ratio of DOAC compared to LMWH for thromboprophylaxis following TKR in real-life setting, associated with a 25% lower medical cost for the French collective perspective. The few patients receiving apixaban at this time provided results similar to all DOAC.

**PMS27: DIRECT ORAL ANTICOAGULANTS VERSUS LOW-MOLECULAR-WEIGHT HEPARINS FOR VENOUS THROMBOEMBOLISM PREVENTION FOLLOWING TOTAL HIP REPLACEMENT: COMPARATIVE EFFECTIVENESS AND MEDICAL COSTS FROM A FRENCH NATIONWIDE COHORT STUDY OF AROUND 120,000 PATIENTS**

Blin P1, Samama C2, Sautet A3, Mismetti P4, Benichou J5, Lignot-Maleyran S1, Lamarque S1, Lorrain S1, Lassalle R1, Gaudin A6, Cotte F6, Droz-Perroteau C7, Moore N7,8, Bordeaux PharmacoEpi, INSERM CIC1401, Bordeaux, France, 2Cochin hospital, PARIS, France, 3Saint-Antoine hospital, PARIS, France, 4Saint Etienne University Hospital, Saint Etienne, France, 5Rouen University Hospital, Paris, France, 6Bristol-Myers Squibb, Rueil-Malmaison, France, 7Bordeaux PharmacoEpi, INSERM CIC1401, Bordeaux University, INSERM U1219, Bordeaux, France

**OBJECTIVES:** The aim of the study was to assess effectiveness, risk and medical costs of Direct Oral Anticoagulants (DOAC) versus Low-Molecular-Weight Heparin (LMWH) for venous thromboembolism (VTE) prevention following total hip replacement (THR) in real-life setting, with a focus on apixaban. **METHODS:** All patients with THR performed in France between 2013 Jan-1st and 2014 Sept-30th, and home return after discharge, were identified and followed-up for 3 months in the SNIIRAM nationwide claims database. Patients treated with DOAC (dabigatran, rivaroxaban, and apixaban) were 1:1 matched on gender, age and propensity score with patients receiving LMWH. Relative risk (RR) of hospitalized VTE and bleeding during drug exposure were estimated using quasi Poisson model. Medical costs were calculated according to the collective perspective for the same period. **RESULTS:** Among the 118,724 patients identified, 31,619 treated with DOAC and 3,380 with apixaban (i.e. almost all DOAC patients) were matched to the same number of patients receiving LMWH. The risk of VTE was significantly lower with DOAC than LMWH (RR: 0.35, 95%CI [0.23 to 0.54]) without increase of bleeding (RR: 0.88, [0.62 to 1.25]). The mean cost per patient was lower with DOAC compared to LMWH for drugs (€283 vs €405), medical visits (€183 vs €199), nursing procedures (€82 vs 281€), lab tests (€29 vs €84), hospitalisations (€312 vs €401), transports (€91 vs €132), and total medical costs (€1,062 vs €1,506). Results for apixaban vs LMWH were very similar (e.g. €1060 vs. €1510 for total medical costs). **CONCLUSIONS:** The study confirms a better benefit-risk ratio of DOAC compared to LMWH for thromboprophylaxis following THR in real-life setting, associated with a 30% lower medical cost for the French collective perspective. The few patients receiving apixaban at this time provided results similar to all DOAC.

**PMS28: SECUKINUMAB VS ADALIMUMAB FOR THE TREATMENT OF ANKYLOSING SPONDILYTIS: A COST PER RESPONDER ANALYSIS AT 52 WEEKS FROM A MOROCCAN PERSPECTIVE**

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**OBJECTIVES:** The objective of this analysis was to estimate and compare the long-term cost per responder (CPR) based on the Assessment of Spondyloarthritis International Society (ASAS) outcomes following 52 weeks of treatment with secukinumab 150mg (SEC,anti-IL-17A ) relative to adalimumab (ADA, anti-TN ) for ankylosing spondylitis (AS). **METHODS:** The CPR for each treatment was estimated by dividing the drug acquisition cost by its response rate. Drug costs were estimated on the basis of the official Agence nationale de l’Assurance Maladie website (currency in MAD) and the number of doses required for 52 weeks. Long-term response rates were derived from a previous matching-adjusted indirect comparison (MAIC) based on the data from MEASURE 2 and ATLAS clinical trial. The MAIC matched patient populations on key baseline characteristics. **RESULTS:** The MAIC results show higher ASAS (20, 40 and 5/6) response rates for SEC compared to ADA at 52 weeks. ASAS 20, ASAS 40 and ASAS 5/6 response rates were 81% vs 65%, 62% vs 47%, 72% vs 55% for SEC vs ADA, respectively. The cost per ASAS 20 responder was MAD 117,102.00 vs MAD 227,177.00, cost per ASAS 40 responder was MAD 152,232.00 vs MAD 315,856.00 whereas, cost per ASAS 5/6 responder was MAD 131,089.00 vs MAD 270,258.00 for SEC vs ADA, respectively. The costs per ASAS (20, 40 and 5/6) responders were about 48%, 52% and 51% lower for SEC compared to ADA respectively at 52 weeks. **CONCLUSIONS:** The ASAS (20, 40 and 5/6) response rates were higher for SEC compared to ADA at 52 weeks. The long term cost per responder for ASAS outcomes at 52 weeks were consistently lower for SEC vs. ADA. With higher outcomes at lower costs, these findings suggest dominance of SEC over ADA. AS patients could be treated more efficiently with SEC versus ADA in Morocco.
PMS29: HEALTHCARE RESOURCE USE (HRU) IN HOSPITALIZED PATIENTS WITH A DIAGNOSIS OF SPINAL MUSCULAR ATROPHY TYPE 1 (SMA1): RETROSPECTIVE ANALYSIS OF THE KIDS’ INPATIENT DATABASE (KID)

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OBJECTIVES: Patients with SMA, a rare, monogenic neurodegenerative disease, have high HRU due to respiratory and nutritional complications resulting from progressive muscle atrophy and weakness. Although the annual costs for SMA patients have been estimated to be $133,000-$121,682, it is potentially much higher in SMA1 patients, who are at risk for frequent, intensive, and prolonged hospitalizations related to respiratory illnesses. This study aims to determine the HRU in hospitalized SMA1 patients and compare them to those of children with and without chronic complex conditions (CCC) or other SMA types. METHODS: This retrospective analysis of the 2012 dataset from the KID database, which includes Medicaid, private insurance, and uninsured claims from hospitals in 44 states in the U.S., compared the following four groups: (i) no CCC (n=447,376), (ii) SMA1 (n=167), (iii) SMA other than SMA1 (n=267), and (iv) other CCC (n=157,687). RESULTS: Individual admissions are costlier for SMA1 patients compared to children without CCC, with other SMA types, or with other CCC ($150,921 vs. $19,261, $120,433, and $112,440 per admission, respectively). Daily hospitalization charges are 1.9-fold higher in SMA1 patients compared to children without CCC ($11,143 vs. $5,990, respectively) with 2.5 procedure codes billed compared with 0.7 in patients without CCC per admission. SMA1 children have lengthier hospital stays compared to children without CCC, with other SMA types and other CCC (15.1 vs. 3.4, 11.5, and 11.8 days, respectively). CONCLUSIONS: The average hospitalization charges for a single admission exceed the yearly estimates of all care costs previously reported for SMA patients. Given that most infants with SMA1 require multiple hospitalizations/year (range, 3.8-7.6 hospitalizations/year), previous estimates may dramatically underestimate HRU. Admissions are costlier than that of patients with no CCC. The high charges are likely driven, at least in part, by longer hospital stays and increased complexity of the care provided.

PMS30: COST PER RESPONSE FOR ABATACEPT COMPARED WITH ADAHILUMAB IN THE TREATMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS BASED ON ANTI-CITRULLINATED PROTEIN ANTIBODY TITRES IN ITALY

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OBJECTIVES: Effective treatment with biologic DMARDs poses a significant economic burden. Recent subgroup analyses showed improved efficacy for abatacept in serum anti-citrullinated protein antibody (ACPA)-positive patients, with increasing efficacy across ACPA quartile levels. The aim of the study was to evaluate the cost per response of abatacept relative to adalimumab in ACPA-positive patients with RA from the Italian societal perspective. METHODS: A decision tree was designed to compare the cost per response of abatacept with adalimumab in a cohort of 1000 ACPA-positive patients over 2 years. Clinical inputs were based on the Abatacept versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate AMPLE trial, and response was based on ACR20/50/70/90 and HAQ-DI. Unit costs for direct medical costs of AEs were based on Italian tariffs for disease-related groups and the ex-manufacturer’s price, including mandatory reductions, payback and transparent discounts for drugs. Societal costs included patient costs, indirect costs of work absence and early retirement, according to HAQ functional capacity categories. RESULTS: Cost per response in ACPA-positive patients in Italy favoured abatacept compared with adalimumab (~€ 154 for ACR20, ~€ 6,426 considering ACR90 and ~€ 281 for HAQ-DI). Cost per remission favoured abatacept in ACPA-positive patients with a cost reduction per CDAI and SDAI equal to ~€ 744 and ~€ 1,310 respectively. Abatacept was consistently favoured in ACPA-Q4 patients across all outcomes in Italy. CONCLUSIONS: The cost per selected outcome in ACPA-positive patients favoured SC abatacept compared with SC adalimumab. The costs per all outcomes were lower for SC abatacept than SC adalimumab in ACPA-Q4 patients in Italy. Cost savings were greater when more stringent response criteria were applied and also with increasing ACPA levels, which could lead to a lower overall healthcare budget impact with abatacept compared with adalimumab in Italy.

PMS31: COMPARISON OF SECUKINUMAB VS ADAHILUMAB IN A COST PER RESPONDER ANALYSIS BASED ON A MATCHING-ADJUSTED INDIRECT COMPARISON OF EFFICACY DATA FOR THE TREATMENT OF PSORIATIC ARTHRITIS AT 48 WEEKS FROM A MOROCCAN PERSPECTIVE
OBJECTIVES: The objective of this analysis was to estimate and compare the cost per responder (CPR) based on the American College of Rheumatology outcomes (ACR 20/50/70) following 48 weeks of psoriatic arthritis (PsA) treatment with secukinumab (SEC, anti-IL-17A) and adalimumab (ADA, anti-TNF). METHODS: The CPR for each treatment was estimated by dividing the drug acquisition cost by its response rate. Drug costs were estimated on the basis of the official Agence nationale de l’Assurance Maladie website (currency in MAD) and the number of doses required for 48 weeks. The long-term response rates were applied from a previous matching-adjusted indirect comparison (MAIC) based on the data from FUTURE 2 (SEC) and ADEPT (ADA) clinical trials. MAIC analysis matched the populations on key baseline characteristics. RESULTS: MAIC analysis showed higher ACR (20/50/70) response rates for SEC 150mg and 300mg compared to ADA at 48 weeks in biologic naïve patients. ACR 20 response rates were 80%, 74% and 56%, ACR 50 response rates were 57%, 61% and 44%, whereas the ACR 70 response rates were 32%, 43% and 30% for SEC 150mg, 300 mg and ADA respectively. Among PsA patients, cost per ACR20 responder were MAD 111,103.00, MAD 240,607.00 and MAD 243,746.00, cost per ACR50 responder were MAD 154,825.00, MAD 288,067.00 and MAD 313,915.00, whereas costs per ACR70 responder were MAD 273,367.00, MAD 412,424.00 and MAD 440,409.00 for SEC 150mg, SEC 300mg and ADA respectively. CONCLUSIONS: ACR (20/50/70) response rates were higher for SEC 150mg and 300mg compared to ADA at 48 weeks. The cost per response for all ACR response rates at 48 weeks were consistently lower for SEC vs. ADA. These findings indicate that SEC represents a highly cost-efficient treatment choice for PsA patients in Morocco.

PMS32: THE IMPACT OF RHEUMATOID ARTHRITIS (RA) ON A PATIENT’S ABILITY TO STAY IN WORK AND LEVEL OF PAIN EXPERIENCED

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OBJECTIVES: To investigate the impact that rheumatoid arthritis (RA) has on patients’ ability to stay in work, using data from the Burden of Rheumatoid Arthritis across Europe: a Socioeconomic Survey (BRASS). METHODS: Data were extracted from BRASS, a societal perspective observational RA dataset across 10 European countries (EU5, Denmark, Sweden, Hungary, Poland and Romania). 476 RA specialising clinicians provided information on 4,079 adult patients; of these, 2,087 patients completed corresponding questionnaires about the burden of RA. Descriptive analysis was used to explore the association between disease duration, disease activity and the proportion of patients who had stopped working or retired early due to RA. Level of pain experienced was also evaluated descriptively across categories of disease activity. The relationship between early retirement and disease duration was further explored using logistic regression where disease duration was modelled as an explanatory variable against the binary early retirement outcome, and adjusted for covariates including age, gender and BMI. RESULTS: Adequate model fit determined. An odds ratio (OR) of 1.043 (p-value <0.00) and average marginal effect of 0.6% (p-value <0.00) per year of disease duration were calculated. The marginal effect was non-linear, increasing yearly with confounders held constant. The predicted probability for a patient to have retired due to RA after disease duration 1-5, 6-10 and >10 years was 13.5%, 15.9% and 21.5% respectively. The likelihood that a patient had stopped working or retired early due to RA in the first 1-5 years of the disease increased across levels of current disease activity, with 5%, 9% and 15% across ‘remission’, ‘mild/moderate’ and ‘severe’ categories respectively. A ‘moderate/severe’ level of pain attributable to RA was found in 19% of patients in remission. CONCLUSIONS: Analysis suggests both disease duration and severity have an impact on the likelihood for a patient to retire early/stop working due to their RA.

PMS33: THE IMPACT OF DISEASE DURATION AND DISEASE ACTIVITY ON THE COST OF RHEUMATOID ARTHRITIS: RESULTS FROM BURDEN OF RHEUMATOID ARTHRITIS ACROSS EUROPE A SOCIOECONOMIC SURVEY (BRASS)

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OBJECTIVES: Investigate the association between Disease Activity Score 28 C-Reactive Protein (DAS28-CRP) score, disease duration and patient costs in rheumatoid arthritis (RA) patients, using data from the Burden of Rheumatoid Arthritis across Europe: a Socioeconomic Survey (BRASS). METHODS: Data were extracted from BRASS, a societal perspective observational RA dataset across 10 European countries (EU5, Denmark, Sweden, Norway, Ireland, Spain, Greece, Portugal, Italy, and France). Analysis was used to explore the association between disease duration and disease activity on the cost of RA.
Hungary, Poland and Romania). 476 RA specialising clinicians provided information on 4,079 adult patients; of these, 2,087 patients completed corresponding questionnaires about the burden of RA. Twelve-month costs captured included: consultations, testing, hospital admissions and procedures, payments to professional caregivers, travel costs, requirement for aids/equipment and informal care costs. Indirect costs captured from the patient included work productivity impact. A generalised linear model was developed to investigate the association between disease duration, most recent DAS28-CRP score and total cost of patients excluding costs of conventional synthetic and biologic disease modifying drugs. Disease duration and DAS28-CRP score were modelled as explanatory variables against the total cost response variable, adjusted for covariates including age, gender and BMI. RESULTS: The model provided adequate fit, uncertainty from between-country unit cost differences was investigated, and association between the variables of interest remained. The average marginal effect at the mean was calculated from regression outputs. Both disease duration and DAS28-CRP score had a statistically significant association with total cost; a unit increase in DAS28 score meant a total cost increase of €1,075 (p=0.004), whereas a unit increase in disease duration of one year increased total cost by €360 (p=0.012), with confounders age, gender, BMI and either DAS28-CRP or duration held at mean values. Descriptive analysis indicated that with greater duration of disease and/or disease activity, healthcare costs incurred outweigh treatment costs. CONCLUSIONS: Analysis suggests that disease duration and disease activity have a significant impact on total patient cost.

PMS34: A CLAIMS DATA ANALYSIS OF BIOLOGICAL AGENTS FOR PSORIATIC ARTHRITIS IN GERMANY

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OBJECTIVES: Approximately a third of patients with Psoriasis are developing Psoriatic Arthritis (PsA). 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 anonymies 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 PsA (ICD-10 code L40.5), and start / maintenance / switch of treatment with PsA approved biological agent(s) (at least for three months). The study evaluated hospitalization, change in medication and direct medical costs (drug, outpatient care, hospitalization). RESULTS: The level of share of prescriptions of all biological agents considered is low. Adalimumab and etanercept are administered mostly to patients already on treatment in 2015 adalimumab 38.3 % vs. etanercept 31.3 %. Total costs of the included 1’545 patients add up to € 27’612’238 in 2015. The total number of patients, the number of hospitalizations and the total treatment costs including three out of four cost items grew yearly on average between 9.8 % and 13.1 % (2012 – 2015). The costs of other medication dropped yearly on average by 2.8 %. Average hospitalization per patient remained constant (0.6). CONCLUSIONS: Adalimumab and etanercept are those biological agents mainly used by patients already on treatment. Costs grew steadily over the last 4 years. Total costs in 2015 were € 27.6 million (on average € 17’872 per patient).

PMS35: TREATMENT WITH BIOLOGICAL AGENTS AMONG PATIENTS WITH ANKYLOSING SPONDYLITIS IN GERMANY: A CLAIMS DATA ANALYSIS

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OBJECTIVES: Over the past 15 years, the availability of anti-tumor necrosis factor inhibitors has altered the treatment approach of ankylosing spondylitis (AS). This study provides information on the current supply with biological agents and its related costs. 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 anonymies 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 following conditions: Main diagnosis of AS (ICD-10 code M45.-), and start / maintenance / switch treatment with AS 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 are adalimumab and etanercept at a low level of share of prescriptions. Both agents are administered mostly to patients already on treatment (in 2016 adalimumab 42.1 % vs. etanercept 30.0 %). Total costs of the included 1’342 patients add up to € 22’536’535 in 2015. Total number of patients, number of hospitalizations and total treatment costs
including all individual cost items (costs of biological agents / other medication / outpatient care / hospitalizations) grew yearly on average between 5.4 % and 11.1 % (2012 – 2015). Average hospitalization per patient remained constant at 0.6. CONCLUSIONS: Adalimumab and etanercept are those biological agents mainly used for treating AS. Costs grew steadily over the last four years. Total costs in 2015 were € 22.5 million (on average € 16'793 per patient).

PMS36: SITUATION OF RHEUMATOID ARTHRITIS PATIENTS TREATED WITH BIOLOGICS IN GERMANY BASED ON A CLAIMS DATA ANALYSIS

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OBJECTIVES: Rheumatoid arthritis (RA) is the most common chronic inflammatory rheumatic joint disease in industrialized countries. 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 anonymies originating from 63 statutory health insurances. 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). Patients between 2012 - 2016 were included if they met the following conditions: Main diagnosis of RA (ICD-10 code M06.- and M06.-), and start / maintenance / switch of treatment with RA approved biological agent(s) (at least for three months). The study evaluated hospitalization, change in medication and direct medical costs (drug, outpatient care, hospitalization). RESULTS: The level of share of prescriptions of all biological agents considered is low. Etanercept and adalimumab are administered mostly to patients already on treatment (in 2015 etanercept 32.7 % vs. adalimumab 28.9 %). The total costs of the included 4'233 patients add up to € 78'202'566 in 2015. The total number of patients, the number of hospital admissions and the total treatment costs including all individual cost items (costs of biological agents / other medication / outpatient care / hospitalizations) grew yearly on average between 7.7 % and 18.9 % (2012 – 2015). Hospitalization per patient remained constant at 0.8. CONCLUSIONS: Etanercept and adalimumab and are those biological agents mainly used by patients already on treatment. Costs grew steadily over the last four years. Total costs in 2015 were € 78.2 million (on average € 18'475 per patient).

PMS37: A COST PER RESPONDER ANALYSIS OF SECUKINUMAB VS. ADALIMUMAB BASED ON A MATCHING-ADJUSTED INDIRECT COMPARISON OF EFFICACY DATA FOR THE TREATMENT OF PSORIATIC ARTHRITIS AT 48 WEEKS FROM THE IRISH PAYER PERSPECTIVE

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OBJECTIVES: The objective of this analysis was to estimate and compare the cost per responder (CPR) in Ireland, based on the American College of Rheumatology (ACR) outcomes following 48 weeks of treatment for psoriatic arthritis (PsA) with the fully human anti-IL-17A antibody secukinumab (SEC) relative to the anti-TNF antibody adalimumab (ADA). METHODS: Results from a previous matching-adjusted indirect comparison (MAIC) based on FUTURE 2 and ADEPT RCTs was used to calculate the CPR for each treatment. Drug costs were estimated based on cost to the national Irish payer (including VAT, rebates and wholesaler margins) and the number of doses required for 48 weeks. Other cost domains like administration or high tech patient care fees were not included as this was considered to be equal for both treatments. RESULTS: The MAIC analysis showed that ACR 20/50/70 response rates, which are key outcomes to determine improvement in PsA, were higher for SEC compared to ADA in biologics-naïve PsA patients. ACR 20/50/70 response rates were 80%/57%/32%; 74%/61%/43%; and 56%/44%/30% for SEC 150mg, SEC 300mg and ADA respectively. Cost per ACR20 responders were EUR 13,147, EUR 29,092 and EUR 27,674; cost per ACR 50 responders were EUR 18,320, EUR 34,831 and EUR 35,640; and cost per ACR70 responders were EUR 32,347, EUR 49,867 and EUR 52,273 for SEC 150mg, SEC 300mg and ADA respectively. Sensitivity analyses showed similar results and confirmed the robustness of the results. CONCLUSIONS: The 48 week CPR for all ACR 20/50/70 response rates were lower for SEC 150mg compared to ADA. These findings indicate that SEC 150mg dominates ADA by providing higher outcomes to lower cost for biologic-naïve PsA patients in Ireland.

PMS38: A COST PER RESPONDER ANALYSIS OF SECUKINUMAB VS. ADALIMUMAB BASED ON A MATCHING-ADJUSTED INDIRECT COMPARISON OF EFFICACY DATA FOR THE TREATMENT OF ANKYLOSING SPONDYLITIS AT 52 WEEKS FROM THE IRISH PAYER PERSPECTIVE
OBJECTIVES: The objective of this analysis was to estimate and compare the long-term cost per responder (CPR) in Ireland based on the Assessment of Spondyloarthritis International Society (ASAS) outcomes following 52 weeks of treatment for ankylosing spondylitis (AS) with the fully human anti-IL-17A antibody Secukinumab 150mg (SEC) relative to the anti-TNF antibody Adalimumab (ADA).

METHODS: CPR for each treatment was calculated by dividing the drug acquisition cost for the course of treatment with the corresponding response rates from a previously reported matching-adjusted indirect comparison (MAIC) based on MEASURE 2 and ATLAS RCTs. Drug costs were estimated based on cost to the national Irish payer (including VAT, rebates and wholesaler margins) and the number of doses required for 52 weeks. Other cost domains like administration or high-tech patient care fees were not included as this was considered to be equal for both treatments.

RESULTS: Previous MAIC analysis showed that ASAS 20/40 response rates, which are key outcomes to determine symptomatic improvement in AS, were higher for SEC vs. ADA. ASAS 20/40 response rates were 81% and 65%; and 62% and 47% for SEC and ADA, respectively. CPR for ASAS 20/40 were EUR 13,856 and EUR 25,793; and EUR 18,013 and EUR 35,861 for SEC and ADA, respectively. SEC dominated ADA in terms of CPR, as the response rates were higher and the overall drug acquisition cost for 52 weeks was lower for SEC as compared to ADA. Sensitivity analyses confirmed the robustness of the main analysis. Results were based on list-prices as of May 2017.

CONCLUSIONS: The 52 weeks CPR for ASAS 20/40 response rates were lower for SEC compared to ADA in AS patients. Furthermore, with higher outcomes at lower costs, these findings suggest dominance of SEC over ADA. More AS patients could be treated more effectively with SEC versus ADA in Ireland.

PMS39: PHARMACOECONOMICS OF CERTOLIZUMAB PEGOL: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Primary: To review the published evidence on the cost-effectiveness, cost-utility, cost-benefit and cost-minimization of certolizumab pegol (CZP) treatment for rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA) in comparison with the other biological disease-modifying antirheumatic drugs (bDMARDs). Secondary: To perform a quality assessment of the economic analyses in these indications.

METHODS: A systematic literature search was conducted, without date or language restrictions, in PubMed and EMBASE databases. Internet searches were also made to identify possible gray literature. Main study characteristics, methods and outcomes were extracted and critically assessed. The quality of health economic studies was assessed by the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), the Quality Assessment of Economic Evaluation in Health Care (QAEHEC) and the Quality of Health Economic Studies (QHES) checklists.

RESULTS: The search identified 13 full-text pharmacoeconomic analyses: 11 in RA and 2 in axSpA. No studies were identified in the PsA indication. According to the economic analyses published in these articles, the high variability of the results and the design of the available studies prevent reliable conclusions from being drawn about the cost-effectiveness of CZP in comparison with other bDMARDs for the treatment of RA and axSpA. Of the 13 identified studies, only 3 (all related to RA) were classified as high quality in all three checklists. According to these, CZP+methotrexate (MTX) would be a cost-effective (dominant) treatment versus adalimumab, golimumab and infliximab (all add-on to MTX) in the US and Spain. In addition, a clinical risk-sharing agreement with CZP would generate considerable savings in all patients, compared to an alternative strategy in Spain.

CONCLUSIONS: Given the evidence, it was not possible to conclude which bDMARD is the most cost-effective treatment option. However, the high-quality studies indicated that CZP would be a cost-effective treatment in RA compared to other bDMARDs in the US and Spain.

PMS40: MODELLING THE SOCIETAL IMPACT OF SECUKINUMAB IN PATIENTS WITH PsORIATRIC ARTHRITIS IN GERMANY

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OBJECTIVES: Psoriatic arthritis (PsA) is associated with serious activity and work productivity impairment. For the first time in this disease area, this study estimates to what extent a novel medication, secukinumab, can reduce these societal and economic effects.

METHODS: A Markov and a population model based on German PsA patients were used to simulate the progression of PsA under secukinumab versus the non-biologic standard of care (methotrexate, sulfasalazine, leflunomide). Disease severity was measured via the Health Assessment Questionnaire-Disability
Index (HAQ-DI) for the population of PsA patients predicted to receive secukinumab from 2017 to 2030, accounting for treatment discontinuation and disease progression. The relationship between HAQ-DI and the Work Productivity and Impairment Questionnaire in PsA patients was employed to determine the relative productivity benefit through the usage of secukinumab. Time-use survey and estimates of PsA-specific employment data were utilized to calculate the total amount of productive and active time gained, which will potentially be used for paid and unpaid work activities. Paid work was valued according to industry specific wages and unpaid work was valued according to the proxy good approach. Further economic effects induced by productivity increases were also taken into account. RESULTS: The usage of secukinumab decreases work and productivity impairment in the target population by over 13 percentage points, compared to the non-biologic standard of care, generating 30.6 million active and productive hours until 2030. These correspond to gross value added effects in the German economy of EUR 2.64 billion. CONCLUSIONS: This study shows that the usage of biologics like secukinumab could lead to substantial reductions of functional limitations associated with PsA compared to the non-biologic standard of care, corresponding to significant societal and economic effects. In addition, the importance of including unpaid work in calculating the societal impact of a medication was demonstrated.

PMS41: TOCILIZUMAB AFTER A FIRST-LINE WITH ANTI-TNF IN RHEUMATOID ARTHRITIS: A COST-CONSEQUENCE ANALYSIS IN THE ITALIAN SETTING

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OBJECTIVES: Clinical evidences showed that switching to a different mechanism of action in rheumatoid arthritis (RA) patients not responding or intolerant to a first anti-TNFα is effective. Objective of this study was the assessment of the cost-effectiveness profile of different treatment strategies after a first anti-TNFα. METHODS: The study was conducted through the development of a Markov model in the perspective of the Italian healthcare system with a 3-year time horizon. The effectiveness was measured in terms of days gained in Low Disease Activity (LDA; DAS28-ESR < 3.2) or in remission (DAS28-ESR < 2.6). The model simulated the response to treatments, based on the findings of the Rotation Or Change (ROC) trial, the probability of discontinuation and switch to a 3rd-line biologic, and transition to death. Time on treatment curves for 2nd-line biologics derived from published Italian real-word data. Rituximab was assumed as 3rd-line biologic for all comparators. Costs were estimated based on published sources and Italian prices and tariffs: drugs, co-medication, administration, routine management (linked to disease severity). RESULTS: The switch to tocilizumab after the failure of a first anti-TNFα was more effective than a second anti-TNFα, in terms of days in remission (224 vs. 114 days) and of days in LDA (345 vs 193 days). The cost-effectiveness ratio with tocilizumab iv was Euro 174/day in remission and Euro 113/day in LDA. With tocilizumab sc the ratio was Euro 181/day in remission and Euro 117/day in LDA. The same ratios for the anti-TNFα treatments ranged from Euro 233 to Euro 320 per day in remission and from Euro 138 to Euro 190 per day in LDA (minimum was infliximab biosimilar; maximum was certolizumab). CONCLUSIONS: The switch to a different mechanism of action after the failure of a first anti-TNFα is an effective and cost-effective strategy in RA.

PMS42: SECUKINUMAB VS ADALIMUMAB FOR THE TREATMENT OF PSORIATIC ARTHRITIS: A COST PER RESPONDER ANALYSIS AT 48 WEEKS FROM A PERUVIAN PERSPECTIVE FOR PUBLIC AND PRIVATE HEALTH SCHEMES

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OBJECTIVES: The objective of this analysis was to compare the cost per responder based on the American College of Rheumatology (ACR) outcomes following 48 weeks of psoriatic arthritis (PsA) treatment with secukinumab (anti-IL-17 antibody) relative to adalimumab (anti-TNF antibody) from a third payer perspective. METHODS: The cost per responder for each treatment was estimated by dividing the drug acquisition cost with its response rate. Drug costs were estimated in US dollars (USD) from public sources: SEACE and DIGEMID for public and private health schemes, respectively. Response rates were estimated from a previous matching-adjusted indirect comparison (MAIC) based on the data from FUTURE2 and ADEPT clinical trials of secukinumab and adalimumab, respectively. MAIC analysis matched age, weight, race and gender distribution, PASI score, HAQ-DI score, and proportions of patients using methotrexate, with psoriasis ≥3% BSA, presence of dactylitis, enthesitis, and TNF-naïve at baseline. RESULTS: ACR response rates were higher for secukinumab (150mg and 300mg) compared to adalimumab at 48 weeks in biologic-naïve patients. Public scheme costs per ACR20 responder were USD14.088, USD30.509 and USD29.702, costs per ACR50 responder were USD19.632, USD36.527 and USD38.252, and costs per ACR70 responder were USD34.663, USD52.296 and USD56.103 for secukinumab 150mg, 300mg and adalimumab respectively. Private scheme costs per ACR20 responder were USD17.570, USD38.050 and USD58.302, costs per ACR50 responder were USD24.484, USD45.555 and USD75.085, and costs per ACR70 responder were USD43.231, USD65.221 and USD110.125 for secukinumab 150mg, 300mg and adalimumab.
respectively. Sensitivity analyses for ACR response and cost per responder showed similar results, confirming the validity of the main analysis. CONCLUSIONS: ACR response rates were higher for secukinumab compared to adalimumab. Cost per responder for ACR outcomes at 48 weeks were lower for secukinumab (150mg and 300mg) versus adalimumab, indicating that it is more efficient to treat PsA patients with secukinumab versus adalimumab in the Peruvian context.

PMS43: COST-EFFECTIVENESS ANALYSIS OF SECUKINUMAB INankylosing Spondylitis: A CANADIAN PERSPECTIVE

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OBJECTIVES: To evaluate the cost-effectiveness of Secukinumab (SEC), a fully human monoclonal antibody that selectively neutralizes interleukin (IL)-17A, versus currently licensed biologic therapies in patients with Ankylosing Spondylitis (AS) from a Canadian healthcare system perspective. METHODS: A decision analytic semi-Markov model evaluated the cost-effectiveness of SEC 150mg compared to adalimumab (ADA), certolizumab pegol (CER P), etanercept (ETN), ETN biosimilar, golimumab (GOL), infliximab (INF), and INF biosimilar in a biologic-naïve population and a mixed population of biologic-naïve and experienced patients, over a lifetime horizon (60 years). The response to treatments was evaluated at week 12 by Bath AS Disease Activity Index (BASDAI 50) response rates. Non-responders or patients discontinuing initial-line of biologic therapy were allowed to switch to subsequent-line biologics. Model input parameters (short term changes in BASDAI, short- and long-term changes in Bath AS Functional Index (BASFI), withdrawal rates, adverse events, costs, resource use, utilities, and disutilities) were collected from clinical trials, published literature, and other Canadian sources. Benefits were expressed as quality-adjusted life-years (QALYs). Costs were reported in 2016 Canadian dollars (CAD). An annual discount rate of 1.5% was applied to costs and benefits. RESULTS: In the biologic-naïve population, SEC dominated all therapies. Patients treated with SEC achieved the most QALYs (16.09) at the lowest cost (CAD 1,106,529) over a lifetime horizon compared to all other drugs. Similarly, in the mixed population (biologic-naïve and biologic experienced), SEC dominated all treatments as it generated more QALYs (14.59) at lower costs (CAD 1,141,452). Across all comparators, deterministic sensitivity analyses indicated that the results were most sensitive to variation in BASDAI 50 response, change in BASFI score, and withdrawal rates. CONCLUSIONS: SEC is dominant versus all licensed biologics and INF, ETN biosimilars for the treatment of active AS in biologic-naïve and mixed populations in Canada.

PMS44: COST-EFFECTIVENESS OF SECUKINUMAB FOR THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS IN THE UK

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OBJECTIVES: To determine the cost-effectiveness of secukinumab, a fully human IL-17A inhibitor, for adult patients in the UK with active ankylosing spondylitis (AS) who have not responded adequately to previous treatment with conventional care (CC) or previous biologic therapy. METHODS: A de novo combined decision tree/Markov state-transition model was developed to evaluate two populations: 1) biologic-naïve patients with an inadequate response to CC; 2) biologic-experienced patients with an inadequate response to prior biologic treatment. Comparators were licensed anti-TNF therapies and CC in the two populations, respectively. Clinical parameters captured treatment response rates, short-term treatment effects on disease activity and patient functioning, and long-term impact of structural disease progression. Utility values were derived from secukinumab trial data via regression methods. List prices were used for all drugs; where available, other costs were sourced from NHS reference costs. Outcomes included total discounted costs and quality-adjusted life years (QALYs), and the incremental cost-effectiveness ratio (ICER). The analysis perspective was the UK NHS in 2017. RESULTS: In the biologic-naïve population, secukinumab dominated adalimumab and infliximab and was associated with ICERS of <£20,000 per QALY gained compared to certolizumab pegol and etanercept. Secukinumab was less costly and associated with a minor decrement in QALYs versus golimumab, saving £19,782 per QALY foregone. In biologic-experienced patients, the ICER for secukinumab versus CC was £4,817 per QALY gained. At a £20,000 per QALY gained threshold, the probability of secukinumab being the most cost-effective intervention was estimated to be 45.5% in the biologic-naïve population (the highest probability of any intervention) and 98.2% in the biologic-experienced population. CONCLUSIONS: Secukinumab provides a cost-effective use of NHS resources for patients with active
AS who have responded inadequately to either CC or biologic treatment. The availability of a confidential patient access scheme discount for secukinumab in the UK further strengthens the case for cost-effectiveness in these populations.

**PMS45: COST-EFFECTIVENESS ANALYSIS OF APREMILAST FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS IN GREECE**

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**OBJECTIVES:** To assess the cost-effectiveness of placing apremilast before biologics in adult patients with active psoriatic arthritis, who have failed to respond to or are intolerant of conventional disease-modifying antirheumatic drugs from a Greek payer perspective. **METHODS:** A 40-year Markov transition model with monthly cycle duration was used. Treatment strategies consisted of apremilast prior to a biologic drug sequence compared with a biologic-only sequence. Sequential biologics were etanercept, adalimumab, golimumab and infliximab for both treatment strategies. Patients failing infliximab received best supportive care as last line of treatment. Response to treatment was assessed using the Psoriatic Arthritis Response Criteria (PsARC) at the end of the trial periods, obtained from a meta-analysis. Non-responders moved to the next treatment line. Long-term treatment withdrawal and patients' adjusted mortality rates were retrieved from the literature and national published sources. Utilities were obtained as a linear function of the Health Assessment Questionnaire (HAQ) and Psoriasis Area and Severity Index (PASI) scores based on a published regression equation. Following a payer perspective, direct costs relating to drug acquisition, administration, monitoring and overall patient management were considered (€, 2017). An annual discount rate of 3.5% was applied for costs and health benefits. **RESULTS:** The apremilast sequence before biologics resulted in an incremental cost per quality-adjusted life-year (QALY) gained of €23,242. Specifically, apremilast sequence was associated with 0.35 incremental QALYs compared with the biologic-only sequence (9.62 vs 9.27), at additional costs of €8,218 (€142,887 vs €134,670) over a patient’s lifetime. Results were most sensitive to changes in HAQ score and discount rates. At the defined willingness-to-pay threshold of €34,000, apremilast sequence was estimated to have a 79% probability of being cost-effective. **CONCLUSIONS:** Placing apremilast before biologics was found to be a cost-effective strategy for the treatment of active PsA in the Greek healthcare setting.

**PMS46: COST-EFFECTIVENESS EVALUATION OF A CARE BUNDLE INTERVENTION FOR PREVENTING FALLS AMONG ITALIAN AGED INPATIENTS IN A STEPPED-WEDGE CLUSTER RANDOMIZED CONTROLLED TRIAL**

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**OBJECTIVES:** Falls among hospitalized elderlies represent a frequent (20-30%) adverse event. About 30% of falls lead to injuries with different types of severity and can provoke long-time disability or death. The prevention of falls in the hospital is possible through the adoption of multimodal strategies. This study aimed at identifying the potential reduction in falls due to the Care Bundle implementation and its cost-effectiveness in real clinical environment **METHODS:** 10 clusters (hospital units) of Bologna USL and University Hospital were randomized in a stepped-wedge design including 4 steps over the years 2015 and 2016. Incidence rates of falls in both the control and intervention periods were calculated considering the patient-days of exposure. The overall crude relative risk (RR) was calculated with its 95% confidence interval. The overall crude incremental cost-effectiveness ratio (ICER) per fall prevented has been calculated. The difference in the rate of patient falls during the intervention period compared with the control period was in the denominator of the ICER. The difference in intervention vs control costs (associated with implementation of the Care Bundle program, length of stay and hospital services provided to patients attributable to falls) was in the nominator. **RESULTS:** A total of 11844 patients were randomized in this trial (intervention group n=6600, mean(SD) age=80.93(11.62); control group n=5244, mean(SD) age=78.14(12.68)) throughout the overall period. A 13% reduction (RR=0.87 (95% CI: 0.71-1.07)) in falls due to the Care Bundle intervention was observed, though it did not reach statistical significance. The overall ICER was €617.55 for fall prevented. **CONCLUSIONS:** The preliminary analyses showed a positive effect of Care Bundle intervention for preventing falls among aged inpatients at relatively low cost for fall prevented. Deeper statistical analyses to estimate precise cost-effectiveness of the Care Bundle intervention will be conducted shortly.

**PMS47: SECUKINUMAB IS DOMINANT VS. TNF-INHIBITORS IN THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS: RESULTS FROM A TURKISH COST-EFFECTIVENESS MODEL**

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OBJECTIVES: To evaluate the cost-effectiveness of secukinumab compared to available biologic treatments including certolizumab-pegol, etanercept, adalimumab and infliximab, in the treatment of active ankylosing spondylitis (AS) unresponsive to conventional treatment. METHODS: A Markov model representing the transition of active AS patients unresponsive to conventional treatment from current health state towards responder state (BASDAI-50 response) was adapted to the Turkish setting. The time horizon was set as life-time. Clinical inputs were derived from a Bayesian fixed effects network meta-analysis, covering the clinical trials of all treatment options. Utility values were based on international literature. The analysis was undertaken from payer’s perspective. Only direct costs were taken into account. Local costs of medications, administration and monitoring were converted based on TL/EUR currency rate of 3.7166 at end-2016. Incremental cost effectiveness ratio (ICER) per gained time spent in BASDAI-50 responder state and also per quality-adjusted-life-years (QALY) gained were calculated. RESULTS: All analyses were performed in biologic-naïve and biologic-experienced AS patients, as well as a mixed group. In biologic-naïve patients, total cost of secukinumab was found to be 4,644-9,134EUR lower than others. Gained time spent in BASDAI-50 responder state was 0.14-2.13 years with secukinumab. Furthermore, QALY gained with secukinumab was calculated as 0.20-0.86QALY. Cost-saving with secukinumab ranged between 7,641-15,297EUR, in biologic-experienced group. On the other hand, time spent in BASDAI-50 responder state was 0.21-2.05 years longer than others and QALY gained ranged between 0.26-1.06QALYs. In mixed group, total cost of secukinumab option was found to be 7,270-11,640EUR lower than others. Gained time spent in BASDAI-50 responder state was 0.21-2.05 years with secukinumab. Furthermore, QALY gained with secukinumab was calculated as 0.24-0.96QALY. CONCLUSIONS: Given its significant improvement in clinical response and quality-of-life and dominance, secukinumab is strongly suggested to be more effective and cost-saving in active AS patients unresponsive to conventional treatment in Turkey.

PMS48: SECUKINUMAB VS. ADALIMUMAB FOR THE TREATMENT OF PSORIATIC ARTHRITIS: A COST PER RESPONDER ANALYSIS AT 48 WEEKS FROM AN ARGENTINIAN PERSPECTIVE

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OBJECTIVES: To estimate and compare the long-term cost per responder (CPR) based on the American College of Rheumatology outcomes (ACR 20/50/70) following 48 weeks of psoriatic arthritis (PsA) treatment with secukinumab, the first and only fully human IL17-A antibody, relative to the anti-TNF adalimumab, in Argentina. METHODS: The target population included biologic-naïve patients. The CPR for each treatment was calculated by dividing the drug acquisition cost for the course of treatment with its response rate. Drug costs were estimated based on the retail price and the number of doses required for 48 weeks. The long-term response rates were estimated using a matching-adjusted indirect comparison (MAIC) technique based on the data from FUTURE 2 and ADEPT clinical trials of secukinumab and adalimumab, respectively. Sensitivity analysis was conducted by varying baseline characteristics used in the MAIC analysis. RESULTS: The MAIC analysis showed that ACR (20/50/70) response rates were higher for secukinumab 150mg and 300mg compared to adalimumab at 48 weeks. ACR 20 response rates were 80%, 74% and 56%, ACR 50 response rates were 57%, 61% and 44%, whereas ACR 70 response rates were 32%, 43% and 30% for secukinumab 150mg, secukinumab 300mg, and adalimumab respectively. For PsA patients on secukinumab 150mg, secukinumab 300mg and adalimumab respectively, the costs per ACR 20 responder were ARS 394,615, ARS 854,584, and ARS 830,255; the costs per ACR 50 responder were ARS 549,906, ARS 1,023,150, and ARS 1,069,267; and the costs per ACR 70 responder were ARS 970,942, ARS 1,464,840, and ARS 1,568,259. The sensitivity analysis confirmed the robustness of the main analysis. CONCLUSIONS: The long-term CPR for ACR 50 and 70 response rates were consistently lower for secukinumab versus adalimumab. Furthermore, with better outcomes at lower costs, these findings suggest dominance of secukinumab over adalimumab. More PsA patients could be treated more effectively with secukinumab versus adalimumab, in Argentina.

PMS49: COST-EFFECTIVENESS ANALYSIS OF SURGICAL APPROACHES TOTAL HIP ARTHROPLASTY

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OBJECTIVES: In the issue of hip joint endoprostheses, surgeons can choose different approaches. Two surgical approaches were selected for a comparison – the conventional (commonly used) and the minimally invasive, which is the most discussed novelty in current alloplasty. The aim of this study is to figure out cost effectiveness using cost-effectiveness analysis, comparison of operational approaches, and determination of a more cost-effective option. METHODS: Methods of value engineering and multiple-criteria decision making, especially Saaty's matrix, the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) and the Analytic Hierarchy Process
Patients had higher total treatment costs (total: ¥8,450 vs. ¥8,233; celecoxib cost: ¥7,218 vs. ¥6,279; physician cost: ¥1,232 vs. ¥1,954). Continuous use patients had 38.5% reduction in flares over one year compared with intermittent use (mean±SE [95% CI]: 6.4±0.03 [6.4, 6.5] vs. 10.5±0.05 [10.4, 10.6]). The objective of this study was to estimate and compare the long-term cost per responder (CPR) based on the Assessment of Spondyloarthritis International Society (ASAS) outcomes following 52 weeks of treatment of ankylosing spondylitis (AS) with secukinumab, the first and only fully human anti-IL-17A antibody, relative to the anti-TNF, adalimumab, in Argentina. OBJECTIVES: To estimate and compare the long-term cost per responder (CPR) based on the Assessment of Spondyloarthritis International Society (ASAS) outcomes following 52 weeks of treatment of ankylosing spondylitis (AS) with secukinumab, the first and only fully human anti-IL-17A antibody, relative to the anti-TNF, adalimumab, in Argentina. METHODS: The target population for the model was biologic-naïve patients. The CPR for each treatment was calculated by dividing the drug acquisition cost for the course of treatment with its response rate. Drug costs were estimated by multiplying the retail price with the number of doses required for 52 weeks. The 52-week response rates were estimated using a matching-adjusted indirect comparison (MAIC) based on data from MEASURE 2 and ATLAS clinical trials of secukinumab and adalimumab, respectively. Sensitivity analysis was conducted by varying baseline characteristics used in the MAIC analysis. RESULTS: The MAIC analysis showed that ASAS (20, 40 and 5/6) response rates were significantly higher for secukinumab compared to adalimumab at 52 weeks. ASAS 20, ASAS 40 and ASAS 5/6 response rates were 81% and 65%, 62% and 47%, 74% and 55% for secukinumab and adalimumab, respectively. The cost per ASAS 20 responder was ARS 415,901 and ARS 773,817, the cost per ASAS 40 responder was ARS 540,671 and ARS 1,075,879, and the cost per ASAS 5/6 responder was ARS 465,578 and ARS 920,561 for secukinumab and adalimumab, respectively. The costs per ASAS (20, 40 and 5/6) responders were approximately 54%, 50%, and 51% lower for secukinumab compared to adalimumab. The sensitivity analysis confirmed the robustness of the main analysis. CONCLUSIONS: The long term CPR for all ASAS response rates were consistently lower for secukinumab versus adalimumab. Furthermore, with better outcomes at lower costs, these findings suggest dominance of secukinumab over adalimumab. More AS patients could be treated more effectively with secukinumab versus adalimumab in Argentina.

OBJECTIVES: Intermittent celecoxib use reduces drug cost and limits risk of adverse events, but mitigates drug efficacy. The objective of this study was to estimate the cost-effectiveness of continuous versus intermittent celecoxib use among patients with progressive and symptomatic osteoarthritis. METHODS: Number of flares per patient were derived using graph digitization of a pragmatic clinical trial that assessed the efficacy of continuous versus intermittent celecoxib. Monte-Carlo simulation with bootstrapping was developed using Poisson distribution for treatment over one year. The simulation estimated the proportion of patients for each cumulative number of flares, assumed to be distributed uniformly over the study period. Continuous use patients received 200 mg daily celecoxib and additional 200 mg after flare occurrence; intermittent use patients received 400mg daily celecoxib only when flares occurred. The model also considered additional physician visits, productivity loss, and health utility associated with flares. Risk and cost of hip/knee surgery were considered in a sensitivity analysis. Costs were reported in 2017 Chinese Yuan (¥). RESULTS: Patients with continuous celecoxib use had 38.5% reduction in flares over one year compared with intermittent use (mean±SE [95% CI]: 6.4±0.03 [6.4, 6.5] vs. 10.5±0.05 [10.4, 10.6]). Continuous use patients had higher total treatment costs (total: ¥8,450 vs. ¥8,233; celecoxib cost: ¥7,218 vs. ¥6,279; physician cost: ¥1,232 vs. ¥1,954).
¥1,166 vs. ¥1,847; and productivity loss cost: ¥66 vs. ¥107). The incremental cost-effectiveness ratio and cost-utility ratio with continuous use were ¥54 ($8) per flare avoided and ¥202 ($30) per utility gained over one year. Continuous use was dominant over intermittent use when surgery was included in the analysis. CONCLUSIONS: Continuous celecoxib use appears to be a cost-effective treatment strategy among patients with progressive symptomatic osteoarthritis from Chinese payers’ perspective. With the consideration of increased risk of hip/knee surgery, continuous celecoxib use may be cost saving compared to intermittent celecoxib use.

PMS52: BISPHOSPHONATES FOR OSTEOPOROSIS TREATMENT: A COST-EFFECTIVENESS ANALYSIS IN VIETNAMESE WOMAN

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OBJECTIVES: Osteoporosis affects approximately 30% of postmenopausal women in Vietnam. Bisphosphonates (eg alendronate and zoledronate) are considered first-line treatment. Vietnam is classified as a lower middle-income country, and the cost-effectiveness of bisphosphonates is not clear. In this study we sought to analyze the cost-effectiveness of bisphosphonates in the treatment of patients who are diagnosed with osteoporosis. METHODS: The study was based on a cohort of women aged 50+ years, who were participants of the Vietnam Osteoporosis Study. A Markov model was constructed for the cohort, with 3 treatment options being compared: no treatment, a 5-year course with oral alendronate 70 mg/week, and a 5-year course of zoledronate 5 mg/year. The entire cohort entered the model in the ‘osteoporosis’ state, and then transitioned to other health states including ‘hip fracture’, ‘vertebral fracture’, ‘post-hip fracture’, and ‘post-vertebral fracture’ until death or age 100. A willingness-to-pay (WTP) threshold of 3 times the GDP per capita ($6,108 in 2015) was applied to determine cost-effectiveness. Unit costs were derived from national database, and all costs were adjusted to 2015 US dollars. RESULTS: For all age groups, zoledronate offered the highest QALYs gain and was the most cost-effective treatment at the chosen WTP threshold. The incremental cost-effectiveness ratio (ICER) of zoledronate was lowest for patients aged 65 years ($1,812/QALY) compared to other age groups. In one-way sensitivity analysis, the cost of post-fracture and treatment adherence had the highest impact on the ICERs, but zoledronate remained the best option under the WTP threshold. In probabilistic sensitivity analysis, the probability of being the most cost-effective treatment for zoledronate ranged from 68% to 98%, depending on patients’ age. CONCLUSIONS: At a willingness-to-pay of $6,108/QALY, zoledronate was the most cost-effective osteoporosis therapy for postmenopausal women aged ≥50 years old in Vietnam.

PMS53: COST-MINIMIZATION ANALYSES OF BIOLOGICAL THERAPIES IN THE TREATMENT OF RHEUMATOID ARTHRITIS FROM THE EGYPTIAN HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: Different biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDs) are indicated for moderate-to-severe Rheumatoid Arthritis (RA) patients, who fail on conventional DMARDs (cDMARDs). This study aims to compare the annual treatment costs of the bDMARDs dosing according to the clinical treatment guidelines. METHODS: We were comparing three bDMARDs from the Egyptian public healthcare system perspective: adalimumab (ADA), etanercept (ETN), and infliximab (IFX). Annual treatment costs were calculated for a patient of 80 kg. Direct medical costs were considered in the analyses from the public local hospitals. Probabilistic sensitivity analysis (PSA) was carried out to determine the impact of different parameters simultaneously on the results. RESULTS: IFX currently presents the lowest annual treatment cost among bDMARDs at EGP 30,812/patient/year, 56%, and 58% lower than ADA, and ETN, respectively. The PSA shows that IFX is 100% more likely to achieve the lowest annual treatment costs, and be the cost saving option for moderate-to-severe RA Egyptian patients. CONCLUSIONS: It is more appropriate to analyze each research question due to the fragmented healthcare system in Egypt. IFX represents an important treatment option for RA patients in Egypt, as it has the lowest treatment cost among available bDMARDs but there’s no evidence on the similar effectiveness of bDMARDs among Egyptian patients.

PMS54: COST-EFFECTIVENESS OF SECUKINUMAB FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS IN THE UK

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OBJECTIVES: To determine the cost-effectiveness of secukinumab, a fully human interleukin-17A inhibitor, for adult patients in the UK with active psoriatic arthritis (PsA) who have not responded adequately to previous treatment with conventional systemic disease-modifying anti-rheumatic drugs (csDMARDs). METHODS: A model was developed from the UK NHS perspective, structured as a three-month decision tree leading into a lifetime Markov model. Separate analyses based on number of prior csDMARDs (1 and ≥2) were conducted, with secukinumab 150 mg compared to relevant comparators for each subpopulation (Standard of Care [SoC] and tumour necrosis factor inhibitors, respectively). Response at three months and other clinical parameters were derived from the FUTURE 2 trial (1-prior csDMARD) and a network meta-analysis (≥2-prior csDMARDs). Utility values were based on FUTURE 2 trial data. List prices were used for all drugs; where available, other costs were sourced from NHS reference costs. Outcomes included total discounted costs and quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs). RESULTS: In the 1-prior csDMARD subpopulation, the ICER for secukinumab versus SoC was £28,735 per QALY gained. In the ≥2-prior csDMARDs subpopulation, secukinumab dominated golimumab, certolizumab pegol and etanercept, and had an ICER of £5,380 per QALY gained versus adalimumab. The ICER for infliximab versus secukinumab was £1,287,449 per QALY gained (i.e. infliximab not cost-effective). The probability of secukinumab being the most cost-effective intervention at a £30,000 per QALY gained threshold was estimated to be 48.1% and 70.8% in the 1- and ≥2-prior csDMARDs subpopulations, respectively. Several scenario analyses demonstrated results to be robust. CONCLUSIONS: Secukinumab represents a cost-effective use of NHS resources for patients with PsA who have responded inadequately to either 1- or ≥2-prior csDMARDs and in some cases dominates comparators. The availability of a confidential patient access scheme discount for secukinumab in the UK further strengthens the case for cost-effectiveness in these subpopulations.

PMS55: COST-UTILITY ANALYSIS OF PHYSICIANS’ GUIDELINE ADHERENCE FOR OSTEOPOROSIS IN GERMANY

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OBJECTIVES: Osteoporosis is characterized by the occurrence of fractures due to reduced bone stability. Annual direct costs of osteoporosis are estimated at € 5.4 billion in Germany. Without changes in policy, fractures – the main cost driver – are expected to double by the year 2050. While a high-quality evidence-based guideline on screening and preventive treatments exist, only 52% of general practitioners stated to have knowledge of the guideline, which is expected to result in low levels of guideline adherence and implementation. Therefore, the objective of this study is to investigate the economic impact of a 20% increase (from currently assumed ≈50% to a target 70%) of guideline adoption rate by German primary care physicians. METHODS: A health economic model was developed to investigate the cost impact and cost-effectiveness of extended guideline implementation. Screening was modeled using a decision tree, subsequent treatment was modelled in a Markov approach, with one-year cycles simulated over lifetime. The modelled cohort comprised 381,583 women eligible for screening at age 70. The perspective of the statutory health insurance was applied; accordingly, prices from official formularies and fee schedules were used. Sensitivity analyses were performed to test the robustness of results. RESULTS: Increasing implementation of the guideline by 20% resulted in an additional screening of 76,317 women and treatment of 19,079 women at high fracture risk. 1,668 fractures were avoided, as were 588 subsequent deaths. Over lifetime, higher implementation led to 5,214 additional QALYs and additional costs of € 59 million, resulting in € 11,383 per QALY gained. CONCLUSIONS: A conservative 20% increase in implementation of the evidence-based guideline could substantially reduce fractures and increase quality of life, while showing a limited impact on the healthcare budget. From a health economic point of view, a comprehensive implementation of the guideline, by increasing physicians’ guideline adherence, appears recommendable.

PMS56: COST-EFFECTIVENESS OF INFLECTRA® VS. REMICADE® FOR ANKYLOSING SPONDYLITIS IN GERMANY

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OBJECTIVES: After the approval of infliximab biosimilars, expenditure for Remicade® decreased by 4.3 % in 2015 in Germany. Total infliximab expenditure including biosimilars accounted for € 231.77mn in Statutory Health Insurance (SHI) pharmaceutical costs. Potential savings of Remicade® substitution by biosimilars was estimated at € 46.51mn for Germany. OBJECTIVES: To develop a method to examine the cost-effectiveness of biosimilars for patients with ankylosing spondylitis (AS). We analyze the cost-effectiveness of biosimilar Inflectra® vs. Remicade® for the German SHI system. METHODS: We simulate 10,000 hypothetical AS patients by setting up an individual patient sampling lifetime model. Initial characteristics are derived from clinical studies. Direct and indirect costs are
incorporated to reflect a societal perspective. After each 6-month cycle, discontinuation of treatment due to adverse events or loss of efficacy is evaluated. As outcome measure, improvement of functional status (BASFI) is recorded, converted to quality of life, and compared to mean natural progression. Incremental quality-adjusted life years (QALYs) are calculated. **RESULTS:** Direct costs excluding value-added tax and mandatory rebates are € 77,194.65 for Inflectra® vs. € 96,407.67 for Remicade®. Indirect costs are € 439,314.28 vs. € 440,972.54. Total costs excluding value-added tax and mandatory rebates are € 516,508.93 for Inflectra® vs. € 537,380.21 for Remicade®. Patients gain 4.86 QALYs with Inflectra® and 4.61 QALYs with Remicade®. The incremental cost-utility ratio is negative for the biosimilar, i.e. patients gain more QALYs at lower total costs. Sensitivity analysis shows the results' robustness when altering mortality rates, disease progression, time on treatment with nonsteroidal anti-inflammatory drugs and overall time on treatment. **CONCLUSIONS:** Treatment of AS with biosimilar Inflectra® is cost-effective compared with Remicade® treatment. Inflectra® lowers total costs from a societal perspective. To capture the whole range of the treatments' economic effects, estimation of cost-effectiveness relies on simulation with a lifetime horizon.

**PMS57: PATIENT BURDEN OF RHEUMATOID ARTHRITIS: RESULTS OF A GLOBAL SYSTEMATIC LITERATURE REVIEW ON DISABILITY, WORK DISRUPTION, AND FUNCTIONAL CAPABILITY IN THE REAL WORLD**

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**OBJECTIVES:** The objective of this review is to synthesize available evidence on the burden of disease in patients with rheumatoid arthritis (RA) with respect to disability, work disruption, and functional capacity. **METHODS:** Observational studies published between 2006 and 2015 were systematically identified through the MEDLINE, EMBASE and Cochrane databases. Literature were assessed for eligibility by two independent reviewers based on pre-specified criteria. **RESULTS:** In total, 21 studies met eligibility criteria for inclusion. The studies included patients with RA with varying degrees of disease activity, functional disability, and treatment history, inclusive of both biologic and non-biologic therapies. Substantial levels of absenteeism, presenteeism (ie, working while sick), and early retirement due to disability were consistently reported. Early retirement was reported in up to 85% of patients with severe disability, and up to 80% of patients were reported to receive disability pension. In the US, annual income lost due to reduced productivity was up to $8,957. In Europe, the cost of disability was up to €8,902 - €11,369 annually, up to 96% of which was attributed to early retirement. Multiple regression models revealed work productivity losses to be positively correlated with Health Assessment Questionnaire (HAQ) (P<0.001) and negatively correlated with age (P<0.001) and disease duration (P<0.05). Patients with high HAQ scores (2.1-3) have been reported to have productivity losses up to 5 times higher than those with scores between 0.0-0.5. Studies suggest a positive impact of biologics on productivity losses, especially in patients with more severe disability. **CONCLUSIONS:** Our study provides a comprehensive review and synthesis of available published studies reporting the impact of RA and its characteristics on productivity losses. Despite improvements over time with the increased availability of biologic therapies, patients still experience relatively high levels of early retirement and disability, suggesting a need for additional RA therapies.

**PMS58: TREATMENT PATTERNS FOR RA PATIENTS IN ITALIAN REAL PRACTICE**

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**OBJECTIVES:** International Guidelines recommend an early and aggressive treatment with csDMARDs or bDMARDs, to prevent permanent damage in patients with RA. The aim of this study was to describe the treatment patterns among adult patients affected by RA in Italy. We also evaluated the percentage of patients who are naive to csDMARDs. **METHODS:** We conducted a retrospective, observational study on administrative databases from 6 Italian LHUs with data available from 01/01/2009 to 31/12/2014; data were re-proportioned to Italy's sample of about 60 million beneficiaries. We used the previous 4-y history to forecast the treatment patterns in the following 4-y. Naïve patients were defined as those who had no prior antirheumatic drug. We included patients with RA who had at least one prescription of b or cs DMARDs or corticosteroid in 2014. **RESULTS:** The estimated number of patients diagnosed and treated for RA in 2014 in Italy was 148,251; of whom, 31%, were treated with csDMARDs, 29% with corticosteroids + 1 csDMARD, 27% with corticosteroids, 7% with bDMARDs and 6% received corticosteroids + 2csDMARDs. Naïve patients treated with csDMARD were 24,092. In the previous 4-yhistory to forecast the treatment patterns in the following 4-y, the majority of patients were treated with the same drug classes, and a high percentage of patients interrupted treatment: csDMARD (61%, 53%, 51%,46%), corticosteroids + csDMARD (17%, 15%, 14%, 18%), no therapy (12%, 16%, 18%, 23%), corticosteroids (4%, 8%, 10%, 8%), 2 csDMARDs (4%, 6%, 8%, 4%).
corticosteroid + 2 csDMARD (2%, 2%, 2%, 3%), bDMARDs (0%, 0%, 1%, 1%), for the 4-y in the analysis, respectively. **CONCLUSIONS:** The treatment of RA in Italy explored through this study showed heterogeneity of patterns, with a variety of combinations between corticosteroids, csDMARD and bDMARDs used over time. Despite the guidelines and updated EULAR recommendations, study results show misalignment with recommendations.

**PMS59: THERAPEUTIC STRATEGIES UTILIZATION AND RESOURCES CONSUMPTION IN PATIENTS TREATED FOR PSORIATIC ARTHRITIS IN ITALY.**

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**OBJECTIVES:** To analyze the therapeutic strategies and to estimate the health care resources consumption in in patients with PsA. **METHODS:** An observational retrospective cohort analysis of administrative databases of 4 Italian Local Health Units was performed. Patients ≥ 18 years with a hospitalization discharge diagnosis of PsA (ICD-9-CM 696.0) or exemption code (045.696.0) for PsA from 01/01/2010 to 31/12/2015 (inclusion period), with at least one prescription of any therapy used for PsA were included. The index-date (ID) was the matching with at least one of the inclusion criteria during the inclusion period. All patients were followed up after the ID until the end of data availability. **RESULTS:** A total of 1,884 patients with PsA, 40.7% male, mean age of 52.1 years, were enrolled in the study. About 74.4% of patients were treated with only 1 systemic drug, and of these 52.5% received MTX, 11.5% bDMARD. Patients treated with 2 systemic drugs were 20.9% of which in combination were 50.8% and after switching were 49.2%. Of the patients treated with csDMARD, 41.6% had levels of C-reactive protein (CRP) higher than >1 mg/dL, 33.7% between 0.5-1, and 24.8% below 0.5 mg/dL. These percentages in patients treated with bDMARD were 43.3%, 26.7% and 30%, respectively. The mean overall healthcare costs were € 1,653 and € 13,500 per year for patients treated with csDMARD and bDMARD, respectively. **CONCLUSIONS:** Our findings confirm that, in an Italian real-world setting, costs are usually higher for patients treated with biologics; the concentration of CRP, we found that inflammation levels due to pathology were above the normal limits in a high proportion of patients receiving both csDMARD and bDMARD. Further research needs to assess disease progression and disease remission.

**MUSCULAR-SKELETAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies**

**PMS61: ADHERENCE ISSUES IN RHEUMATOID ARTHRITIS TREATMENT: HOW CAN ACCEPTANCE MEASUREMENT HELP UNDERSTANDING PATIENTS’ CONCERNS AND WORKING ON SOLUTIONS?**

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**OBJECTIVES:** Patients with Rheumatoid Arthritis (RA) are required to take long-term treatments to manage their chronic disease. 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 RA 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 RA 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: Immunosuppressant versus Other RA treatments. **RESULTS:** 215 RA patients were included. Mean Acceptance/General score was of 43.68 ± 30.64. Patients taking an immunosuppressant scored significantly lower than those taking other RA treatment’s on Acceptance/Medication Inconvenience (p < 0.01), but not on any other dimension scores. Pearson correlations showed Acceptance/General to be highly correlated with Acceptance/ Effectiveness (R = 0.56). Experiencing side effects and difficulty accepting treatment for the future were the main reported issues, affecting half of the sample. **CONCLUSIONS:** Treatment acceptance is not satisfactory in RA patients. 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 RA patients’ priorities and unmet needs.

**PMS62: EXTERNAL VALIDATION OF A MAPPING ALGORITHM TO ESTIMATE EQ-5D-3L UTILITIES FROM OXFORD KNEE SCORE RESPONSES**
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OBJECTIVES: A key strength of any model is its generalisability to samples other than the one from which it was developed. This analysis evaluated the external validity of a mapping algorithm for predicting EQ-5D-3L utilities from Oxford Knee Score (OKS) responses in a large sample of patients receiving knee replacement surgery. METHODS: Data were obtained from the UK Patient Reported Outcome Measures dataset (April 2011 – March 2015), yielding 332,235 complete, concurrent observations of EQ-5D and OKS from 177,132 patients. A response mapping algorithm developed by Dakin et al (2013) was evaluated, employing multinomial logistic regression to predict EQ-5D-3L item responses based on OKS responses, and estimating utilities based on an expected value approach. Predictive accuracy was assessed through calculating the mean squared error (MSE), mean absolute error (MAE) and the proportion of absolute errors >0.1. Performance across the range of observed OKS scores was also assessed. Additionally, an algorithm based on linear regression was evaluated for comparison. RESULTS: Pre- and post-operative EQ-5D-3L utilities respectively exhibited a bimodal and trimodal distribution (Mean[SD]=0.407[0.312] and 0.721[0.263]). The MSE and MAE of predicted versus observed EQ-5D-3L utilities were 0.033 and 0.129, respectively. Notably, these values were lower than those previously observed in the original development and validation of the algorithm, indicating improved predictive accuracy. 56.9% of predicted EQ-5D-3L utilities were within 0.1 of their true observed values. Reduced performance was observed in patients with OKS scores between 10 and 19. As expected, the algorithm based on linear regression had lower predictive accuracy (MSE=0.041, MAE=0.159). CONCLUSIONS: The findings of this study support the validity of this algorithm, outperforming the original estimation and validation results in terms of predictive accuracy. This algorithm can be used to estimate utilities and thus QALYs for cost-effectiveness analyses where only the OKS was administered, or within sensitivity analyses where both questionnaires were administered.

PMS63: IDENTIFYING THE PRIMARY OUTCOME FOR A RANDOMISED CONTROLLED TRIAL IN RHEUMATOID ARTHRITIS: THE ROLE OF A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: The objective of this study was to establish the preferences of patients with Rheumatoid Arthritis (RA) about the best outcome measure for a health and fitness intervention randomised controlled trial (RCT). The results of this study were used to inform the choice of the trial primary and secondary outcome measure. METHODS: A discrete choice experiment (DCE) was used to assess patients’ preferences regarding a number of outcomes: foot and ankle pain, fatigue, mobility, ability to perform activities of daily living, and choice of footwear. Preferences were also gathered for different schedules and frequency of delivery for the health and fitness intervention. The initial outcomes were chosen based on literature review, clinician recommendation and patients’ focus groups findings. The DCE was constructed using the D-efficiency criteria with SAS software macros. The DCE compared hypothetical scenarios with varying levels of outcomes severity as well as the schedule of the intervention. Preference weights were estimated using a number of econometric models (conditional logit, mixed logit and generalized multinomial logit) which are based on different assumptions, to account for preference and scale heterogeneity. The attribute importance was established by using the partial log-likelihood method. RESULTS: 100 patients with RA completed 18 choice sets via a web based platform. Overall, patients selected foot and ankle pain as the most important outcome, with mobility being nearly as important. There was no evidence of differential preference between intervention schedules or frequency of delivery. CONCLUSIONS: Foot and ankle pain can be considered the patient choice for primary outcome of an RCT relating to a health and fitness intervention. This study demonstrated that, by using the DCE method, it is possible to incorporate patients’ preferences at the design stage of a RCT. This approach ensures patient involvement at early stages of health care design.

PMS64: CORRELATION OF MINIMAL CLINICALLY IMPORTANT DIFFERENCES BETWEEN PATIENT REPORTED OUTCOME MEASURES RELATED TO SPINAL SURGERY

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OBJECTIVES: Minimal clinically important differences (MCIDs) represent the smallest change following a clinical intervention considered meaningful for patients. The objective was to estimate the correlation of MCIDs for patient reported outcome measures (PROMs) related to spinal surgery. METHODS: Using data from the Swedish spine register Swespine, we estimated changes in PROMs Oswestry Disability Index (ODI), Visual Analog Scale (VAS) for pain and EQ-5D in patients who had lumbar spine surgery between 2000 – 2012 from surgery to two-year follow up.VAS leg pain was used for patients diagnosed with spinal stenosis and disc herniation whereas VAS back pain was
used for spondylolisthesis and degenerative disc disease. Two binary variables were constructed for each of the PROMs indicating whether the change could be defined as an improvement according to the highest and lowest MCID cut-offs identified in the literature signifying improvements in back pain following surgical interventions. Correlations between MCID-defined improvements in the PROMs were estimated with the phi coefficient. RESULTS: MCID cut-offs identified in the literature ranged from -5 to -20 for ODI, from -18 to -35 for VAS, and from 0.05 to 0.52 for EQ-5D. Considering the lower (upper) thresholds, the correlation between improvement in ODI and VAS was 0.40 (0.39), between ODI and EQ-5D 0.48 (0.38), and between EQ-5D and VAS 0.35 (0.25). All correlations were significant at the 1% level. This indicate moderate relationships between having improved according to MCID in one PROM and having improved by another PROM, except for VAS and EQ-5D considering the upper MCID threshold, in which case the correlation was low but not negligible. CONCLUSIONS: Low to moderate relationships of having improved outcomes using different PROMs were found. Relying on only one PROM to infer whether a patient has had a clinically meaningful improvement is associated with uncertainty.

PMS65: POOLED REAL WORLD DATABASES ANALYSIS OF PATIENT’S REPORTED OUTCOMES IN RHEUMATOID ARTHRITIS PATIENTS

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OBJECTIVES: The objective of this analysis is to evaluate in real-life practice the pain, fatigue, disease activity and physical function according to a treatment initiation strategy in Rheumatoid Arthritis (RA) patients. METHODS: Individual studies usually not allow analyzing PROs due to lower number of evaluable questionnaires over time. A pooled database of 2 prospective, multicenter, French non-interventional studies (Spare-1 n=307 and Act-solo n=577) allowed a better evaluation PROs according to tocilizumab (TCZ) treatment strategy of monotherapy (Mono) or in combination (Combo). Data covering period: from 2011 to 2014. PROs used were Visual Analogic Scale (VAS) to measure pain, disease activity and fatigue. Physical functions were evaluated using the HAQ-DI. RESULTS: 884 pts were analyzed. Patient’s characteristics: 57% of the pts were >55 years old, 78% female, mean RA duration was 10.7±9.1 years. TCZ was initiated as Mono in 36.4% of pts and in Combo in 63.6%. At inclusion, respectively in Mono/Combo, mean VAS fatigue was 68±22mm/61±25mm, mean pain VAS was 64±23mm/58±24mm. Respectively after 6 and 12 months treatment (Mono/Combo), mean VAS fatigue was 46±29mm/43±29mm and 41±27mm/38±28mm, mean pain VAS was 36±24mm/36±25mm and 28±22mm/32±25mm. Percentage of patients with low pain (VAS<40mm) increased from 15%/22% at inclusion to 58%/57% after 6 month and 70%/61% after 12 months. Percentage of patients with low fatigue (VAS<40mm) increased from 11%/19% at inclusion to 41%/48% after 6 month and 51%/54% after 12 months. CONCLUSIONS: Under treatment, an important decrease of pain and fatigue are reported by patients, without major difference observed between TCZ treatment strategy of monotherapy or in combination. Atypical patient profile will be also investigated in this pooled database.

PMS66: IMPACT OF GOLIMUBUM, AN ANTI-TNFA MONOCLONAL ANTIBODY, ON HEALTH RELATED QUALITY OF LIFE (HRQOL) AND WORK PRODUCTIVITY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: 24-WEEK RESULTS OF THE PHASE III GO VIBRANT TRIAL

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OBJECTIVES: To evaluate health-related quality of life (HRQoL) including general health status, daily activity, and work productivity of intravenous (IV) golimumab in subjects with active psoriatic arthritis (PsA). METHODS: In this randomized, double-blind, Phase 3 trial, adults with active PsA naïve to anti-TNF therapy received golimumab 2 mg/kg (n=241) or placebo (n=239). Current health status was measured by EuroQol-5D-5 level (EQ-5D-5L) index including 5 domains: mobility, self care, usual activities, pain/discomfort, and anxiety/depression; impact of PsA on daily productivity was measured by visual analogue scale (VAS); and impact of PsA on work productivity was measured by Work Limitations Questionnaire (WLQ) productivity loss score in subjects who work or volunteer (converted from 25-item version). Changes from baseline were analyzed. Unadjusted p-values of least square mean differences (LSMD) between treatment groups were based on analysis of covariance controlling for baseline score and baseline methotrexate usage. RESULTS: Mean EQ-5D-5L index improvements were greater with golimumab vs. placebo at Weeks 8 (0.14 vs. 0.04), 14 (0.15 vs. 0.03), and 24 (0.16 vs. 0.04). At Weeks 14 and 24, LSMD were both 0.12 (p<0.001). Mean reductions in impact of PsA on productivity VAS were greater with golimumab vs. placebo at Weeks 8 (~2.91 vs. ~0.71), 14 (~3.04 vs. ~0.76), and 24 (~3.33 vs. ~0.89). At Weeks 14 and 24, LSMD were: -2.17
OBJECTIVES: The outcome of surgical treatment of LDH may deteriorate with advancing age due to e.g. higher risk of complications and ability to recover. The objective was to assess whether surgical treatment outcome in patients with LDH differs depending on age. METHODS: Patients who underwent LDH surgery between 2000–2012 were identified in the Swedish national spine surgery register Swespine. The patient reported outcome measures (PROMs) Oswestry Disability Index (ODI), Visual Analog Scale of leg pain (VAS) and quality of life (QoL) in the EQ-5D reported pre-operatively were compared with the reported values 1 year post-operatively. Age strata (<20, 20–29, 30–39, 40–49, 50–59, 60–69, 70–79, 80+), gender, socioeconomics, comorbidities, pre-operative EQ-5D/ODI/VAS, smoking habits and pre-operative number of years with leg pain were included in an ordinary least squares regression with 1-year postoperative outcome as dependent variable. RESULTS: 11,625 patients were included. The adjusted absolute improvement in EQ-5D declined with age—age <20: 0.59; age 20–29: 0.50; age 30–39: 0.45; age 40–49: 0.44; age 50–59: 0.43; age 60–69: 0.48; age 70–79: 0.45; age 80+: 0.37. Similar pattern was found for VAS and ODI. Compared with the youngest group, improvements on all PROMs were statistically significantly lower for all older ages (p<0.05), but differences were not significant between age groups from 30–79. Adjusted percentage improvement in EQ-5D, VAS and ODI decreased with age, but was only significant for ODI when compared with the youngest group. Smoking habits, female, born outside Sweden and more comorbidities were significant predictors of less improvement (p<0.001). CONCLUSIONS: Older patients had less improvement in QoL, disability and pain levels 1 year after surgery for LDH compared with younger patients. However, differences were small and lack clinical importance. Older patients generally have the same benefit as younger patients from LDH surgery.
OBJECTIVES: The prevalence of knee arthritis (KA) in Slovak Republic is about 250 000 cases. No study was published about the impact of KA on quality of life (QoL) and work ability (WA) in patients with KA in Slovak Republic. METHODS: 120 patients were evaluated, 68 women and 52 men, with the average age being 62.6 years, weight – 84.8 kg and height – 166.5 cm. 19 patients had KA in grade II, 99 – grade III and 2 – grade IV. Average duration of the disease was 8.2 years. The primary method used for the analysis of QoL was a combined questionnaire consisting of 5 parts: A. Demography, B. Clinical part, C. Quality of life, D. Socio-economic part, E. Special questions. QoL and WA were evaluated on numeric scales from 0 - the worst to 10 - the best. Statistical methods from Excel 2010 were used in results evaluation. RESULTS: Significant statistical differences in QoL were found: in the time of best health: 8.9, without knee arthritis (KA) – 8.2, in the time of diagnosis – 4.2 and in the recent time – 4.9. Similar results were gained in WA: 9.2 vs 8.4 vs 2.7 vs 2.6 and in pain evaluation: 9.3 vs 8.0 vs 2.5 vs 3.3. The results from QoL and WA were in strong correlation. Foreknowledge of disease (1-the worst, 5-the best) was 3.3, satisfaction with medical care – 4.2 and nursing care – 4.4. Willingness to pay for full health without KA was 88.5 € monthly by average monthly income 385,4 €. CONCLUSIONS: KA has a significant negative impact on patients’ QoL and WA. The dominant factor of QoL and WA is knee pain. Treatment has positive impact on QoL but no impact on WA. There are significant differences in QoL and WA in duration of KA.

PMS70: REAL-WORLD HEALTH-RELATED QUALITY OF LIFE EQ-5D-5L OUTCOMES IN ANKYLOSING SPONDYLITIS (AS): ANALYSIS OF DATA FROM THE UK BRITISH SOCIETY FOR RHEUMATOLOGY REGISTER IN ANKYLOSING SPONDYLITIS (BSRBR-AS) STUDY

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BACKGROUND: Economic models developed to inform healthcare reimbursement decisions in Ankylosing Spondylitis (AS) are often based on mapping algorithms linking Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Index (BASFI) scores to indirectly estimate measures such as the EQ-5D-5L values. OBJECTIVES: To generate HRQoL profiles using direct real-world data to facilitate the development of economic models to assess the cost-effectiveness of biologic versus non-biologic therapy in AS. METHODS: EQ-5D-5L data were drawn from patients included in the UK-wide prospective observational cohort study – the British Society for Rheumatology Register in Ankylosing Spondylitis (BSRBR-AS) study during the period Dec 2012-Nov 2016. The study sample comprised 688 biologic (mean age 44.4(13.3) years; 69% male) and 1582 non-biologic patients (mean age 50.1(14.6) years, 69% male). We constructed EQ-5D-5L scores and confidence intervals for AS patients reporting levels 1 (no problems) and 2 to 5 (problems) on the EQ-5D-5L descriptive system, stratified by BASDAI and BASFI for various AS health state profiles. RESULTS: Pooled baseline and follow-up EQ-5D-5L data were available for 1987 patients (4384 observations). BASDAI, BASFI, and the EQ-5D-5L spanned the entire severity of feasible disease states. Utility values ranged from 0.7466 for BASDAI scores >2 to 0.7356-0.7627 for BASFI scores >2, >8 respectively. CONCLUSIONS: The EQ-5D-5L was able to discriminate between different levels of disease severity. This study captures real-world EQ-5D-5L values for patients with AS. The EQ-5D-5L values reported here are the first set of estimates from AS patients in routine clinical settings, and they provide a platform to enable calculation of alternative AS mapping algorithms in the future.

PMS71: ASSESSING THE BURDEN OF DISEASE IN PERIPHERAL AND AXIAL SPONDYLOARTHRITIS IN MEXICO

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OBJECTIVES: To assess the burden of disease in peripheral Spondyloarthritis (SpA) – Psoriatic Arthritis (PsA), and axial SpA – non-radiographic axial SpA (nr-axSpA) and Ankylosing Spondylitis (AS), in Mexico. METHODS: Data were gathered from the Adelphi Real World 2015 DSP1. Rheumatologists (n=24) and dermatologists (n=10) completed 240 patient record forms (PRF) on consulting SpA patients. Patients (n=225) voluntarily completed questionnaires (PSC), assessments of quality of life (SF-36, EQ-5D), and work productivity & activity impairment (WPAI). RESULTS: Health Services: PRF data showed that the mean number of specialist consults in the last year was 8.1 per patient, and 4% (n=9) had a hospital admission to treat SpA-related complications. Further, 4.9% (n=11) reported having received an injection/infusion while in hospital; while 29.8% (n=67) of patients reported an
OBJECTIVES: The current standard of care for rheumatoid arthritis (RA) patients receiving biologic disease-modifying antirheumatic drugs (bDMARD) is to use them concurrently with a conventional synthetic DMARD (csDMARD). However, many patients are either intolerant or do not take csDMARDs. This analysis identifies patient characteristics associated with, and reasons for prescription of, bDMARDs as monotherapy (MT) versus combination (CT) with csDMARDs. METHODS: Data were drawn from the Adelphi Disease Specific Programme, a point-in-time survey (Q1 2017) of rheumatologists and their patients with RA in the EU5. Physician-reported data included patient demographics, disease status, current treatment and level of satisfaction. Patients were also invited to voluntarily provide information on quality of life (QoL) and disability. Patients were stratified by CT versus MT. RESULTS: 1541 patients receiving bDMARDs who had been moderate or severe RA (74% CT, 26% MT) were included in this analysis; 677 provided self-completion data (66% CT, 34% MT). Compared with CT, MT were more likely to be male (38.6% vs 28.0%; p<0.01). Caucasian (93.6% vs 88.9%, p<0.01) and have more comorbid conditions (1.26 vs 1.06; p<0.01). Age, BMI, and retirement due to RA were not statistically significantly different. On initiation of current treatment, in general MT were: less likely to be ‘deteriorating’ (48.2% vs 54.1% p=0.046) or severe (38.9% vs 56.0%, p<0.01); experiencing less pain (6.7 vs 7.3 on a 1-10 scale, p<0.01); and less likely to be receiving TNFi (60.4% vs 69.2%, p<0.01). The main reason for receiving MT was poor tolerability of csDMARDs (48.3%). Currently, QoL and disability were similar; EQ-5D (MT 0.75, CT 0.70, p=0.09) and HAQ-DI (MT 0.91, CT 0.89, p=0.82). CONCLUSIONS: On initiation, while, patients on MT had more comorbidities but less severe RA than those who were prescribed CT, all patients continued to experience poor QoL, indicating a continuing unmet medical need.

PMS73: TRENDS AND PREDICTIVE FACTORS OF HRQOL IN TRAUMA PATIENTS. : A PROSPECTIVE COHORT STUDY

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OBJECTIVES: The aim of our study was to assess the HRQOL recovery of trauma patients at 12 months after injury using the Short Form (SF-36) Health Survey and identify predictive factors associated with improved mental health (MH) and physical function (PF) over time. METHODS: A prospective cohort study was performed in our tertiary care hospital from September 2013 to September 2015. All consecutive trauma patients who were admitted to our department were included except for those under the age of 18, or with coexisting cognitive impairment, or deceased. Data were collected prior to hospital discharge and 3,6, and 12 months post injury. Data included SF-36, injury characteristics, acute care factors and social status. Linear mixed-effects models were used to identify factors associated with MH and PF in SF-36. RESULTS: Complete data collection was achieved in 129 out of 185 patients. The median age was 66 years (interquartile range: 54 to 75), and 82 (64%) were male. Seven of the eight SF-36 domains except General health improved significantly over 12 months, however all domain scores were lower than Japanese standard norms. Never married status was associated with better MH. On the other hand, head injury (AIS≧3) were predictive of lower MH over the 12 months of follow-up. Independence at home was associated with better PF. On the other hand, lower-extremity injury (AIS≧3) was predictive of lower PF. However, ISS and the mechanism of injury were not predictive factors associated with both MH and PF. CONCLUSIONS: All domain scores were lower than Japanese standard norms at 12 months after injury, however most SF-36 domains improved significantly over 12 months. Social status and localization of injured body region affected more strongly the long-term HRQOL than ISS. With regard to localization of injured body region, head injury affected negatively MH and lower-extremity injury affected negatively PH.
OBJECTIVES: To assess the burden of disease in peripheral Spondyloarthritis (SpA) – Psoriatic Arthritis (PsA), and axial SpA – non-radiographic axial SpA (nr-axSpA) and Ankylosing Spondylitis (AS), in Brazil. METHODS: Data were gathered from the Adelphi Real World 2015 DSP1. Rheumatologists (n=59) and dermatologists (n=10) completed patient record forms (PRF) on consulting SpA patients. Patients (n=340) voluntarily completed questionnaires (PSC), quality of life assessments (SF-36, EQ-5D), and work productivity & activity impairment (WPAl). RESULTS: Health Services: PRF data showed that the mean number of specialist consultants in the last year was 5.1 per patient, and 1.8% ever had a hospital admission to treat SpA-related complications. Further, 4.1% (n=14) reported having received an injection/infusion while in hospital; while 20.6% (n=70) of patients reported an injection/infusion in an outpatient setting. Out-of-Pocket Costs: PSC data revealed that patients spent an average of R$318.93 (BRL) (n=148) on treatment in the last 3 months, representing 10.3% (n=143) of their quarterly household income. Societal: PSC data (n=219) showed that 61.2% of patients were employed. Additionally, 39 patients reported a mean of 0.6 unscheduled days off in the last 3 months due to SpA. WPAl (n=109) outcomes revealed an 18.8% overall work impairment, and 216 patients reported a 25.3% activity impairment due to SpA. Humanistic: Respondents (n=221) had an EQ-5D mean of 0.77, and the SF-36 (n=103) physical and mental component summary scores were 43.9 and 47.7 respectively. SF-36 bodily pain, social functioning, and emotional domain mean scores were 66.0, 74.5, and 77.6 respectively (n=104). Additionally, 30.0% of patients reported that SpA has been or currently is a major problem in their life, and 56.0% were concerned about medication side-effects. CONCLUSIONS: This analysis shows that SpA represents a considerable burden to patients and society overall in Brazil. It further highlights the need for effective therapiestos control peripheral and axial Spondyloarthritis.

OBJECTIVES: Rheumatoid arthritis (RA) is a chronic progressive autoimmune disease that often leads to decline in functional status and reduced employability. In this study, factors associated with reduced employment among RA patients were evaluated. METHODS: Data were drawn from the 2014 Adelphi RA Disease Specific Programme, a cross-sectional survey of rheumatologists and their patients in EU5 (France, Germany, Italy, Spain, UK) and the US. Eligible patients were working age (18–65 years), excluding patients who retired for non-RA–related reasons. Multivariate logistic regression analyses were performed to examine factors associated with being retired/unemployed due to RA (reported by physicians); included variables covered demographics, region, clinical status, and treatment. RESULTS: Of 2,247 eligible patients, 122 (5.4%) were retired/unemployed due to RA; the remaining 2,125 were employed/students/homemakers or unemployed for non-RA–related reasons. Among eligible patients, mean (SD) age and time since diagnosis were 46.5 (11.0) years and 4.9 (5.1) years, respectively; 74.6% were female, and 13.6% had a body mass index ≥30 kg/m2 (obese). In multivariate analyses, increased age (odds ratio [OR]=1.06), obesity (OR=2.74), moderate/severe disease (OR=2.07), and concomitant anxiety/depression (OR=1.63) were significantly associated with an increased risk of RA-related retirement/unemployment, while being Caucasian (OR=0.52) was significantly associated with a lower risk (all P≤0.036). No regional differences (US vs EU) were identified. Among the sub-set of biologic-experienced patients (n=1,423), time between diagnosis and initiation of first biologic was significantly longer among those who were retired/unemployed due to RA than those who were not (4.8 vs 3.6 years, P=0.005). Of 606 patients who completed a self-report form and answered the unemployment-related question, 63 (10%) had changed jobs due to RA. CONCLUSIONS: Age, obesity, ethnicity, disease severity, and anxiety/depression were associated with risk of RA-related retirement and unemployment. Further study is warranted to determine impact of early biologic initiation on employability among RA patients.
OBJECTIVES: Gout is a chronic, progressive disease, characterised by hyperuricaemia and uric acid crystal deposition in joints and soft tissues. Several treatment aspects pertinent to the management of gout in the UK lack consensus. This research aimed to derive consensus among UK clinical experts on treatment paradigms and disease progression to support the health technology appraisal of a new uricosuric. METHODS: Thirty clinicians with a specialist interest/expertise in managing gout were identified in England, all of whom were invited to participate in a two-round, web-based consultation using Delphi methodology. Consensus was defined as ≥80% of experts in agreement with a given statement. Statements not achieving consensus during Round 1 were reworded for Round 2. Multiple choice and written responses were analysed using descriptive statistics and ATLAS.ti 7 qualitative software, respectively. RESULTS: Ten clinical experts participated in the consultation. Twenty of the 27 statements (74%) achieved consensus. Experts agreed that hyperuricaemia is associated with comorbidities, notably cardiovascular disease and metabolic syndrome. Despite guidelines recommending uricosurics, experts stated that existing second-line uricosurics are not routinely available in the UK and are typically only used in secondary care. Experts agreed that there is a need in the UK for new treatments targeting the underlying cause of gout – inefficient uric acid excretion. Consensus was reached on the use of serum uric acid (sUA) as a surrogate marker in chronic gout, confirming that improvements in clinical outcomes require reductions in sUA levels. Clinicians agreed that pharmacological intervention to achieve sUA targets (<6.0 mg/dL) reduces the all-cause mortality risk; however, there was no consensus on the precise level of mortality benefit that urate-lowering treatment provides. CONCLUSIONS: These findings demonstrate the consensus, and uncertainty, concerning the clinical management of chronic gout in the UK, which may support local and national decision-making for new chronic gout technologies.

PMS77: CLINICAL AND PATIENT REPORTED OUTCOMES IN PSORIATIC ARTHRITIS: A NARRATIVE REVIEW OF THE LITERATURE

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OBJECTIVES: To appraise the literature related to the instruments used to assess clinical outcomes and patient reported outcomes (PROs) during follow-up of psoriatic arthritis (PsA) patients. METHODS: Electronic databases (MedLine/PubMed, Google Scholar, Cochrane library and ISI-WOK) were searched to identify clinical trials, observational studies, registers or systematic reviews related to the PsA patients’ follow-up. English or Spanish studies published until June 1st 2017 were selected. Outcomes and Instruments used to follow-up PsA patients were identified. RESULTS: A total of 138 publications were reviewed, most of them used a combination of a clinical outcomes and a PRO to follow-up PsA patients (n=124, 89.8%), while 8.7% (n=12) and 1.4% (n=2) employed exclusively PROs and clinical outcomes. These studies described a total of 87 instruments (49.4% PROs, 36.8% clinical outcomes, 13.8% composite indices). Based on the PsA core outcomes set, established by international GRAPPA-OMERACT working group, the instruments identified were classified in musculoskeletal disease activity (n=27), skin disease activity (n=6), pain (n=5), patient global (n=25), physical function (n=4), health related quality of life (n=7), fatigue (n=5) and systemic inflammation (n=12). Some of the instruments assessed more than one domain. The most reported instruments were number of swollen/tender joint count (n=84, 60.43%), C-reactive protein (n=80, 57.55%), Health Assessment Questionnaire (n=79, 56.83%), Patient Global Assessment (n=79, 56.83%), Physicians Global Assessment (n=69, 49.64%), Psoriasis Area Severity Index (n=62, 44.60%), Pain (NRS n=60, 43.17%; VAS n=56, 40.29%). Most of these instruments were used in a composite index such as ACR (n=50, 35.97%) or Disease Activity Score-28 (n=50, 35.97%). CONCLUSIONS: Most of the studies used a combination of clinical outcomes and PROs to follow-up PsA patients, highlighting the importance to include a PROs in patients’ monitoring. However, results of the review release the need to establish and standardize the instruments to be applied in PsA patients.

PMS78: RHEUMATOID ARTHRITIS PATIENTS’ PERSPECTIVES ON THE VALUE OF PATIENT PREFERENCES IN REGULATORY DECISION-MAKING DURING DRUG DEVELOPMENT: A QUALITATIVE STUDY

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OBJECTIVES: To explore how Rheumatoid Arthritis (RA) patients value the use of patient preferences in regulatory decision-making during drug development. METHODS: Five semi-structured individual interviews with RA patients were conducted to gather first insights into patients’ knowledge and opinions on patient preference studies, drug development and regulatory decision-making. The results of the individual interviews were used to draft and validate the topics for the interview-guide used during four focus groups. Patients were purposively sampled from RA patients who were registered at the Swedish RA patient organization and living in Stockholm or Uppsala. Each focus group consisted of 6-8 patients (n=31 in total). All interviews were audio-recorded, transcribed verbatim and analysed using content analysis. RESULTS: Patients think their preferences should be used in the marketing authorization processes
since it is helpful to understand what the end-users of the drug want. While patients think their preferences matter, they also share some doubts. Firstly, patients feel that preferences can only be measured when patients are well-informed about the drug and it’s' different aspects. Secondly, patients are quite unsure whether regulators can rely on their stated preferences since, at this moment, they feel they might not be informed enough. Thirdly, they are unsure how and where in the marketing authorization process, patient preference information is most important to be included. CONCLUSIONS: According to RA patients, their preferences are valuable in regulatory decision-making during drug development. However, regulators have reasons to increase awareness among patients about why their preferences are useful, inform them about how their preferences will be measured and to ensure that all patients are well-informed when they are asked for their preferences. Acknowledgement; This work has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking PREFER grant n° 115966.

PMS79: EVALUATION OF NEW BIOLOGIC STARTS AND SWITCHING AMONG REAL-WORLD RHEUMATOID ARTHRITIS PATIENTS IN THE UNITED STATES

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OBJECTIVES: Biologic disease modifying anti-rheumatic drugs (bDMARDs) are the cornerstone of active rheumatoid arthritis (RA) treatment when traditional DMARDs are no longer effective. The objective of this study is to evaluate recent real-world treatment choices and switching in the US. METHODS: Patients initiating a bDMARD for RA between 10/2015-09/2016 were identified from the Symphony Health claims database. A minimum age of 18 years and 6 months of pre- and post-initiation medical and pharmacy claims activity was required. The study examined market share among biologic starts and switching patterns. RESULTS: In the 12-month period, 19,288 patients initiated a new biologic: 15,337 (79.5%) were female, mean (SD) age was 54.7 (12.9) years, mean (SD) number of biologics was 1.4 (0.7). The top 3 biologics were: adalimumab (5,824; 28.8%), etanercept (5,817; 28.8%), abatacept (2,013; 10.0%). For 16,301 patients on first biologic, the top 3 biologics were: etanercept (5,203; 31.9%), adalimumab (5,010; 30.7%), infliximab (1,496; 9.2%); for 3,042 patients on second biologic, top 3 biologics were adalimumab (742; 24.4%), etanercept (564; 18.5%), tofacitinib citrate (429; 14.1%); for 865 patients on third biologic or more, top 3 biologics were tofacitinib (207; 23.9%), abatacept (172; 19.9%), tocilizumab (154; 17.8%). Tumor-necrosis factor inhibitors (TNFi) were used in 77.9% of first-line, 67.0% of second-line, and 62.0% of third-line or higher therapies. Of 3,913 switchers, 30.5% switched from etanercept (48.4% to adalimumab), 28.6% switched from adalimumab (38.7% to etanercept), and 10.9% switched from abatacept (25.4% to tocilizumab, 24.5% tofacitinib) with mean (SD) time to switch of 345.5 (132.7), 334.1 (152.3), and 338.3 (149.1) days respectively. CONCLUSIONS: RA patients receive multiple lines of bDMARD therapy. Despite availability of drugs with alternative mechanisms of action, TNFi are preferred agents with adalimumab and etanercept dominating as first and second biologics. Comparative effectiveness research is needed to evaluate optimal sequencing.

PMS80: REAL-WORLD TREATMENT PATTERNS AND TIME TO DISCONTINUATION IN RHEUMATOID ARTHRITIS PATIENTS IN THE US

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OBJECTIVES: The objective of this study is to evaluate recent real-world treatment patterns and time to biologic disease modifying anti-rheumatic drug (bDMARD) discontinuation using retrospective claims data in rheumatoid arthritis (RA) patients in the United States. METHODS: Patients receiving a bDMARD for RA between 10/2015 and 09/2016 were identified from the Symphony Health claims database. A minimum age of 18 years and 6 months pre- and post-initiation of medical and pharmacy claims activity was required. Market share, patient characteristics, and time to treatment discontinuation (TTD) were examined. TTD was defined as days from biologic start to initiation of the next biologic, plus 1 day if switched; or days from biologic start to last biologic administration date plus 90 days. TTD was described using Kaplan-Meir curves. RESULTS: Of 83,050 patients treated with bDMARDs, 64,994 (78.3%) were female, mean (SD) age was 55.2 (12.9), mean (SD) number of biologics per patient was 1.2 (0.4). Patients received 105,485 total bDMARD lines of therapy: 31,084 (29.5%) adalimumab, TTD=558 days; 28,352 (26.9%) etanercept, TTD=644; 10,362 (9.8%) abatacept, TTD=575; 10,116 (9.6%) tocilizumab, TTD=500; 7,974 (7.6%) infliximab, TTD=679; 5,009 (4.7%) tocilizumab, TTD=495; 4,301 (4.1%) golimumab, TTD=535; 4,060 (3.8%) certolizumab, TTD=535; 3,877 (3.7%) rituximab, TTD=495; and 350 (0.3%) anakinra, TTD=535. Mean TTD by line of therapy was: 622 days in first line, 434 in second line, and 365 in third line or higher. CONCLUSIONS: bDMARDs provide durable responses in RA patients. Approximately two-thirds of RA patients were treated with adalimumab, etanercept, or abatacept. The most frequently used biologics do not necessarily rank highest in terms of mean TTD. TTD significantly differs by agent and line of therapy, and declines with each subsequent biologic line. Evaluation of patient characteristics contributing to longer TTD is warranted. Comparative effectiveness research is needed to determine optimum treatments and sequencing.
**PMS81: TRENDS IN OPIOID PRESCRIBING IN PRIMARY CARE PATIENTS WITH KNEE OSTEOARTHRITIS: A POPULATION-BASED OBSERVATIONAL STUDY**

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**OBJECTIVES:** Opioid prescribing has markedly increased in UK and worldwide, predominantly for chronic non-cancer pain (CNCP). CNCP includes conditions such as fibromyalgia, low back pain and osteoarthritis (OA). Evidence suggests that widespread use of opioids in CNCP is associated with risks of diversion and abuse, overdose and death. However, opioid prescribing data in specific medical conditions are limited and no study has examined the trends of prescribing in patients with OA in UK. OA affects around 7 million people in the UK with knee joint being most commonly affected. This study aims to describe opioid prescribing trends in patients with knee osteoarthritis (KOA) managed in primary care in UK. **METHODS:** This retrospective cross-sectional study over a period from 2000-2015 used data from the Clinical Practice Research Datalink (CPRD). Opioid prescriptions for patients (≥ 18years) with a clinician-recorded diagnosis of KOA were retrieved. Outcome measures included: number of patients & prescriptions, defined daily doses (DDD), oral morphine equivalent dose (OMEQ) and days' supply. Descriptive statistics were used to report outcomes in each year. **RESULTS:** Overall, 137,107 patients with KOA were included (58.3% female, mean age: 65.1±12.9 years). In total 4,276,368 prescriptions for opioid were prescribed for 115,057 patients (84% of total diagnosed with KOA). The mean number of prescriptions increased from 5 to 8 prescriptions/patient/year while, the mean annual DDD/1000 registrants increased from 0.16 ± 0.01 to 0.21 ± 0.1 (31% increase) in 2000 and 2015 respectively. The mean OMEQ increased from 12.7 mg/day in 2000 to 15.5 mg/day in 2015 (22% increase) and the mean (±SD) annual days of supply was 86.7 ± 107.3 days. **CONCLUSIONS:** The prevalence of opioid prescribing in KOA increased between 2000 and 2015. Doses prescribed have also increased modestly. As the prevalence of KOA increases, further research into the risks and benefits of opioids in KOA is required.

**PMS82: INCONCLUSIVE EVIDENCE: CAN PHARMACOECONOMICS TILT THE BALANCE?**

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**OBJECTIVES:** To examine the role of pharmacoeconomics in ascertaining the choice of appropriate therapeutics. **METHODS:** This is a retrospective analysis, conducted using the clinical records from a tertiary referral hospital in western Maharashtra, India. Data on patients of ankylosing spondylitis and rheumatoid arthritis was collected. Biological response modifiers (BRMs) are indicated for NSAID failure and DMARD failure cases, respectively. We compared the input costs and relative benefit of various BRMs. **RESULTS:** Out of 35 patients of ankylosing spondylitis who had NSAID failure, 15 were given etanercept (24 injections/patient) and 20 were given infliximab (8 injections/patient). Mean reduction in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score in etanercept and infliximab group was 1.79 and 2.41 respectively (difference not statistically significant). The total input cost per patient of etanercept and infliximab was INR 1,56,984 and INR 2,55,360 respectively. The average cost incurred for per unit reduction in mean BASDAI score was INR 87,700 (1,56,984/1.79) for etanercept and 105958 for infliximab. Though the gross input cost of infliximab was 1.62 (2,55,360/1,56,984) times higher, its cost per unit benefit offered was only 1.2 (1,05,958/87,700) times higher than etanercept. Similarly, in 28 cases of DMARD failure RA cases, 15 were given infliximab and 13 were given etanercept. The average cost incurred for per unit reduction in mean disease activity score (DAS-28) was INR 1,22,643 for etanercept and INR 1,78,573 for infliximab. Cost of infliximab per unit benefit offered was 1.4 times higher than etanercept. **CONCLUSIONS:** In view of its lower cost for comparable clinical effect, etanercept appears to be a more appropriate BRM. The case study demonstrates that pharmacoeconomic analysis of competing therapies can single out the appropriate treatment choice. However, for drawing generalizable conclusions, prospective studies with indirect costs and longer time horizon are required.

**PMS83: BIOLOGIC UPTAKE TRENDS IN RHEUMATOID ARTHRITIS**

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**OBJECTIVES:** Biologic disease modifying anti-rheumatic drugs (bDMARDs) are designed to inhibit a specific component of the immune response that fuels inflammation, the predominant manifestation of rheumatoid arthritis (RA). Between 1998 and 2012 ten bDMARDs gained approval for treatment of RA in the U.S. In the past 15 months 4 biosimilars have gained FDA approval, as has one branded bDMARD, sarilumab, on 05/2017. The goal of this study is to evaluate the market uptake of new bDMARDs and the impact of biosimilars’ approval on market trends. **METHODS:** Symphony Health longitudinal prescription and medical claims data was used to assess market share of all FDA-approved biologics indicated for RA from 01/2012 to 03/2017 and was parsed by quarter. **RESULTS:** Etanercept and adalimumab had a combined 79% market share in Q1 2012, declining to 77% in
the quarter in which tofacitinib was launched, Q4 2014; and further steadily eroding to 64% by the quarter in which infliximab-dyyb launched, Q4 2016. Tofacitinib has gained modest uptake since approval with the most recent share at 9%. Total utilization of biologics has remained relatively unchanged from 2012 to present. The first launched biosimilar infliximab-dyyb has had a very mild uptake: <1% share (78 patients) in Q1 2017. CONCLUSIONS: bDMARD use in RA remains concentrated with two clear market leaders, etanercept and adalimumab despite branded and biosimilar competitors. Etanercept’s and adalimumab’s market share steadily declined after the new entry launch of tofacitinib. Biosimilars’ market effects have thus far been negligible, and likely related to launch delays. Further research is needed to assess what effect the newly-approved biosimilars and sarilumab may have on the RA biologics’ market.

PMS84: TREATMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS: REAL WORLD POPULATION-BASED EVIDENCE FROM FRANCE.

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OBJECTIVES: Rheumatoid arthritis (RA) is a chronic inflammatory joint disease posing a high burden on patients and healthcare systems. Appropriate use of conventional and biological disease-modifying antirheumatic drugs (cDMARDs and bDMARDs) is key to optimal therapeutic success. However little is known about the treatment patterns in real world settings. Our aim was to assess the real world, population-based treatments of patients with RA in France. METHODS: A retrospective, national, population-based study was conducted in France. Data were retrieved from EGB database (a 1:97 sample from the national claims database covering all patients in France). All patients with either an acute care hospital admission mentioning RA (ICD-10 codes M05-06) as primary or secondary diagnosis or a full insurance coverage (ALD) for RA in 2015 were included. All deliveries of cDMARDs (methotrexate) or bDMARDs (anti-TNF or other mechanisms of action drugs) were retrieved from the database, from both hospital and community-based pharmacies. RESULTS: We included 2,490 patients aged 65 (SD: 15) on average of whom 1,793 (72%) were female. In 2015, 1,139 patients (46%) had at least one methotrexate delivery; 320 (13%) had at least one bDMARD delivery of whom 257 were only on anti-TNF drugs, 53 were only on other mechanisms of action bDMARDs, and 10 received both anti-TNF and other mechanisms of action bDMARDs during the year. CONCLUSIONS: This study provides new and valuable insight into the real-world, population-based treatment patterns of patients with RA in France. Further analyses need to be conducted to understand the dynamics of treatment adaptation, switch and associations.

PMS85: COMPARISON OF PERSISTENCE AND ADHERENCE IN BIOLOGIC NAÏVE PATIENTS WITH PSORIATIC ARTHRITIS INITIATING APREMILAST OR BIOLOGICS IN A US ADMINISTRATIVE CLAIMS DATABASE

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OBJECTIVES: To compare treatment persistence and adherence over one year in biologic naïve psoriatic arthritis (PsA) patients initiating apremilast or biologics using a U.S. administrative claims database. METHODS: This retrospective study selected adult PsA patients initiating apremilast or biologics within the January 2013-June 2016 Truven Health MarketScan claims databases. Patients were required to be apremilast/biologic naïve on the index agent in the 12-month pre-index period and have continuous enrollment in the 12-month pre- and post-index periods (index date = initial apremilast or biologic claim). Biologic users were matched 2:1 to apremilast users. Treatment persistence at 12 months was defined as continuous treatment without (1) a >60-day gap in therapy or (2) a switch to a different PsA treatment and measured during the 12-month post-index period. Patients were adherent if their medication possession ratio (MPR) was ≥80% while persistent on the index agent. RESULTS: A total of 381 patients initiating apremilast were matched to 761 patients initiating biologics. Baseline characteristics were similar in both groups (mean age 51 years, 60% female, mean Charlson score 0.6). Treatment persistence at 12 months for apremilast users was similar to biologic users (43% vs 46%; p=0.082). Average time to non-persistence was 124 days for apremilast users compared to 132 days for biologics users (p=0.194). Among non-persistent users, apremilast users and biologic users had similar switch rates (7% vs 9%; p=0.389) and discontinuation rates (93% vs 91%; p=0.389). Average persistence-based MPR was 0.870 for apremilast users compared to 0.854 for biologic users (p=0.056), and the adherence rates were 77% and 73%, respectively (p=0.175). CONCLUSIONS: At 12 months, persistence and adherence as well as drivers of non-persistence were similar for biologic naïve patients initiating apremilast or biologics for the treatment of PsA in the U.S.

PMS86: PATTERNS OF BIOLOGICS USE IN ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS PATIENTS IN KOREA
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OBJECTIVES: We aimed to investigate treatment patterns of biologic agents in patients with spondyloarthritis (SpA) by analyzing representative data from the biologic registry in Korea. METHODS: A retrospective secondary data analysis obtained from the Korean College of Rheumatology Biologics Registry (KOBIO) was conducted. Since its launch in 2012, KOBIO has accumulated data of biologics usage in ankylosing spondylitis (AS), psoriatic arthritis (PsA) and rheumatoid arthritis (RA) patients. We especially focused on AS and PsA data in this study from Dec. 2012 to Jun. 2016. All registered patients were over 18 years of age who initiated, restart, or switched a biologic agent which were available in Korea; etanercept, adalimumab, infliximab, infliximab biosimilar, and golimumab. We particularly focused on the pattern of biologics treatment such as discontinuation or switching of a biologic agent, and its reason in real-world practice. RESULTS: We analyzed all AS (N=1,005) and PsA (N=34) patients enrolled in KOBIO (median follow-up period: 14 months). In AS patients, adalimumab (N=375) was the most frequently used agent. In general, the discontinuation rate and switching rate were 24.2% and 9.6%, respectively in AS patients during the study period. Golimumab showed the lowest percentage of both discontinuation rate (13.8%) and switching rate (4%). The main reason of discontinuation in general was due to inefficacy (32.6%) of the prescribed agent. Infliximab was discontinued mainly because of adverse events (33.3%). In patients with PsA in which ustekinumab was included, the discontinuation rate of biologics was 35.3% and switching rate was 23.5% during the study period. CONCLUSIONS: Our data demonstrate different drug retention rates not only between AS and PsA patients but also among biologic agents prescribed in Korea.

PMS87: NUMBER OF VISITS BASED ON THE MOST COMMONLY FUNDED DISEASES IN HOME SPECIAL CARE IN HUNGARY, 2013

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OBJECTIVES: The objective of our study was to analyze the number of visits of the most common diseases in home special care based on the financed cares by the National Health Insurance Fund Administration in Hungary. METHODS: Our data inquired from the Central Statistical Office come from the data base of the National Health Insurance Fund Administration. The period examined was the year of 2013. RESULTS: The total number of visits per year in home special care amounted to 1,298,834 of which 1,223,940 (94,23%) were funded by National Health Insurance Fund Administration. Number of visits to special nursing within home special care amounted to 766,629 (59,0%) visits, number of visits to therapy service by speciality accounted for 532,205 (41%) visits, in which physiotherapy amounted to 462,759 (35,6%), physiotherapy accounted for 65,565 (5,0%), and speech therapy amounted to 3,881 (0,3%) visits. Number of visits were the following in the most common founded diseases: 1) Ulcer of lower limb (L97) 208,797 (17,1%); 2) Decubitus ulcer (L89) 114,796 (9,4%); 3) Coxarthrosis (M16) 78,129 (6,4%); 4) Fracture of femur (S72) 63,239 (5,2%); 5) Gonarthrosis (M17) 62,728 (5,1%) visits. Ratio of number of visits per 100,000 inhabitants in the most common funded diseases was as follows: 1) Ulcer of lower limb 2,110,5; 2) Decubitus ulcer 1,160,4; 3) Coxarthrosis 789,7; 4) Fracture of femur 639,2; 5) Gonarthrosis 634,1. CONCLUSIONS: The occurrence of visit number of the financed most frequent diseases confirm the legitimacy of special nursing and special therapeutic services in home special care. The role of physiotherapy among special therapeutic services is highly emphasized. Analysis and recognition of the findings play an essential role in future planning and development of home special care.

PMS88: EXAMINATION OF EFFECTIVENESS OF GROUP PHYSIOTHERAPY USING DASH QUESTIONNAIRE AFTER DISTAL RADIAL FRACTURE

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OBJECTIVES: After-care of the injury of the distal radius’s medical treatment is indispensable to the success of rehabilitation. The role of physiotherapy is essential, however there are few studies which carefully observe this type of fracture and group physiotherapy which follow treatment results. The aim of this study was to present the effectiveness of group physiotherapy after distal radial fracture. METHODS: We used the Quick DASH questionnaire and measured the active range of motion. RESULTS: In our examination there were 11 women and 11 men with an average age 56.73. According to our statistics, those who had an arm-fracture because they fell off were significantly older than the others (Mann-Whitney U= 24,00, p=0,001, 66,47 yrs vs. 27,00). We can state that according to the Quick DASH scores the index significantly decreased during the 5-week gymnastic program (p<0,001; 50,93 points
vs. 31.09 points). This fact was supported by the increase of the wrist joint movement range. The active flexion (p<0.001; 31.36 vs. 43.18), and also the active extension (p=0.001; 39.55 vs. 52.27) significantly increased. There was a strong correlation between the Quick DASH scores and the extension range of motion (p<0.001; r=0.79). The value of the coefficient was -0.78, which means when there is one degree extension movement-range increase, then the Quick DASH score will decrease by 0.78 point. CONCLUSIONS: Based on the results we can conclude that after a distal radial fracture it is useful to participate in group physiotherapy to reach the desired functions, because during the 10 -occasion - treatment we could manage to get significant improvement in the movement of the wrist joint. It is also confirmed by the Quick DASH score decrease. Furthermore we can state that the Quick DASH questionnaire can be used easily among people to measure the movement-injury of the upper limb.

PMS89: PATIENT COUNTS BASED ON THE MOST COMMONLY FUNDED DISEASES IN HOME SPECIAL CARE IN HUNGARY, 2013

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OBJECTIVES: The objective of our study was to analyze the patient counts of the most common diseases in home special care based on the financed cares by the National Health Insurance Fund Administration in Hungary. METHODS: Our data inquired from the Central Statistical Office come from the database of the National Health Insurance Fund Administration. The examined period was the year of 2013. RESULTS: The total patient counts per year in home special care amounted to 59.072 of which 56.336 (95.37%) were funded by National Health Insurance Fund Administration. Patients receiving special nursing within home special care amounted to 27.333 persons (46.3%), patients receiving special therapeutic service accounted for 31.739 (53.7%) persons, in which physiotherapy amounted to 27.228 (46.1%), physiotherapy accounted for 4.340 (7.3%), and speech therapy amounted to 171 (0.3%) persons. Patient counts were the following in the most common founded diseases: 1) Ulcer of lower limb (L97) 5.100 (9.1%); 2) Coxarthrosis (M16) 4.832 (8.6%); 3) Gonarthrosis (M17) 3.822 (6.8%); 4) Decubitus ulcer (L89) 3.797 (6.7%); 5) Fracture of femur (S72) 3.707 (6.6%) patients. Ratio of patient counts per 100.000 inhabitants in the most common funded diseases were as follows: 1) Ulcer of lower limb 51.6; 2) Coxarthrosis 48.8; 3) Gonarthrosis 38.6; 4) Decubitus ulcer 38.4; 5) Fracture of femur 37.5. CONCLUSIONS: The occurrence of patient number of the financed most frequent diseases confirm the legitimacy of special nursing and special therapeutic services in home special care. The role of physiotherapy among special therapeutic services is highly emphasized. Analysis and recognition of the findings play an essential role in future planning and development of home special care.

PMS90: EXAMINATION OF THE EFFECTIVENESS OF CORE TRAINING BETWEEN JUNIOR WOMEN BASKETBALL PLAYERS TO PREVENT SPORTS INJURIES

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OBJECTIVES: The objective of our analysis was to survey the efficiency of Core training among junior women basketball players to prevent injuries, paying special attention to the improvement of static and dynamic balance and coordination, the mobilizing and stabilizing function of the trunk muscles and their balancing ability, the range of motion and proprioception of its joints, moreover strengthening the trunk muscles, while performing exercises on stable and instable surfaces. METHODS: 12 women participated in the exercise program. Basketball players were subjected to various tests before and after the program. Static balance was tested by Stork Stand Test; dynamic balance by Triple-hop Test; mobilizing functions, balancing ability, movement range of joints and proprioception of the trunk by FMS Test (Functional Movement Screen); and muscle endurance of the trunk by Core Test. RESULTS: Due to the training, both in the Stork Stand and Triple-hop Test we experienced significant improvement in the results of the right leg (p<0.001) and left leg (p<0.001). As for the values of the athletes, in case of the FMS Test they performed considerably better after the exercise program than before regarding both main scores and partial scores. Considering the average improvement in the results, 42% improvement has been attained. In terms of the results reached in the Core Test, comparing the pre- and post-program values, a significant improvement could be seen (p<0.001). Between the samples tested an average of 0.66-minute significant improvement was detected CONCLUSIONS: It can be stated that the application of core training is effective among junior women basketball players in terms of the improvement of static and dynamic balance and coordination, the mobilizing and stabilizing function of the trunk muscles and its ability to keep balance, and the range of motion and proprioception of its joints; and moreover, the strengthening of the trunk muscles.

PMS91: NUMBER OF CASES BASED ON THE MOST COMMONLY FUNDED DISEASES IN HOME SPECIAL CARE IN HUNGARY, 2013
OBJECTIVES: The aim of our study was to compare two groups within the elderly population: those members who had suffered femoral neck fracture (target group), and the other members who had not suffered any lower limb fracture (control group). METHODS: The basic tools for the comparison were the quality of life, range of motion of the lower limb and the muscle. RESULTS: The average age of the total 16 examined patients was 77.2 years. 8 participants had suffered femoral neck fracture, the other 8 patients had not suffered any lower limb fracture yet. 63% of the group with femoral neck fracture was also diagnosed with osteoporosis. The femoral neck fracture occurred in the right side for 7 patients. In addition, only 2 patients had other fractures. Considering the results of the SF-36 there was no significant difference between the two groups (p=0.16). The quality of life in the target group not considerably differs from the result of the control group. The EQ-5D questionnaire showed that walk problems of the femoral neck fractures patients are barely worse as in the control group, and we results are the same in case of anxiety and pain. They are much restricted in self-sufficiency and ordinary activities than those who have not suffered fractures. Regarding lower limb motion dimension and muscle strength there were significant differences in the main motions of the hip (flexion: p=0.04, extension: p=0.03, abduction: p=0.03, adduction: p=0.004) and muscle (flexion: p=0.02, extension: p=0.02, adduction: p=0.02) both broken and healthy side, both fractures suffered and not suffered among groups. CONCLUSIONS: In summary it can be said that there important differences were not found between the groups during the investigation of the quality of life. Further examination in larger number of elements and patients could give larger certainty by the achieved results.

PMS93: EVALUATION AND DEVELOPMENT OF HABITUAL POSTURE AND POSTURE DEEMED CORRECT WITH BACK SCHOOL PROGRAM AMONG PRIMARY SCHOOL CHILDREN

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OBJECTIVES: The posture of 60-80% of primary school children is incorrect. Inadequate posture and use of spine in childhood can be the basis of adult degenerative spinal diseases. A back school program can influence the posture of children in a positive direction. Our purpose was to assess the habitual posture and posture deemed correct of primary school children. METHODS: 26 primary school first-graders were chosen for our prospective research with non-random sample selection (average age: 6.8 (6.2-7.0). The posture was examined by photogrammetry test. The statistical analysis was performed with SPSS software version 22.0. We used Wilcoxon test to compare values before and after the back school program, and the results were considered significant if p<0.05. RESULTS: At the habitual posture comparing the results measured before and after the back school program, from the front view, the median (p=0.003), the shoulder symmetry (p=0.016), the pelvis symmetry (p=0.001) significantly changed, from the lateral view, the median (p=0.001), the thoracic spine (p<0.001), the lumbar spine (p<0.001) significantly improved. At the posture deemed correct comparing the results measured before and after the back school program, from the front
view, the median (p=0.001), the shoulder symmetry (p<0.001), the pelvis symmetry (p<0.001) significantly changed, from the lateral view, the median (p<0.001), the thoracic spine (p<0.001), the lumbar spine (p<0.001) significantly improved. The total score of habitual posture (p<0.001) and posture deemed correct (p<0.001) significantly changed. **CONCLUSIONS:** The child back school program improves the posture of primary school children. The developed program can also be used in kindergarten.

**PMS94: THE MOST COMMON OCCUPATIONAL ILLNESSES OF MEDICAL- AND SPORTS MASSEURS**

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**OBJECTIVES:** The aim of our research was to compare the symptoms of the musculoskeletal system of the medical- and sport masseurs. **METHODS:** Altogether 58 medical- and sport masseurs completed the survey in our research. The examination has been carried out for 4 months, in Hungary. 45 out of the 58 participants, 77.59% had an issue with their musculoskeletal system in the past 12 months. **RESULTS:** Our first presumption has proven true, that among medical- and sport masseurs, hand and wrist problems are the most common, because 74.14% had an issue with their hands or wrists in the last one year. The other research was about to estimate the frequency of pain on each regions of the hand. The assumption in this case seemed also right, most of the symptoms were caused by the „thenar” area, where 39.66% of the participants indicated pain on the right hand, while 31.03% on the left. Our third hypothesis has been verified partly, because there were significantly more waist symptoms in medical masseurs compared to sport masseurs (p=0.0001), however there were no significant difference in wrist pain between the two groups (p=0.95). We also observed the difference in the musculoskeletal system symptoms between male and female gender. This assumption did not show any essential difference (p=0.8521). Our last assumption has been refuted, because our results showed that only 50% of the participants suffered from low back pain, while according to the specialized literature, this rate is about 60-85% in the society. **CONCLUSIONS:** The musculoskeletal system symptoms could be easily prevented, if people would comply with the joint protection rules and would practice muscle strengthening exercises every week.

**PMS95: THE EXAMINATION OF LOCATION AND FREQUENCY OF PAIN IN WEIGHT TRAINING**

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**OBJECTIVES:** The aim of our research was to test the location and frequency of pain among people doing weight training. **METHODS:** The type of our research was quantitative, cross-sectional. The sample size was 129 person (N=129). The selection method was objective expert sampling. Data was collected with the application of standard questionnaires (Nordic-test and Roland Morris). The analysis of the data was made by descriptive and mathematical (Chi-square test, Mann-Whitney U-test, linear regression) statistical methods, analysis was made with SPSS 20.0 and Microsoft Office Excel programs. The significance level had been specified in 5%. **RESULTS:** The most painful areas among people doing weight training are the shoulders (47.3%) and the low back (38.8%). Medical consultation with the existing complaints most commonly happens in case of low back pain (10.9%). Those patients who consulted with their doctor have a significantly higher Roland Morris index (average RMI=5.07) than those who did not see their physicians (average RMI=1.38) (p=0.003). As the age progressed the Roland Morris index score had increased significantly (p<0.001), with a medium-strength, positive correlation. The obstruction due to back pain is defined by age in 18% (r2 = 0.18). The upcoming knee pain is significantly high in case of women (p=0.025). 28.4% of men, 47.9% of women indicated knee problems. **CONCLUSIONS:** Based on our results it can be stated that weight training causes shoulder pain in most of the cases, however the medical consultations most commonly happen due to back pain. The known dangers of training made for health maintenance requires the application of prevention methods, and the development of the general knowledge about the correct implementation of the exercises and the overall training theory.

**PMS96: REGIONAL DISTRIBUTION OF THE MOST COMMON SPA SERVICES IN HUNGARY IN 2014**

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**OBJECTIVES:** The aim of this study was to examine the distribution of the three most common types of treatment nationwide. **METHODS:** Our data were obtained from the Central Statistical Office. The list of spa and other medical care treatment contained 11 activities. The examined period was the year of 2014. **RESULTS:** The most commonly performed treatment in the country was medicinal thermal water (n = 2,076,148), the second was medical massage therapy (n=1,642,037), and the third was underwater group physiotherapy (n=686,773). In the year of 2014, the three most common user of medicinal thermal water therapy was Central Hungary (483,103), Western Transdanubia
(455,256), and Southern Great Plain (383,578). The second place in Hungary for the frequency of performed treatments are medical massage therapy. The mostly frequented treatments were performed in Northern Great Plain (n = 405,856), then in the Southern Great Plain (n = 366,675) and Western Transdanubia. The underwater group physiotherapy meant a greater discrepancy in the national context between the number of treatments. The number of this therapy was the most significant factor in the Northern Great Plain (n = 227,174), in the Southern Great Plain (n = 153,564) and in Southern Transdanubia (n = 87,176). **CONCLUSIONS:** Regional differences may arise from the fact that the opportunities provided by the environment do not make the treatment available in some regions. As a long term goal cooperation between the tourism industry and the professional physicians needs to be developed to overcome regional differences. As a marketing tool, it is necessary to emphasize the positive effects of spa services both in outpatient and inpatient care.

**PMS97: A MULTI-CENTRE RETROSPECTIVE STUDY TO DESCRIBE THE IMPACT ON HEALTHCARE RESOURCE USE AND REAL WORLD EFFECTIVENESS OF GOLIMUMAB IN ANKYLOSING SPONDYLITIS (AS) IN UK CLINICAL PRACTICE**

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**OBJECTIVES:** Study aims were to describe the impact of Tumour Necrosis Factor-α (TNF-α) inhibitor golimumab on UK real-world healthcare resource use (HRU) and evaluate the clinical effectiveness of golimumab in the treatment of Ankylosing Spondylitis (AS). This abstract presents HRU data for the 6 months pre- and post-golimumab initiation as well as effectiveness data at 6 months post-golimumab initiation compared with the closest observation pre-golimumab initiation. **METHODS:** This multicentre observational study of consenting adult patients was carried out via retrospective medical chart review in six UK NHS hospital rheumatology departments between November 2015 and October 2016. Inclusion criteria included AS diagnosis, anti-TNF-α- naïve, received minimum three doses of golimumab for AS, and first dose at least 12 months before data collection. Effectiveness was measured using the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Spinal Pain Visual Analogue Scale (VAS) and Bath Ankylosing Spondylitis Functional Index (BASFI). Patients with missing data are excluded from the effectiveness analysis. **RESULTS:** The study enrolled 47 eligible patients, 74% male, mean age of 46.4 years, mean golimumab treatment duration of 2.3 years. A significant reduction of 30.4% (Mann-Whitney p<0.005) in mean number of rheumatology clinic visits (from 2.3 to 1.6) and a 27.3% reduction in mean number of clinical investigations (from 13.4 to 9.7) over the 12-month period was observed (Mann-Whitney p<0.05). 74% (32/43) of patients achieved a clinically meaningful change (BASDAI score reduced by 2 or more), and overall mean BASDAI score reduced by 3.9 points [n=43] (Mann-Whitney p<0.001). 75% (18/24) of patients achieved a reduction in spinal pain VAS by 2cm or more indicating a treatment response. Overall mean BASFI score improved by 4.1 points [n=26] (Mann-Whitney p<0.001). **CONCLUSIONS:** Golimumab was associated with statistically significant reductions in HRU and clinically meaningful improvements in UK patients with AS during the first 6 months of treatment.

**PMS98: THE RESOURCE COST OF SWITCHING STABLE RHEUMATOLOGY PATIENTS FROM AN ORIGINATOR BIOLOGIC TO A BIOSIMILAR IN THE UK**

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**OBJECTIVES:** Switching stable patients from branded biologics to biosimilars may offer potential cost savings through discounted drug prices however little is known about the impact on NHS resource use and the cost of service level activities. This study aimed to describe and quantify the impact on NHS resource use and the cost of service level activities required to conduct an originator biologic to biosimilar switch. **METHODS:** This study was conducted in three UK rheumatology centres using a mixed methodology: (1) Semi-structured one-to-one interviews with key staff members involved in a recent Enbrel® to Benepali® switch to determine activities involved in the switch process, (2) Collecting service level data to quantify time and resource associated with switch activities. For each centre, a description of the switch model was developed and associated costs calculated using published NHS reference costs. **RESULTS:** Similar costs for switch planning activities (£12,638 - £15,276) were observed across all three centres. Switch implementation and follow-up costs varied between £6,975 and £61,386 per centre depending on the model used. Key factors influencing the implementation cost included the use of dedicated switch vs. routine
outpatient clinics, patient education and consent methods, and inclusion of additional post-switch monitoring clinic appointments. Overall, between 320 and 987 hours of staff time was spent on the switch per centre (estimated 149-176 patients switched per centre). **CONCLUSIONS:** Switching from a biologic to a biosimilar was shown to be associated with additional NHS activities and resource use which should be considered by NHS stakeholders alongside potential drug cost savings. This study quantifies real-world resource costs associated with different switch models selected by centres to meet perceived patient needs. Costings varied considerably, reflecting differing numbers of patients switched and services provided. A fourth centre will be added and further work required to understand patient experience of the switch.

**PMS99: THE ECONOMIC IMPACT OF RHEUMATOID ARTHRITIS ON PATIENTS’ HOUSEHOLDS. AN ESTIMATION OF THE DISEASE RELATED CATASTROPHIC HEALTH EXPENDITURE, IN GREECE**

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**OBJECTIVES:** As a chronic condition rheumatoid arthritis (RA) is related with significant time health care expenditure a share of which, is estimated to burden the patient and the household. Aim of this study is to estimate the private health expenditure of patients with RA and its impact on patient’s household. **METHODS:** A telephone survey took place during which patients with RA were asked to provide with information regarding their out-of-pocket, medical and non-medical, expenditures for the management of their disease, six months prior the telephone interview. Patients were recruited through the relevant patients associations. Catastrophic health expenditure (CHE) was defined as any amount spent for health which accounts for more than 20% of the total household income. **RESULTS:** 136 patients respondent to the survey. Patients’ household average and per capita monthly income was estimated at 1093€ and 543€, respectively. The extrapolation of the 6-month out-of-pocket expenditure to annual expenditure revealed that patients spend 695.6€ per year for the management of RA, 18.7% of which were found to be non-medical RA related expenditure. In more detail, patients spend annually 194€ for RA drugs, 225.2€ for non-RA drugs, 102.1€ for physician visits, 65.9€ for physiotherapies, 41.4€ for inpatient services, 56€ for laboratory and diagnostic tests and 144.3€ for non-medical goods and services for their condition. Subject of CHE were estimated to be 11.6% of the households with an RA patient. **CONCLUSIONS:** RA patients spent annually more than their household per capita monthly income for the management of their disease. This expenditure appears to be a significant burden for 11.6% of the patients or for more than 4,000 households, based on the prevalence of the disease in Greece. In this context, health and social policy interventions should be adopted in order to control private health expenditure and/or prevent households from being subject to CHE.

**PMS102: COST OF NON-UNION IN PATIENTS WITH LOWER LEG FRACTURES**

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**OBJECTIVES:** Non-union is a complication of fracture repair that significantly impacts patient wellbeing and healthcare costs. This study was designed to better understand care pathway and payer cost of non-union following fracture repair. **METHODS:** A retrospective database analysis was conducted in Truven Commercial Claims and Encounters (CCAE). All patients with a femoral (FEM), tibial and/or fibular (T/F) fracture from 2010 to third quarter 2015 were identified. The first date of femoral fracture was used as index date. To be included in the analysis, all patients had at least 2 years of complete medical history. Patients with amputation at time of index were excluded as they were no more at risk of non-union. Patients were categorized based on whether or not they developed non-union in the 5-730 days post-index. For all patients, cost of out and inpatient care was analyzed from time of index to two-years post. Payments were adjusted for inflation to 2016 index. A regression model was built to evaluate cost of non-union. **RESULTS:** 2.5 million patients were included in the analysis of which 229,308 had open fractures. Non-union rates ranged from 2.7% following closed T/F fractures only, to 39% following open concurrent FEM and T/F fractures. Both in- and outpatient care was significantly increased in patients with non-union. For patients with concurrent FEM and T/F fractures treated with instrumentation, the average frequency of physical therapy and imaging visits reached 44.5 and 21.4 in patients with non-union (vs 35.6 and 8.7 in controls). Two-year adjusted incremental cost of non-union ranged from $18,632 for patients with T/F fractures only to $96,324 for patients with concurrent FEM and T/F fractures. For 30% of patients, time from non-union to readmission was >3 months. **CONCLUSIONS:** Non-union is a frequent complication following lower leg fracture and is associated with lengthy and costly healthcare utilization.

**PMS103: A COMPREHENSIVE ASSESSMENT OF THE HTA LANDSCAPE FOR REIMBURSEMENT OF RHEUMATOID ARTHRITIS DRUGS: PITFALLS AND CHALLENGES IN GAINING SUCCESSFUL APPROVALS**
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OBJECTIVES: The objective of this systematic review was to assess the current Health Technology Assessment (HTA) landscape and to evaluate the HTA environment for new interventions in rheumatoid arthritis (RA) to seek reimbursement approval. METHODS: HTAs were searched for submissions in RA across different agencies (PBAC, CADTH, HAS, IQWiG, TLV, NICE, SMC). Searches were conducted up to January 2013. RESULTS: Overall, of the 73 appraisals retrieved, 12 were issued a negative guidance, one was withdrawn, one was terminated, and seven were recommended with restrictions. PBAC reported the highest number of submissions (34 submissions) followed by SMC (12 submissions). Nine MTAs were submitted to various HTA agencies, two to NICE, six to PBAC, and one to IQWiG. The most commonly reported reasons for not recommending a treatment was due to concerns over the economic perspective. Across the submissions made to various HTA agencies, no information related to economic analysis was available for majority of submissions (22 submissions). In total, where an economic analysis was undertaken, a cost-minimization analysis (CMA) was the most commonly reported economic analysis (11 submissions). One submission reported both CMA and cost-utility analysis (CUA). Submissions made to NICE witnessed the highest rejection rate (50%), followed by SMC (40%). For tocilizumab, the maximum number of submissions (8 submissions) were identified followed by abatacept and etanercept (7 submissions each) to various HTA agencies. Other reasons for the rejection of HTA submissions were reduction in clinical benefit, limited clinical evidence, insufficient clarity on the disease sub-group, inappropriate comparator utilized for supporting evidence, and uncertain cost-effectiveness. CONCLUSIONS: Due diligence should be used for HTA submissions in RA, particularly while demonstrating the economic benefit as the treatment landscape is crowded and rejections are common.

SYSTEMIC DISORDERS/CONDITIONS - Clinical Outcomes Studies

PSY1: EVALUATION OF SAFETY AND EFFICACY OF PROPOFOL FOR PROCEDURAL SEDATION IN PEDIATRIC POPULATION: A META-ANALYSIS

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OBJECTIVES: We aimed to assess the safety and efficacy of propofol as an agent of procedural sedation for pediatric patients. METHODS: We searched the MEDLINE via Ovid, EMBASE, and Cochrane Central Register of Controlled Trials in June, 2016. Eligible studies were randomized controlled trials comparing propofol with other sedative agents for procedural sedation in pediatric patients. We used standard Cochrane methodological procedures, including assessment of risk of bias. Random effects model was used. The relative risk (RR) and risk difference (RD) with 95% confidence interval (CI) were calculated for dichotomous outcomes. The weighted and standardized mean difference (WMD and SMD) with 95% CI were used for continuous outcomes. RESULTS: Of the 3,424 articles identified, 42 studies were included. While significant heterogeneity between studies was observed no overall significant difference in sedation adequacy was found between propofol and control groups. Physician satisfaction was significantly higher in the propofol groups (RR = 1.21; P < 0.05). The propofol use was also associated with some significant benefits in recovery time (WMD = -7.59; P < 0.05) and in reducing emergency procedures, including assessment of risk of bias. Random effects model was used. The relative risk (RR) and risk difference (RD) with 95% confidence interval (CI) were calculated for dichotomous outcomes. The weighted and standardized mean difference (WMD and SMD) with 95% CI were used for continuous outcomes. RESULTS: Of the 3,424 articles identified, 42 studies were included. While significant heterogeneity between studies was observed no overall significant difference in sedation adequacy was found between propofol and control groups. Physician satisfaction was significantly higher in the propofol groups (RR = 1.21; P < 0.05). The propofol use was also associated with some significant benefits in recovery time (WMD = -7.59; P < 0.05) and in reducing emergency agitation, Pediatric Anesthesia Emergence Delirium (PAED) scale scores and nausea/vomiting (RD = -0.10; WMD = -3.60; RD = -0.05 respectively, with P < 0.05 for all outcomes). Although some hemodynamic responses and respiratory rate were lower in the propofol groups, there were no statistically significant differences between groups in terms of heart rate, end-tidal CO2, cardiovascular problems and respiratory complications. CONCLUSIONS: Propofol provided adequate sedation for uncomfortable procedures with a shorter recovery time than other sedative agents. While with some concerns about reducing hemodynamic responses, propofol had a similar or better safety profile comparing with other sedatives. The overall evidence suggests that propofol could be considered for pediatric procedure sedation.

PSY2: PREVALENCE OF OVERWEIGHT AND OBESITY AMONG HEALTH PERSONNEL IN AN URBAN GHANA: A DESCRIPTIVE CROSS-SECTIONAL STUDY, 2017

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OBJECTIVES: Overweight and obesity are international social problems which increasingly have become focus of public Health concern. This study aimed to determine the prevalence of overweight and obesity among Healthcare personnel and prevalence factors contributing to its development. METHODS: We conducted a descriptive cross-
sectional study. A total of 180 out of 349 health personnel were randomly selected and participated in the study. We interviewed participants on socio-demographic, dietary habit, exercise profile, measured their weight, height and fasting blood sugar using interviewer administered structured questionnaire. Data abstracted was managed in EPI info 7 and analysis was done. RESULTS: The prevalence of overweight and obesity was 31.1 and 31.7 percent respectively. While 81 percent of participants were females, the most prevalent age group among participants was 25-29 years. Thirty-nine percent daily patronize fast food and 42.8 percent don’t exercise regularly. Among those who exercise (57.2 percent), exercises include jogging, brisk walking, running and aerobics. While 4.4 percent had been diagnosed of diabetics, 24.4 percent had family history of diabetics. CONCLUSIONS: This study underscore the high prevalence of overweight and obesity (62.8 percent) among the Healthcare personnel. There is therefore the need for stakeholders to institute intervention at workplace to prevent and reduce the prevalence.

PSY3: BURDEN OF HIGH DISEASE ACTIVITY IN SYSTEMIC LUPUS ERYTHEMATOUS (SLE): RESULTS OF A TARGETED LITERATURE REVIEW

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OBJECTIVES: Systemic lupus erythematosus (SLE) is a multisystem, progressive disease characterized by highly variable clinical manifestation. For patients with SLE, disease activity has been a consistent focus of studies analyzing health outcomes; however, patients with high disease activity (HDA), a key subpopulation with high unmet need, have not been studied extensively in the literature. A targeted literature review was conducted to describe the criteria for defining HDA and the burden of HDA. METHODS: Articles were identified via PubMed search through 2016, complemented by additional hand searches. Both abstract and full-text were reviewed for relevance. Data on the clinical definition of HDA, clinical and humanistic burden of HDA under different definitions, and economic burden associated with patients with high levels of disease severity/activity were extracted. RESULTS: The literature search yielded 670 articles; 52 were included for data extraction. Fourteen studies evaluated the measurement of disease activity, 35 assessed the disease burden of HDA, and of 17 studies reporting economic outcomes, only one assessed the economic burden of HDA. The literature lacks a widely-accepted approach for measuring disease activity in this heterogeneous disease—a number of different instruments and clinical criteria have been developed for defining HDA, and the threshold used to define HDA varies across studies. Across definitions, elevated disease activity exacts heavy burden that manifests as elevated mortality risk, long-term organ damage, an array of burdensome comorbidities (e.g., psychosis, seizures, artery calcifications), heavy corticosteroid use, increased risk of work disability, and high resource utilization. CONCLUSIONS: This literature review revealed that HDA status is currently defined by varying assessment tools. Uniformly, HDA is found to exact significantly high disease burden, confirming the importance of this patient population, but comparability across measures is not well established. Further, gaps exist in quantifying economic burden of HDA which require additional study.

PSY4: COMPARING EFFICACY OF GUSELKUMAB VERSUS USTEKINUMAB IN MODERATE TO SEVERE PSORIASIS PATIENTS : AN ADJUSTED COMPARISON BASED ON VOYAGE 1&2 AND NAVIGATE TRIALS

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OBJECTIVES: Guselkumab is an anti-interleukin-23 monoclonal antibody shown to be superior versus adalimumab and placebo in Voyage 1&2, two large Phase III trials of patients with moderate-to-severe psoriasis. The Navigate trial showed superiority versus ustekinumab in patients with an inadequate response to ustekinumab. No direct comparison is available between guselkumab and ustekinumab in ustekinumab-naïve patients. As such, an adjusted comparative analysis was performed to compare efficacy of guselkumab versus ustekinumab, using pooled patient-level trial data from Voyage 1&2 and Navigate, adjusting for cross-trial population differences. METHODS: Patient level data, including baseline characteristics and outcome data on PASI 75, 90 and 100 responses at weeks 16, 28 and 40, from the guselkumab-arms of Voyage 1&2 were pooled with the data from the ustekinumab-arm from Navigate. To adjust for differences in patient characteristics across trials, a multivariate logistic regression model was estimated, including the following baseline characteristics: age, gender, BMI, psoriasis duration, PASI and IGA scores, BSA, presence of psoriatic arthritis, and exposure to prior systemic and biological treatments. RESULTS: Patients on guselkumab (n=825) had generally similar baseline characteristics compared to patients on ustekinumab (n=718). The probability of reaching a PASI 90 response was significantly higher for guselkumab at weeks 16 (OR=2.70 [2.17:3.33]), 28 (OR=2.27 [1.79:2.94]) and 40 (OR=2.38 [1.85:3.03]) (all p<.0001), after adjusting for baseline characteristics. Similar results were obtained for the probability of reaching PASI 75 and 100 responses across all timepoints. CONCLUSIONS: An adjusted comparison using patient level data from Phase III studies suggests guselkumab is significantly more effective versus ustekinumab for treating psoriasis.
Such comparisons can provide useful insights to clinicians and reimbursement decision makers on the relative efficacy of both treatments.

**PSY5: HEALTH EFFECTS OF MICRONUTRIENT FORTIFIED MILK AND CEREAL FOOD FOR CHILDREN AND ADOLESCENTS: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** Micronutrient (MN) deficiencies cause a considerable burden of disease for children in many middle and low income countries, with impaired physical and cognitive development and increased morbidity. MN fortified milk or cereals are an important food component during adolescence and often used in school feeding programmes, but their specific impact on health is poorly documented. **METHODS:** We performed a systematic review and meta-analysis to assess the impact of MN fortified milk and cereal food on the health of children and adolescents (aged 5-15 years) compared with non-fortified food. We reviewed randomised controlled trials (RCT) using electronic databases (MEDLINE, EMBASE, Cochrane library; latest search: January 2017), reference list screening and citation searches. Three pairs of reviewers independently assessed 1916 studies for eligibility and extracted data. We assessed the risk of bias and rated quality of evidence using the GRADE approach. **RESULTS:** We included 23 RCT (often multi MN fortification) with 29 pair-wise comparisons. A modest and non-significant increase of haemoglobin values emerged (0.07 g/dl [95%-CI: -0.02 to 0.17]; 13 RCT with iron fortification; very low certainty). In one ex-post subgroup analysis, multi MN fortification had a significant effect on haemoglobin (0.13 g/dl [95%-CI: 0.03 to 0.23]; 6 RCT), when comparing fortified to non-fortified milk and cereals. No significant impact was found on anaemia risk (risk ratio 0.90 [95%-CI: 0.78 to 1.03]; 11 RCT), but on iron deficiency anaemia (risk ratio 0.38 [95%-CI: 0.18 to 0.81]; 5 RCT). Fortified milk and fortified cereals showed similar effects. Follow-up periods were often short and the impact on anthropometric measures was weak. Some moderate-quality evidence emerged for the improvement of cognitive performance, functional measures and morbidity. **CONCLUSIONS:** Fortification of milk and cereal food had only marginal health effects in children and adolescents from 5-15 years, but iron deficiency rates at baseline were relatively low.

**PSY6: THE MODELLED EFFECTIVENESS OF RUXOLITINIB ON SURVIVAL IN POLYCYTHEMIA PATIENTS WITH HYDROXYUREA RESISTANCE/INTOLERANCE IN TURKEY**

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**OBJECTIVES:** To evaluate the clinical effectiveness of ruxolitinib as compared to best available treatment (BAT) based on control of leucocytosis and thus prolongation of life-years, in polycythaemia (PV) patients, with hydroxyurea (HU) resistance/intolerance. **METHODS:** A Markov model demonstrating the progression of HU resistant/intolerant PV patients through health states defined by the presence (>15x10⁹/L) or absence of leucocytosis, was adapted to the Turkish treatment and epidemiology setting. The model time horizon was 15 years. The cycle length was defined as three months. Clinical data, derived from Phase III RESPONSE trial, were reviewed by a local expert panel. The model relied on white blood cell control as a prognostic marker for overall survival (OS). The statistical relation between leucocytosis and OS was derived from the literature. Utility values were based on international literature. The patient population modelled is assumed to be 61 years old in average, 65.8% male, and mean duration of disease 9.24 years. HU resistant/intolerant ratio 35%/65% respectively, proportion of patients without leucocytosis at the beginning 43%. The patients are treated with ruxolitinib or BAT (HU 59%, interferon 11%, other medications 13% and phlebotomy only 17%). **RESULTS:** Patients treated with ruxolitinib experienced additional life-years without leucocytosis compared with patients on BAT (6.47 vs. 4.39 years). OS for patients treated with ruxolitinib was 1.15 years longer than patients treated with BAT (8.21 vs. 7.06 years). When the duration of life-years was adjusted for quality of life, patients treated with ruxolitinib experienced an incremental QALY gain of 1.38 years compared to patients treated with BAT (6.67 vs. 5.29 QALYs). **CONCLUSIONS:** Modelled survival outcomes demonstrate the improvements in quality-of-life and overall survival for HU intolerant/resistant patients who are treated with ruxolitinib compared to BAT. Therefore, ruxolitinib may be considered in PV patients who experience resistance or intolerance to HU, in Turkey.

**PSY7: SWITCHING MAINTENANCE INFlixIMAB THERAPY TO BIOSIMILAR-INFlixIMAB DOES NOT LEAD TO SIGNIFICANT CHANGES IN HEALTH-RELATED QUALITY OF LIFE AND CLINICAL OUTCOMES IN INFLAMMATORY BOWEL DISEASE PATIENTS**
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OBJECTIVES: The objective of this study was to evaluate the clinical efficacy and effectiveness of biosimilar-infliximab during the maintenance therapy of inflammatory bowel diseases (IBDs). METHODS: In this single-centre prospective observational study, all IBID patients receiving maintenance infliximab therapy were switched to biosimilar-infliximab. The health-related quality of life (HRQoL) measures used were the generic 15D instrument and the disease-specific Inflammatory Bowel Disease Questionnaire (IBDQ). Patient reported outcomes were collected at four infliximab administration visits: before the last originator infusion, before the first biosimilar infusion, before the third biosimilar infusion and one year after the switching. Clinical disease activity (Harvey-Bradshaw Index (HBI) or partial Mayo score) was collected from patient records. The primary endpoints of the study were the changes in HRQoL and clinical outcomes during the follow-up. RESULTS: 56 patients were included in the analysis (24 Crohn’s disease, 29 ulcerative colitis and 3 IBID unclassified). The mean 15D score (SD) was 0.915 (0.067) before the last originator infusion, 0.909 (0.072) before the first biosimilar infusion, 0.913 (0.080) before the third biosimilar infusion, and 0.911 (0.084) one year after the switching. The respective mean IBDQ scores (SD) were 180 (29.006), 177 (31.789), 182 (29.166), and 185 (28.909). Before the last originator-infliximab infusion the mean HBI (SD) was 1.80 (3.34) and the mean partial Mayo score (SD) 0.95 (1.69), whereas the mean HBI (SD) was 1.93 (3.71) and the mean partial Mayo score (SD) 0.60 (1.05) before the third biosimilar-infliximab infusion. No statistically significant differences were observed between the 15D (p=0.737), IBDQ (p=0.284), HBI (p=0.317), and partial Mayo score (p=0.481) before and after the switching. No safety concerns were observed during the follow-up. CONCLUSIONS: These data suggest that in maintenance therapy of IBD biosimilar-infliximab was, in light of 15D, IBDQ, HBI, and partial Mayo score, comparable to originator-infliximab during one year following switching.

PSY8: BLEEDING-RELATED EPISODES (BRE) IN PATIENTS WITH IMMUNE THROMBOCYTOPENIA (ITP) RECEIVING ELTROMBOPAG (EPAG) OR ROMIPLOSTIM (ROMI): REAL WORLD EVIDENCE FROM 26 US INSTITUTIONS

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OBJECTIVES: To examine burden of BREs in ITP patients treated with EPAG or ROMI. METHODS: We investigated BREs, a complication of ITP that leads to significant morbidity and mortality, using a syndicated electronic medical records network that contains records for inpatient and outpatient services and procedures, diagnoses, adverse events (AEs), prescriptions and labs for >27 million patients from 26 US hospital institutions. Adult patients diagnosed with primary ITP and treated with EPAG or ROMI with prior steroid treatment were included. Patients with secondary ITP, history of HBV, HCV, HIV, malignancy, severe aplastic anemia, myelodysplastic syndrome, myelofibrosis and splenectomy were excluded. BREs were identified based on bleeding codes (BE) and/or uses of rescue therapy [RES] (intravenous (IV) immunoglobulin administration, IV steroid administration, or platelet transfusion (PT)) using a combination of diagnosis, procedure, and medication codes. BREs requiring PT were considered severe (sBRE). BREs after initiation of EPAG or ROMI were compared using Z-tests (two-tailed α=0.05). RESULTS: 140 patients were identified: EPAG (90) or ROMI (50). Mean age (standard deviation) was similar: EPAG 53 (21) / ROMI 56 (23). Liver function tests ALT (EPAG 16.50 (7.97) / ROMI 16.00 (5.96) U/L), AST (EPAG: 18.75 (1.79) / ROMI 18.00 (4.85) U/L), and mean platelet volume (EPAG 10.67 / ROMI: 10.60 fL) were also similar across cohorts. The BREs identified through RES were not significantly different between ROMI and EPAG (20 vs 22%, p=0.759), while those identified through BE were significantly higher in ROMI vs. EPAG (40 vs 22%, p=0.026). CONCLUSIONS: This retrospective RWE study emphasizes the significant burden of BREs in ITP patients despite treatment which aims to prevent these episodes. BRE rates identified as BE after controlling for confounding, were significantly higher in ROMI-treated patients as compared to EPAG-treated patients.

PSY9: SECOND-LINE TREATMENT FOR STEROID-REFRACTORY GRAFT-VERSUS-HOST DISEASE WITH MESENCHYMAL STROMAL CELLS. A CONCEPTUAL DISEASE MODEL

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OBJECTIVES: The aim of this study was to evaluate the potential of MSCs as second-line treatment for SR-GVHD. METHODS: A conceptual disease model was developed to describe how MSCs may affect SR-GVHD in different scenarios. The model was created using Qubes, a graph-based simulation environment. The model consisted of compartments representing the patient, the disease, and the treatment. The patient compartment was divided into compartments representing different organ systems affected by SR-GVHD. The disease compartment represented the disease progression and was divided into compartments representing different stages of SR-GVHD. The treatment compartment represented the MSC transplantation. The model was parameterized with data from the literature. RESULTS: The model was able to simulate the disease progression and treatment response in different scenarios. The model showed that MSC transplantation can delay the disease progression and improve the treatment response in SR-GVHD. CONCLUSIONS: The model provides a useful tool for understanding the potential of MSCs as second-line treatment for SR-GVHD. Further research is needed to validate the model and to develop a personalized treatment strategy for SR-GVHD.
Netherlands

OBJECTIVES: Success rates of allogenic haematopoietic stem cell transplantation are tarnished by high incidences of acute graft-versus-host disease (aGvHD). For those patients not responding to first-line steroid therapy, there is no approved second-line treatment available and long-term outcome remains poor. Since 2004, mesenchymal stromal cells (MSC) are studied as treatment for steroid-refractory aGvHD (SR-aGvHD) in a number of phase II trials. However, no disease model (DM) exists to integrate and extrapolate currently available evidence on MSC treatment. We aimed at developing such a DM to assess the long-term costs and effects of MSC treatment. METHODS: The DM was developed in collaboration with experts in the field haematology-oncology which are all part of EU sponsored research initiative to investigate the usefulness of MSC for the treatment of aGvHD (RETHRIM). Model input parameters for transition and survival estimates were informed by patient-level data of 12 phase II clinical trials. Several parametric distributions were used to estimate long-term survival rates after MSC treatment. Sub-group analyses were conducted. RESULTS: The DM consists of nine health stages: (1) treatment response, (2) treatment failure, (3) tapering schedule of steroids and/or other immune-suppressive drugs, (4) 3rd-line therapy, (5) sustained response, (6) relapse/persistent aGvHD, (7) chronic GvHD, (8) relapse and adverse events of hemolgogenic disease, and (9) death. Data of 209 patients (median age: 30.5 years; range = 0.4 – 69.0) was recorded. Median survival time for all observations with valid survival data (n = 110) was 2.5 years after treatment. Further results include: transition rates from aGvHD stages II-IV to aGvHD stages 0, I, II, III, and IV, subgroup analysis (female/male, several age groups), as well as extrapolated survival estimates of different parametric functions. CONCLUSIONS: We created a DM that can eventually aid clinical decision-making and serve as a template for future model-based cost-effectiveness studies.

PSY10: KNOWLEDGE, ATTITUDES AND PERCEPTIONS OF KETAMINE USE BY MEDICAL PRACTITIONERS IN SOUTH AFRICA

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OBJECTIVES: A proposed mechanism for the pathophysiology of catatonia is N-methyl-D-aspartate (NMDA) hyperactivity. It can be argued that ketamine (which acts as an NMDA antagonist) can mitigate the effects of glutamate in catatonia and can potentially be used as treatment for catatonia. The primary aim of the study was to analyse the knowledge, attitudes and perceptions of medical practitioners on the use of ketamine, including its use in catatonia. METHODS: A structured questionnaire survey on ketamine was conducted during 2015. Twenty-three medical practitioners at three public sector hospitals in the Nelson Mandela Metropole participated. Respondents included anaesthesiologists (43.5%), psychiatrists (34.8%) and medical officers (21.7%). RESULTS: Respondents, who have prescribed ketamine (82.6%), used it primarily for sedation, anaesthesia and analgesia. Ketamine in children was mainly used for analgesia and sedation, and in adults for anaesthesia. The majority of respondents were aware of ketamine’s mechanism of action, anaesthesiologists was anaesthesia (40.0% and 87.5%, respectively) and sedation by medical officers (60.0%). The majority of anaesthesiologists and medical officers questioned the use of ketamine in catatonia, whereas psychiatrists knew of preliminary studies but indicated they would not use it until proven safe. Regarding ketamine’s mechanism of action, anaesthesiologists responded that ketamine acts on the NMDA receptor; most psychiatrists responded similarly and added its action on opioid receptors. Anaesthesiologists and medical officers were not aware of its use in schizophrenia or depression. The majority of respondents were aware of ketamine’s abuse potential. CONCLUSIONS: Different specialties had different views on the use of ketamine, including its use in catatonia.

PSY11: DO CHARACTERISTICS OF PATIENTS INFLUENCING THE CHOICE OF PAIN TREATMENT BY GPS DIFFER IN OSTEOARTHRITIS AND CANCER? – AN ITALIAN REAL WORLD EVIDENCE STUDY

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OBJECTIVES: To understand whether patients’ features underneath the choice of pain treatments by Italian GPs differ between osteoarthritis and cancer. METHODS: Retrospective analysis on Real World Data from IMS Health Italian Longitudinal Patient Database. For both osteoarthritis and cancer, three cohorts of patients have been identified based on anti-inflammatory and antirheumatic (M01) and analgesic (N02) drugs prescriptions recorded during 2016: a) patients receiving a treatment with M01 drugs and not having N02 prescriptions, b) patients receiving a treatment with N02 and not having M01 prescriptions, c) patients treated with both M01 and N02 drugs. Descriptive statistics, Chi-square and t-tests were used to compare demographic and clinical characteristics of the patients in the three cohorts for osteoarthritis and cancer. RESULTS: Patients receiving a treatment with M01 drugs were 32,238 (70%) and 2,496 (31%) for osteoarthritis and cancer, respectively. Patients receiving a treatment with N02 were 8,569 (19%) and 4,450 (55%) for osteoarthritis and cancer, respectively. Patients treated with both M01 and N02 drugs were 5,026 (11%) and 1,107 (14%) for osteoarthritis and cancer, respectively. In osteoarthritis, the highest
proportion of men was observed among patients treated with M01 only (33% versus 25% and 25%), while in cancer, higher proportions of men were observed among patients treated with N02 and among those treated with both M01 and N02 (46% and 47% versus 41%). For osteoarthritis, as well as for cancer, the oldest patients were those treated with N02 only, with a mean age of 77 and 71 years, respectively. Both in osteoarthritis and in cancer, patients treated with N02 only and with both N02 and M01 had a more impaired health status. All the comparisons were statistically significant. CONCLUSIONS: Despite all the considered patients’ features seem to be correlated with treatment choice, only gender shows opposite effects when comparing osteoarthritis and cancer.

PSY12: AN EVIDENCE-BASED APPROACH TO PREDICT LONG-TERM PATIENT OUTCOMES AND KEY VALUE DRIVERS

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OBJECTIVES: Given the unique issues associated with clinical trials for rare indications, there is usually limited information about long-term patient outcomes and key value drivers at the time of product launch. The objective of this study was to develop a predictive model framework to provide clarity on potential long-term outcomes of interest and associated key value drivers. METHODS: In this study, we focused on a product used to treat a rare genetic syndrome that inhibits the body’s ability to break down fat (lipids). The first step was to gather information on patient outcomes from the product clinical trials and via a structured literature review. Pre-determined criteria were then used to evaluate and rank the evidence for quality, plausibility, and relevance. The outcomes were filtered further to focus on those most likely linked to disease progression and mortality. A patient flow was constructed to link short-term outcomes to potential long-term ones with and without treatment. Probabilistic modelling was applied to determine the likelihood of each complication/outcome to occur. RESULTS: The model provided a probabilistic comparison of different outcomes with and without treatment. The outputs of the predictive model were then entered into an early health economic model to assess key value areas of interest to payers, healthcare systems, and patients. The model framework helped form a reasonable hypothesis that could predict the potential impact of the product on this rare disease. CONCLUSIONS: Predictive models have their limitations, and unexpected outcomes can occur in a real-world setting. Nonetheless, this model provides an early indication of key areas that a new rare disease therapy should focus on to provide improved value. As a next step, monitoring will focus on how closely real-world outcomes compare with those from the predictive model to allow for further refinements.

PSY13: EPIDEMIOLOGICAL ESTIMATES AND TREATMENT PRACTICE PATTERN IN POLYCYTHEMIA VERA PATIENTS IN TURKEY: RESULTS BASED ON AN EXPERT PANEL

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OBJECTIVES: The aim of this study was to estimate the treatment patterns and parameter values for patients with polycythemia vera (PV) in Turkey. METHODS: Two-stage Delphi panel was conducted seeking consensus of expert opinions, which included 7 local haematology experts. Initial diagnosis, first and subsequent lines of treatments were reviewed. RESULTS: The incidence and prevalence rates of PV are estimated to be 1.3 and 11.6 per 100,000 in general population in Turkey, respectively. Approximately one-third of patients are observed without any treatment or receive phlebotomy. 58.3% of patients are administered only hydroxyurea (HU) and 8.3% are prescribed interferons. Among patients not responding or are resistant/intolerant to 1st line treatment, frequency of patients on HU decreases to 52.3%; interferons are administered more frequently (21.5%). Medications which are not administered at 1st line are initiated in some patients (immunomodulators -thalidomide/lenalidomide- 10%, ruxolitinib 6.7% and anagrelide 2.5%). In 3rd line treatment, 44.7% are prescribed HU. Other medications are administered more frequently than previous lines (interferons 24.8%, immunomodulators 10.3%, ruxolitinib 9% and anagrelide 5.8%). Proportion of PV patients who are HU resistant/intolerant is estimated to be 16.7%. Of these patients, 49.3% are administered HU due to the lack of alternative treatment options currently available. Use of interferons, anagrelide and other medications following HU represent 35%, 10% and 5.6%, respectively in this group of patients. CONCLUSIONS: Uncontrolled PV may cause complications such as thromboembolic events, acute myeloid leukemia, haemorrhagic complications or even death. Almost half of PV patients who are treated with HU, continue to receive HU regardless of response, resistance or intolerance. New treatment options with improved effectiveness in HU resistant/intolerant patients are needed.

PSY14: DRUG UTILISATION STUDY OF ANTI-OBEITY PRODUCTS DISPENSED BY PHARMACIES IN SOUTH AFRICA
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**OBJECTIVES:** The aim was to investigate the dispensing patterns of prescription-only anti-obesity products (excluding diet products) in South Africa (classified under Anatomical Therapeutic Chemical (ATC) group A08). **METHODS:** A retrospective, cross-sectional drug utilisation study using electronic dispensing records of private sector community (or retail) pharmacies in South Africa was conducted. All patients who received one or more anti-obesity products in ATC group A08 in 2015 were included in the study. Outcome measures included the number of patients by age and gender, prescribing frequency and cost, and trends observed. **RESULTS:** A total of 32968 patients were prescribed 67583 products at a sales value of R17103909.59 for anti-obesity medication during 2015. The average cost per prescription was R253.08 (SD=R90.62). The average age of patients was 41.55 (SD=11.36) years, with male patients on average older than female patients (46.13 and 39.86 years, respectively). More female patients (73.03%) were dispensed anti-obesity products. Five active ingredients were dispensed. Phentermine was the prescription most, accounting for 84.99% of anti-obesity prescriptions, followed by D-norpseudoephedrine (8.90%), orlistat (3.61%), phendimetrazine (2.29%), and diethylpropion (0.21%). These results were similar to the findings of a 2013 South African study, except that the prescribing frequency of D-norpseudoephedrine has increased. Orlistat was on average the most expensive per prescription (R 485.75). Most patients (76.73%) received only short-term therapy (one or two prescriptions for an anti-obesity product during the year). A small percentage (0.24%) of young patients (younger than 18 years) received anti-obesity products, despite the fact that the safety of these products in children has not been proven. D-norpseudoephedrine was the only active ingredient showing seasonal patterns, with more products dispensed before the summer months. **CONCLUSIONS:** Phentermine was the most commonly dispensed active ingredient, followed by D-norpseudoephedrine which was recently rescheduled in South Africa. Studies on patient outcomes and the cost-effectiveness of these products should be conducted.

**PSY15: FLARING AMONG ATOPIC DERMATITIS PATIENTS – THE PERCEPTION OF FLARING BURDEN BETWEEN PHYSICIANS AND PATIENTS**

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**OBJECTIVES:** To evaluate flare frequency, severity and duration among all Atopic Dermatitis (AD) patients and hand eczema patients with AD aetiology. **METHODS:** Data were drawn from the 2015 Adelphi AD Disease Specific Programme, a cross-sectional survey of physicians and their adult AD patients in the United States, France, Germany and UK. Each physician completed a patient record form including affected body areas, flare status/severity/frequency, and each component of the Eczema Area and Severity Index (EASI). Patients voluntarily provided information regarding flare frequency/duration. **RESULTS:** 609 physicians provided records for 3037 patients, of whom 1946 experienced flares and 73 were affected only on their hands. 1026 patients who experienced flares completed the patient questionnaire. Physicians reported: the majority of patients had flared in the last 12 months (AD: 88%; hand: 89%), all AD patients experienced an average of 3.2 flares in the last 12 months (1.1 mild, 1.5 moderate, 0.6 severe), hand patients experienced an average of 2.3 (0.6 mild, 1.5 moderate, 0.2 severe). Patients reported a greater number of flares in the last 12 months (AD: 5.4; hand: 5.2) and reported flares lasting on average 12.0 days (AD), 12.7 days (hand). Regardless of EASI score, patients experienced flares of all severities; EASI clear/almost clear: 2.0 in the last 12 months (1.0 mild, 0.8 moderate, 0.2 severe), EASI mild: 2.6 (1.0 mild, 1.3 moderate, 0.3 severe), EASI moderate: 3.7 (1.2 mild, 1.7 moderate, 0.8 severe), EASI severe/very severe: 5.2 (1.4 mild, 2.1 moderate, 1.7 severe). **CONCLUSIONS:** AD patients experience flares of all severities regardless of regions affected or EASI score. The potential impact on patients caused by flares may last for more than two weeks. The burden of disease seems to be higher for the patients than that reported by the physicians, as patients, in particular hand patients, report more frequent flares, on average almost double.

**PSY16: BURDEN OF LYSOSOMAL ACID LIPASE DEFICIENCY**

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**OBJECTIVES:** Lysosomal acid lipase deficiency (LAL-D) is a rare, underdiagnosed, progressive, systemic disease, generally manifesting early in life. It is a medical emergency in infants and causes significant morbidity and early mortality in children and adults. The objective was to characterize signs and symptoms of LAL-D over time, highlighting evidence gaps to guide future research. **METHODS:** A systematic review of published literature describing burden of LAL-D was conducted. Given the paucity of published LAL-D studies, a broad search strategy of English-language studies in Medline/PubMed and EMBASE was performed, without limits by publication date or study design. All studies describing disease burden were included. **RESULTS:** 701 abstracts were identified, with 194
articles eligible for inclusion. Clinical burden was primarily described in case reports and case series, with 214 cases in 138 articles. Of these, 103 cases were infants (onset of characteristic clinical manifestations before six months of age); the remainder were children/adults. Two-thirds of data provided some longitudinal follow-up, allowing some exploratory analysis of temporal progression. Mean time between symptom onset and diagnosis was two years, with reported prior misdiagnoses of other lipid storage and related diseases in 9% of individuals. The majority of diagnoses were made based on LAL enzyme analysis, either alone (23.8%), in combination with liver biopsy and/or genotyping (49.9%). In all individuals, hepatomegaly was most commonly-reported (82% in infants, 84% in children/adults); hepatomegaly was also the most common factor leading to LAL-D diagnosis. Sixty-two percent of infants had severe morbidity or mortality reported, typically by one year of age. Dyslipidemia and elevated transaminases were frequently reported in all age groups. CONCLUSIONS: Very limited data are published on burden of disease in LAL-D. The available reports show substantial disease burden in both infants and in children/adults. Prospective cohort studies or registries are needed to better characterize disease progression.

PSY17: COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE MANAGEMENT OF PAI

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OBJECTIVES: Complementary and Alternative Medicine (CAM) has become an acceptable and popular treatment in the management of pain. The primary aim was to determine the extent and effectiveness of the different CAM modalities in the management of pain. METHODS: A questionnaire survey was conducted under community members in South Africa using convenience sampling. A total of 193 responses were received. RESULTS: The average age of respondents was 31.6 (SD=13.1) years (53.4% females). Pain was classified according to body regions. Pain intensity was, on average, moderate. The majority of respondents suffered pain in the head (e.g. headache and migraine) and back (e.g. lower back pain). Thirty-four respondents (17.6%) were migraine sufferers. A third (37.3%) of respondents indicated that other family members also use CAM. The CAM classifications indicated for treating pain were cross-cultural (e.g. yoga), external (e.g. chiropractors, massage and heat therapy), internal (e.g. herbal supplements) and mind-body healing therapies (e.g. prayer therapy, sleep and meditation). The CAM modality reported to be most effective in treating pain was cross-cultural therapies with an average effectiveness of 3.6 out of a maximum score of 4.0. The most popular therapies were external body healing therapies (reported by 33.6% of respondents). Nearly half of the therapies were used in conjunction with conventional analgesics, with 43.0% indicating that they obtain their treatment for pain from pharmacies. CONCLUSIONS: CAM was used either on its own or in combination with conventional medication for the treatment of pain. Therapies seemed to be effective. The choice of CAM therapy was highly individualised.

PSY18: OCCURRENCE OR REMISSION OF ANTIDIABETIC TREATMENT SIX YEARS AFTER BARIATRIC SURGERY: A NATIONWIDE MATCHED COHORT STUDY

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OBJECTIVES: Few large long-term prospective cohorts have assessed the evolution of antidiabetic treatment after bariatric surgery (BS). The aim of our study was to study, under real life conditions and at a national level, remission and occurrence of antidiabetic treatment over 6 post-operative years after BS, compared to a matched control group, using the French national health insurance database. METHODS: Each patient undergoing primary BS in France in 2009 was matched on age, sex, BMI categories and antidiabetic treatment with one control patient hospitalised for obesity in 2009 who had no BS between 2005-2015. Reimbursements of antidiabetic treatment were extracted from the French National Health Insurance database (SNIIRAM) between 2008-2015. Mixed-effects logistic regression models analysed factors of remission or occurrence of antidiabetic treatment over 6 years. RESULTS: In 2009, 15,650 patients (85% female; 1,633 with antidiabetic treatment) had undergone primary BS: gastric banding (AGB) 48%, gastric bypass (GBP) 28%, sleeve gastrectomy (SG) 24%. For patients with antidiabetic treatment at baseline, discontinuation of treatment at 6 years was more frequent after BS than in controls (50% vs. 9%; P<0.001). In multivariate analysis, the main predictive factors of discontinuation were overall (OR; 95%CI): GBP=16.7 (13.0-21.4); SG=7.3 (5.5-9.5), AGB=4.3 (3.3-5.6), no baseline insulin (5.9 (4.5-7.7)) and no hypolipidemic treatment (1.5 (1.1-1.6)). For patients without antidiabetic treatment at baseline, occurrence of treatment at 6 years was much less frequent after BS than in controls (1% vs. 12%; P<0.001). All types of procedures were protective factors: GBP=0.06 (0.04-0.09), SG=0.08 (0.06-0.1), AGA=0.16 (0.14-0.19). CONCLUSIONS: Our large study confirms that BS leads to a significant discontinuation rate of antidiabetic treatment compared to baseline and to non-surgical obese controls over 6 post-operative years, as well as to a lower occurrence rate of antidiabetic treatment, with GBP being the most effective procedure.
OBJECTIVES: The objective of this review was to collate evidence on the incidence and prevalence of painful diabetic neuropathy (PDN) and postherpetic neuralgia (PHN) in 5 major European countries (United Kingdom [UK], Germany, France, Italy and Spain), the United States (US) and Japan. METHODS: A narrative review was conducted through searching Embase®, MEDLINE® and Cochrane databases, from 2010 to February 2017. The incidence and prevalence data obtained was summarised according to geographies. RESULTS: Of 4,425 citations reviewed, 26 studies reported the incidence and/or prevalence of PDN and/or PHN. The included studies were diverse in their study designs: population based studies, surveys, cross-sectional/longitudinal, prospective/retrospective and single/multicentre. The incidence of PDN was 3.1/10,000 population (UK) and prevalence varied from 8.2% to 25.7% (US), among all diabetic patients. The prevalence of PDN varied with type of diabetes: type-1 8.2% (US) to 22.7% (UK) or type-2 9.0% (France) to 35.0% (UK), prediabetes (4.2% [Germany] to 16.0% [US]). Studies differed in their respective diagnosis of PDN; different PRO instruments or PRO instrument combined with clinical examination. The incidence of PHN varied from 1.2% (Germany) to 47.6% (Spain) and the prevalence varied from 8.0% (Italy) to 59.2% (Spain). The incidence and prevalence of PHN increased with the age of patient (incidence: 1.2% [30-39 years; Germany] to 33.0% [>80 years; US] and prevalence: 21.4% [<50 years; Spain] to 59.2% [≥70 years; Spain]), and varied with the definitions for duration of pain. CONCLUSIONS: Although a reasonable body of research was identified for both PDN and PHN, heterogeneity in study designs and diagnostic criteria limits the ability to generalise and compare incidence and prevalence across geographies. Studies from diverse populations and of larger sample size are needed to expand our insight on the incidence and prevalence of PDN and PHN.

OBJECTIVES: Low back pain (LBP) patients with neuropathic pain (NP) had substantially impaired quality of life. We investigated possible factors associated with NP in chronic LBP patients. METHODS: Data were extracted from the NLBP OR [the NP in chronic LBP patients; Korean epidemiological study]. It was a multicenter and cross-sectional study where 1,200 patients older than 20 years of age with chronic LBP longer than 3 months, with a visual analog scale (VAS) pain score higher than 4, and with pain medication at least 4 weeks prior to enrollment were recruited at 27 general hospitals from December 2014 to May 2015. Potential factors related to NP were age, sex, LBP duration from diagnosis, Quebec Task Force Classification for Spinal Disorders (QTFCD-S), comorbidities, and pain VAS and were collected by medical chart review. Douleur Neuropathique 4 (DN4) was used for diagnosis of NP (DN4≥4). RESULTS: Analysis was performed on 880 patients (mean age 64 years, male 34%) who had complete data of all measured variables. 362 (41%); mean age 63 years, male 40% patients were classified as NP. In multiple
logistic regression analysis, independently associated factors of NP prevalence were male (adjusted odds ratio, 1.7; 95% Confidence Interval, 1.2-2.3) and having pain of severe intensity compared to moderate pain (1.8; 1.4-2.4). In addition, compared to pain without radiation, pain with proximal extremity radiation (3.5; 1.8-6.8), pain with distal extremity radiation (7.4; 4.1-13.6), pain with radiation and neurologic finding (7.6; 3.6-16.3), spinal nerve root compression (5.9; 2.8-12.4), and spinal stenosis (4.6; 2.3-9.2) were respectively associated with NP prevalence. CONCLUSIONS: When physicians treat chronic LBP, more attention should be given to those patients with related factors of NP.

**PSY21: ESTIMATES OF PFS, TTNT PER TREATMENT LINE AND THEIR RELATIONSHIP FOR MULTIPLE MYELOMA PATIENTS**

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**OBJECTIVES:** The aim of this research was to study how progression free survival (PFS) and time to next treatment (TTNT) changed by line of treatment among multiple myeloma (MM) patients and assess the relationship between the two. **METHODS:** Consecutive patients diagnosed with MM between 2000 and 2011 at various medical centers in Sweden were included. TTNT and PFS were defined as the time between the start date of the administered drugs in the current treatment line and the start date of the administered drugs in the next treatment line; or until progressive disease respectively. In both cases, death was defined as an event. Multi-variate Cox model including prognostic factors and line of treatment were used in the analysis. **RESULTS:** Among the 1616 total MM population 1125 patients were not eligible for stem cell transplant. Their median PFS and median TTNT decrease significantly as the line of treatment increases and the difference between these two endpoints decreases by treatment lines. Median PFS and TTNT in months (with 95% CI) in 1st line are: 8.5 (7.9, 9.2), 12.3 (11.1, 13.3), in 7th line 3.0 (1.5, 5.2), 3.9 (2.2, 7.2). The risk of disease progression or death increased significantly by line of treatment with a more profound increase between 2nd line vs. 1st line (hazard ratio, HR, 1.39 [1.26, 1.53]) than line 3+ vs. their corresponding previous lines (HR 1.18 [1.12, 1.23]). The same trend was observed for TTNT. Median survival times and HRs have similar significant pattern for stem cell transplant eligible patients. **CONCLUSIONS:** The time to progression and TTNT decrease the most after the first line treatment, suggesting that an effective treatment in first line could have a bigger impact on survival than an effective treatment in later lines.

**SYSTEMIC DISORDERS/CONDITIONS - Cost Studies**

**PSY22: BUDGET IMPACT ANALYSIS OF LOW-DOSE METHOXYFLURANE FOR THE TREATMENT OF MODERATE-TO-SEVERE TRAUMA PAIN IN SWEDEN**

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**OBJECTIVES:** To assess the budget impact of introducing low-dose methoxyflurane (LDM), self-administered by the patient via a handheld inhaler (Penthrox®), as a treatment for trauma patients with moderate-to-severe pain in the pre-hospital setting for Sweden. **METHODS:** A budget impact model was developed from the Swedish healthcare system perspective to evaluate the resource use associated with LDM vs standard of care (SoC; morphine IV, fentanyl nasal spray and ketamine injection) over a 5-year time horizon. Model inputs included costs (drug acquisition, staff, equipment and management of adverse events [AEs]) and resource use (total trauma treatment time from arrival of medical staff at the trauma scene to discharge from the emergency department) and were derived from published data supplemented by the results of a retrospective chart review and physician survey. **RESULTS:** The model estimated that, annually, approximately 682,000 patients would be eligible for analgesic treatment for moderate-to-severe trauma pain in the pre-hospital setting. Introducing LDM at a 1% annual uptake rate resulted in a net decrease of >1M minutes in average treatment time for the total patient population in Year 1 due to reduced time for first pain relief, treatment setup, administration and monitoring. Estimated cost savings ranged from SEK 5M in Year 1 to SEK 24M in Year 5, with increased drug acquisition costs (ranging from SEK 1M in Year 1 to SEK 5M in Year 5) offset by savings in trauma treatment costs, equipment costs and management of AEs (SEK 4M, 1M and 0.02M in Year 1 and SEK 22M, 7M and 0.08M in Year 5, respectively). **CONCLUSIONS:** Using LDM instead of SoC for treating moderate-to-severe trauma pain in the pre-hospital setting is associated with shorter treatment times and healthcare costs savings, driven by reductions in staffing costs, and may improve both patient care and flow through the hospital.

**PSY23: BUDGET IMPACT ANALYSIS OF BIOSIMILAR RITUXIMAB (CT-P10) FOR THE TREATMENT OF DIFFUSE LARGE B-CELL AND FOLLICULAR LYMPHOMA IN THE 28 EU MEMBER STATES**
OBJECTIVES: In February 2017, the European Medicines Agency has recommended granting marketing authorization to biosimilar rituximab (CT-P10) in all indications of the reference product including diffuse large B-cell (DLBCL) and follicular lymphoma (FL). This study aims to assess the budget impact of the introduction of CT-P10 into the treatment of DLBCL and FL in the 28 EU member states. METHODS: A third party payer’s perspective budget impact analysis was performed to evaluate the one-year cost outcomes under two scenarios with and without the availability of CT-P10. Market uptake of CT-P10 was assumed to be 30%. Based on expert opinion, it was assumed that when CT-P10 is entering the market it will be at 50-70% of the official list price of originator rituximab in each country. The initial number of patients treated with rituximab was estimated from IMS sales data on total annual consumption of originator rituximab in 2016. Sensitivity analysis was undertaken to test the robustness of model assumptions. RESULTS: The one-year budget impact of adopting CT-P10 is estimated to be €39.02 million in the 28 EU member states. Countries responsible for the majority of the cost savings are Germany (€8.91 million), Italy (€6.90 million), France (€5.28 million), Spain (€3.28 million) and the UK (€2.94 million). If the cost savings were used to treat additional patients with CT-P10, a total of 2,263 patients could be treated annually throughout Europe. The potential cost savings are in a direct correlation with the price and market uptake of CT-P10. Applying discount of 40% and 50% in drug prices, cost savings are projected to €52.02 and €65.03 million, from which further 3,520 and 3,771 patients could be treated with CT-P10, respectively. CONCLUSIONS: Biosimilar rituximab has the potential to improve the affordability of DLBCL and FL treatments and easing the burden of healthcare costs in Europe.

PSY24: THE BURDEN OF SPONDYLOARTHROPATHY – PAASPORT A POPULATION-BASED STUDY

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OBJECTIVES: Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are chronic inflammatory disorders that impact significantly the patient’s quality of life (QoL), health care systems and society. PAASPORT is a sub analysis of EpiReumaPt aiming to estimate the prevalence of PsA and AS in Portugal, characterize Portuguese patients and assess the disease impact on patients QoL. METHODS: EpiReumaPt is a cross-sectional study of Portuguese population (>18 years old) conducted from September 2011 to December 2013. This study included 10,661 subjects screened for rheumatic and musculoskeletal diseases (RMD) through a structured face-to-face questionnaire in participants’ households. Spondyloarthropathy (SpA) were evaluated through the new ASAS criteria. Logistic regressions were used to compare subjects with AS or PsA and other RMD. RESULTS: The prevalence of SpA (AS, PsA and other SpA), was of 1.6% (CI 1.2%-2.1%). No differences were observed by gender. North Region had lower prevalence of all types of SpA (1.30% (CI: 0.65%; 1.96%)). AS patients reported worse QoL when compared with other SpA reflected both in EQ-5D score (0.71±0.35) and SF36 dimensions scores. Patient with AS or PsA also presented higher early retirement related to disease (OR=4.95; p=0.007) than patients with other RMDs. A significant proportion of patients with SpA (13.6%) referred absenteeism in the last 12 months CONCLUSIONS: Results of PAASPORT / EpiReumaPt emphasize the burden of SpA in Portugal presenting poor QoL and high early retirement related to disease, particularly for AS patients. These results showed the need to increase SpA awareness and adjust policies associated with resources allocation.

PSY25: A BUDGET IMPACT MODEL OF THE ADDITION OF TELOTRISTAT ETHYL TREATMENT IN PATIENTS WITH UNCONTROLLED CARCINOID SYNDROME

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OBJECTIVES: Carcinoid syndrome (CS) is a rare condition in patients with neuroendocrine tumors (NETs), characterized by flushing and diarrhea that severely impact patients’ quality of life. Though typically treated by somatostatin analogs (SSAs) as standard of care, many patients nevertheless experience uncontrolled CS symptoms despite therapy. Telotristat ethyl (TE) is a novel tryptophan hydroxylase inhibitor granted EMA orphan designation that has been shown in phase 3 studies to effectively reduce bowel movement frequency in CS. We developed a model to evaluate the 5-year budget impact of introducing TE in combination with SSAs (TE+SSAs) in patients with uncontrolled CS in Sweden. METHODS: Results from the phase 3 TELESTAR trial (NCT01877910) informed TE efficacy in the model, based on the 12-week treatment response, after which health states were captured by a Markov model using 4-week cycles. The model also allowed for TE discontinuation based upon treatment response data from the TELESTAR open-label extension period. Systematic and targeted literature reviews informed CS and
canceroid heart disease (CHD) prevalence, incidence and mortality. These data were used to estimate the number of patients in Sweden eligible for treatment. Real-world CS and CHD-related costs (healthcare resource use, drug acquisition, SSA dosage) were obtained from a Swedish database study. Market share of TE was assumed to increase annually, from 2% to 10% uptake by Year 5. RESULTS: The net 5-year budget impact of TE+SSAs was 11,899€, which translated to a cost of less than 4.86€ per patient per month in each year of the analysis. CONCLUSIONS: As a much-needed treatment for a rare and potentially debilitating condition, the 5-year budget impact of the addition of TE to existing standard of care was projected to be 11,899€ according to our model, suggesting that TE may be an affordable treatment option for patients with this rare disease.

**PSY26: INTRAVENOUS IRON TREATMENTS FOR IRON DEFICIENCY ANEMIA IN INFLAMMATORY BOWEL DISEASE: A BUDGET IMPACT ANALYSIS OF IRON ISOMALTOSIDE 1000 IN THE UK**

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**OBJECTIVES:** Iron deficiency (ID) is the leading cause of anemia in patients with inflammatory bowel disease (IBD). Intravenous iron should be considered the first-line iron-correction treatment in patients with clinically active IBD, hemoglobin <10g/dL, previous oral iron intolerance, or requiring erythropoiesis-stimulating agents. The study objective was to evaluate resource use and costs associated with using iron isomaltoside (Monofer; IIM) relative to other intravenous iron formulations in patients with iron deficiency anemia (IDA) associated with IBD. METHODS: A budget impact model was developed to evaluate the cost of IIM relative to ferric carboxymaltose (Ferinject; FCM), low molecular weight iron dextran (Cosmofer; LMWID) and iron sucrose (Venofer; IS). Iron deficits were modeled using dosing tables and the need for retreatments was modeled using a pooled retrospective analysis of randomized trial data. The analysis was conducted over 5 years in patients with mean bodyweight of 75.4 kg (SD 17.4 kg) and hemoglobin levels of 10.8 g/dL (SD 1.4 g/dL) based on observational data from patients with IBD. Costs were modeled using healthcare resource groups. RESULTS: Using IIM required 1.29 infusions (per treatment) to correct the mean iron deficit, compared with 1.64, 1.29 and 7.14 with FCM, LMWID and IS, respectively. Patients using IIM required multiple infusions in 28.7% of cases, compared with 64.3%, 28.7% and 100% with FCM, LMWID and IS, respectively. Total costs were estimated to be GBP 2,593 per patient with IIM or LMWID, relative to GBP 3,309 with FCM (savings of GBP 717 with IIM) or GBP 14,382 with IS (savings of GBP 11,789 with IIM). CONCLUSIONS: Using IIM in place of FCM or IS markedly reduced the number of infusions required to correct ID in patients with IBD and IDA. The reduction in infusions was accompanied by substantial reductions in cost relative to FCM and IS.

**PSY27: AN EVALUATION OF THE BUDGET IMPACT OF THE NEW 20% SUBCUTANEOUS IMMUNOGLOBULIN (IG20GLY) FOR THE MANAGEMENT OF PRIMARY IMMUNODEFICIENCY DISEASES IN SWITZERLAND**

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**OBJECTIVES:** Patients with primary immunodeficiency diseases (PID) are frequently treated with immunoglobulin (Ig) replacement therapy, either intravenously (IVIG) or subcutaneously (SCIG), to prevent infections. The objective of this analysis was to evaluate the budget impact of the introduction of CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% solution (IG20GLY; Shire) for the treatment of children and adults with PID in Switzerland. METHODS: A budget impact model assessing Ig for patients with PID was developed in Microsoft Excel from the perspective of a Swiss health insurance provider. The model focused on the administration cost of Ig, with all types of Ig, in all treatment settings, and did not include infections or adverse events based on the assumption that all Ig formulations have similar efficacy. Literature-based sources were used to estimate the prevalence of PID, proportion of patients treated with Ig, and treatment site of care. Market research and assumptions were used to estimate Ig treatment patterns and changes in treatment patterns over time. Unit costs were based on a recent cost-minimization analysis of SCIG in Lausanne, and drug costs came from the Spezialitätenliste. All costs were reported in 2016 Swiss Francs (CHF). Future costs were not discounted. RESULTS: Costs of Ig treatment for PID in Switzerland over 3 years were estimated to be: CHF 11.16m, with drug costs comprising CHF 9.28m, and ancillary costs comprising CHF 1.87m (healthcare professional time and other administration costs, [e.g., pumps and needle sets]). The analysis found that using Ig20GLy in place of other SCIG formulations would be cost neutral, while using Ig20GLy in place of IVIG would result in savings of 4.0%. CONCLUSIONS: Ig20GLy would be cost neutral relative to existing SCIG products and would result in cost savings relative to IVIG in patients with PID in Switzerland, even with modest uptake.

**PSY28: IDELVION FOR THE TREATMENT OF HEMOPHILIA B: A BUDGET IMPACT ANALYSIS IN THE ITALIAN SETTING**
OBJECTIVES: Enhanced PK profile of Idelvion, compared to existing FactorIX therapies, allows to prolong the interdose period in the prophylactic setting, maintaining higher trough level, and to reduce dosage to stop a hemorrhagic episode. This improvement could lead to a better efficiency of the hemophilia B treatment. Purpose of this analysis was to estimate the impact of this new drug on the Italian NHS. METHODS: The model estimated the budget impact, from the NHS perspective, of treating patients with severe hemophilia B with reimbursed recombinantFIX over 3 years in Italy. Target population was based on data from the Italian Registry. Treatment options were: albutrepenonacog-α (Idelvion®), efrenonacag-α (Alprolix®) and nonacog-α (BeneFIX®). The model considered annual bleeding rate, dose and infusions number needed to treat an episode based on clinical trials data. RESULTS: Mean costs per patient were calculated for prophylaxis and bleeding treatment by age groups. Applying these costs to the patient pool, according to age and drugs utilization, the impact of Idelvion on the NHS budget corresponded to €7.5 million of savings cumulated in 3 years. At Regional level, there was a wide difference between Lombardy (€1.3 million) and Trentino Alto-Adige (€50,000), according to epidemiology. The model turned out to be more sensitive to the drug dosages. CONCLUSIONS: The positive impact on the expenditure related to Idelvion introduction is due to the lower drug consumption in prophylaxis and reduced bleeding rate compared to the other alternatives. Main limitations of this analysis were related to the conservative assumptions that all severe patients receive prophylaxis and that positive clinical and economic effects of hemorrhagic complications reduction (with consequent lower need of physiotherapy/prosthetic substitution) were not considered. In conclusion, the introduction of Idelvion as therapeutic option for hemophilia B is expected to improve patient’s quality of life due to less frequent infusions and to decrease pharmaceutical costs.

PSY29: BUDGET IMPACT ANALYSIS COMPARING BLINATUMOMAB IN THE TREATMENT OF ADULTS WITH PHILADELPHIA CHROMOSOME-NEGATIVE RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) WITH FLAG-IDA AND HYPER CVAD.

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OBJECTIVES: Blinatumomab, FLAG-IDA and HYPER CVAD are used in the treatment of adults with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The main objective is to do a budget impact analysis of the introduction of Blinatumomab compared to FLAG-IDA and HYPER CVAD from the perspective of the public health system in Mexico. A cost per response analysis versus FLAGIDA was developed as secondary analysis. METHODS: A time horizon of five years was used, considering the use of resources, direct medical costs and population characteristics to quantify the economic consequences of the introduction of Blinatumomab as a new therapeutic alternative in Mexico. A cost per response analysis was conducted considering the use of resources, response rates and number needed to treat (NNT) for both therapeutic treatments. Response rates were obtained from literature and were 73% for Blinatumomab and 32% for FLAGIDA. All costs are expressed in 2017 USD (exchange rate: 19.0137 MXN/USD). RESULTS: Considering a total budget of $3.5 billion for the Mexican public healthcare system, the introduction of Blinatumomab would require an average increment of 0.14981% for the first 5 years, generating an average cost of $5,204,192. With a use of resources of $130,764 for Blinatumomab and $83,985 for FLAG IDA, we obtained a NNT of 1.37 for Blinatumomab and 3.13 for FLAG-IDA that turned out into a cost per response for Blinatumomab of $179,129 and $262,455 with FLAG-IDA CONCLUSIONS: The incorporation of Blinatumomab to the Mexican healthcare system, as a new therapeutic alternative would generate an average increment of 0.14981%, for the first 5 years, generating an average cost of $5,204,192 of the healthcare system budget. The cost per effectively treated patient turned out to be more expensive when using FLAG-IDA ($262,455) versus Blinatumomab ($179,129).

PSY30: ECONOMIC EVALUATION OF SUBCUTANEOUS METHOTREXATE FOR LONG-TERM TREATMENT OF MODERATE-TO-SEVERE PSORIASIS IN THE UNITED KINGDOM

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OBJECTIVES: Psoriasis is a chronic disease that requires long-term treatment, resulting in substantial costs to the National Health Service (NHS). We assessed the economic impact of including subcutaneous methotrexate (SC-MTX) in treatment pathways for moderate-to-severe psoriasis in adult patients. METHODS: A five-year sequencing model was developed to investigate the economic impact of discontinuing conventional systemic therapy for moderate-to-severe psoriasis. Five sequences of conventional systemic therapies were compared, considering the impact of including SC-MTX at different positions in a standard treatment pathway with oral methotrexate (O-MTX) and cyclosporin (CSA), and as a direct replacement for O-MTX. Conventional systemic therapy was followed by four lines of biologic therapy (adalimumab, ustekinumab, etanercept, infliximab) and best supportive care (BSC). Registry
data provided long-term drug survival and serious infection rates. Psoriasis Area and Severity Index 75 (PASI75) data were derived from an indirect treatment comparison of randomised controlled trials. The analysis was conducted from a payer perspective and included costs relating to drug acquisition and administration, serious infections, and medical resource use. Total costs, treatment switches, PASI75 responders, time on treatment, and cost per PASI75 responder were calculated for each sequence. **RESULTS:** SC-MTX as first, second, or third line treatment in addition to O-MTX and CSA generated cost savings of £300–£311 million (£9.395–£9.728 per patient) over 5 years. Including SC-MTX also delayed biologic treatment by 13.9 months. **CONCLUSIONS:** SC-MTX is a viable alternative to conventional systemic treatments for moderate-to-severe psoriasis in the UK. Its inclusion in the treatment pathway is likely to be of considerable economic benefit.

**PSY31: A LITERATURE ANALYSIS OF COST STUDIES ON CANCER**

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**OBJECTIVES:** Pharmacoeconomic studies present and measure the use of cost-effectiveness analysis mainly at country basis, in the literature. In Turkey, the ratio of total health expenditures to GDP is 5.4%. Around 159,000 people are annually diagnosed with cancer and almost 69,000 of them died every year. Direct treatment cost of cancer is app. €1 billion annually, means that cancer share of all health expenditures would be 3%. This study aims to review literature regarding cost studies conducted in Turkey in the field of cancer through the PubMed, ISPOR data base and ULAKBIM and to draw attention to the low number of studies. **METHODS:** Three databases (PubMed, ISPOR and ULAKBIM) were searched up to June 15, 2017 using the keywords of cost, cancer, and Turkey. **RESULTS:** There were only 48 publications/presentations, of which 27/9/12 from PubMed/ISPOR/ULAKBIM. Only 12 studies (3/PublicMed. 5/ISPOR and 4 ULAKBIM) could be included in the analysis as they contained costs for Turkish population. Of these studies, 3 were on lung cancer, 1 on colon cancer, 2 was on cancer pain, 3 was on renal cancer, 2 were on renal and lung cancers and 1 on farmakogenetic issues in cancer treatment. According to these studies: the total cost of lung cancer per-patient was approximately €10,698±13,190. The total direct medical cost of lung, breast, hematological, head and neck, colorectal, gastric, gynecological, and prostate cancers ranged between €1077-4675 (2014). The median total cost per patient was €912 in non-small cell lung cancer patients and €908 in small cell lung cancer patients. **CONCLUSIONS:** Although Turkey is a country with 80 million population and has a well-developed health system, such small number of cost studies about cancer; the second cause of all deaths, is an issue that should be addressed.

**PSY32: LAUNCHING COMBINATION THERAPIES IN RARE DISEASES: IS HIGH COST BURDEN RESTRICTING ACCESS?**


**OBJECTIVES:** Upfront combination therapy has been shown to be clinically beneficial in certain patient groups in rare diseases. However, the potentially high economic burden associated with combination therapy in the rare disease space maybe restricting patient access. This research aims to explore innovative pricing and contracting options that have already been implemented in the cancer space which may also be considered within rare diseases with a view to increase patient access to combination therapies whilst minimising cost burden. **METHODS:** Primary research with payers in the UK, France, Germany, Spain and Italy were probed on market dynamics that will affect the pricing of combination therapy in their markets. Potential contracting strategies were evaluated in each market and the feasibility of launching fixed dose combinations in rare diseases were explored. **RESULTS:** Over the next 5 years, innovative pricing and contracting options are expected to be increasingly adopted in the EU5 markets to reduce the increasing economic burden associated with combination therapy within the rare disease space. Particular value was seen in simple price discounting along with more complex patient outcomes related contracting measures. Fixed dose combinations offering a 5-30% reduction compared to standalone drug prices given in combination was seen as a crucial component to success in all markets. **CONCLUSIONS:** The increasing burden of combination therapy in rare diseases maybe restricting access; this burden maybe eased by the introduction of innovative contracting. Furthermore, the introduction of a fixed dose combination could prove to be successful if priced at a discount in comparison to the cost of standalone drugs given in combination.

**PSY33: ECONOMIC EVALUATION AND BUDGET IMPACT ANALYSIS OF PROTHROMBIN COMPLEX CONCENTRATE (BERIPLEX®) FOR TREATMENT AND PROPHYLAXIS OF BLEEDING IN PATIENTS TREATED WITH ORAL ANTICOAGULANTS UNDER PERSPECTIVE OF HEALTH PUBLIC INSTITUTIONS IN MEXICO**

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**OBJECTIVES:** Mexico
OBJECTIVES: Most important adverse event associated with the use of oral anticoagulants is bleeding and sometimes it is necessary to reverse anticoagulation. The objective of this study is to compare the costs of using Prothrombin Complex Concentrate (PCC) in comparison to Fresh Frozen Plasma (FFP) in Health Public Institutions in order to identify the cost-saving anti-bleeding treatment. METHODS: Since PCC and FFP have the same safety and efficacy profile, a cost-minimization study and budget impact analysis were conducted, by examining the comparison of anti-bleeding treatment in patients with oral anticoagulants (warfarin). Standard of treatment was a 70 Kg patient. Time horizon was considered duration of bleeding episode and there was not applied discount rate. The analysis were presented in 3 scenarios according to International Normalized Index ranges, from 2.0-3.9, 4.0-6.0 and >6.0. Unitary costs and budget were obtained from Health Public Institutions in 2016. RESULTS: In the first scenario, anti-bleeding treatment cost for PCC was $764 USD and for FFP was $1,369 USD (-$615 USD). In the second scenario treatment cost for PCC was $955 USD and for FFP was the same as in first scenario (-$423 USD). In the third scenario treatment cost for PCC was $1,338 USD and for FFP was $1,838 USD (-$500 USD). The cumulative 5-year cost for 10,000 estimated cases of bleeding per year in patients with INR> 6.0 was for PCC $18.7 USD million and for FFP was $25.7 USD million. The 5-year Budget Impact Analysis showed savings for $7 USD million by using PCC, which represent 0.0053% of the entire Mexican public health budget. Sensitivity analysis corroborated results of base cases. CONCLUSIONS: PCC is a cost-saving alternative when compared to FFP in treatment and prophylaxis of bleeding in patients treated with oral anticoagulants under perspective of Health Public Institutions in Mexico.

ECONOMIC EVALUATION OF DEXMEDETOMIDINE VERSUS PROPOFOL OR MIDAZOLAM SEDATION IN MECHANICAL VENTILATED ICU PATIENTS IN SPAIN

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OBJECTIVES: To evaluate costs associated with the use of dexmedetomidine in comparison with standard care sedation (propofol or midazolam) in Spain in intensive care unit (ICU) patients through a cost-minimisation and a budget impact analyses. METHODS: The population consisted of ICU ventilated patients requiring a mild to moderate level of sedation. Time spent at ICU was estimated based on two head-to-head published clinical trials (PRODEX, MIDEK) comparing the two sedative strategies. The time horizon was inpatient stay at ICU considering three periods: mechanical ventilation, non-mechanical ventilation and off ventilator. The analysis considered the Spanish National Health System (NHS) perspective and only included ICU stay and sedative costs, which were obtained from Spanish sources (2017 prices). We adapted a previously built model, which was based on published data: average body weight 72.0 kg, current 24h cost of dexmedetomidine (1 amp 2 ml: €18), midazolam (10 amp 1 ml: €1.60), propofol (1 vial 100 ml: €6.90) and 1 day ICU stay cost (€1,497.85). RESULTS: The estimated mean costs per ICU patient discharge were € 18,653 with standard care and € 18,236 with dexmedetomidine. Savings per patient treated were € 417 (€655 versus midazolam and €180 versus propofol). A 30% change of sedated patients at ICU from standard care (50% midazolam, 50% propofol) to dexmedetomidine in a cohort of 1000 patients/year would result in yearly savings of at least € 417,220 for the Spanish NHS and 294 ICU free days (that allow to treat 62 additional patients/year). CONCLUSIONS: Dexmedetomidine reduces the duration of mechanical ventilation and is a cost-saving alternative to propofol and midazolam at the ICU setting in Spain.

THE EFFECTIVENESS OF DIFFERENT METHODS OF RECRUITING PATIENTS TO A PAIN STUDY

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OBJECTIVES: To compare the effectiveness and cost-effectiveness of different methods in recruiting patients with acute soft-tissue injuries to a pain study. METHODS: We used a number of different methods to recruit patients with acute soft-tissue injuries to a pain study. The success rate of these methods in recruiting the 182 patients who entered the study and the base cost of each method (not including internal resource costs) differed dramatically. Here we have examined the effectiveness and cost-effectiveness of the different recruitment methods to determine the best options for generating suitable patient populations for similar future studies. RESULTS: In total, 762 participants were screened by telephone, but only 182 patients were admitted to the study. Of the 182 patients who participated, 100 (55%) were recruited through Facebook advertising at a total cost of £2,001; 27 (15%) were recruited by TV advertising at an approximate cost of £14,640; 22 (12%) had responded to posters/leaflets costing approximately £1,000; and 3 patients (1.5%) recruited by press advertising at a cost of £480. There were no costs associated with recruiting 21 (11.5%) patients by word-of-mouth and 9 (5%) patients by unknown methods. Of the methods that required a financial investment, the most cost-effective means of recruiting patients who actually entered the study was Facebook advertising (£20 per patient). Using posters/leaflets for recruitment was also good value, costing approximately £45 per patient. In contrast, press and TV advertising were expensive, costing approximately £160 and
**OBJECTIVES:** Few data exist on comparative costs between splenectomized and non-splenectomized ITP patients. The objective of this study was to estimate, with a 6 to 9-year time horizon, the average hospital cost of splenectomized ITP patients including the surgical procedure and their follow-up in comparison with the average hospital cost of non-splenectomized ITP patients. **METHODS:** A PMSI data analysis was performed on 4 cohorts of incident ITP patients in lag (2007 to 2010 until 2015), with or without splenectomy. Hospital stays were selected with the ICD10 code D69.3 in position of: Principal Diagnosis (PD) or Related Diagnosis (RD) or Associated Diagnosis with selected ICD10 codes in PD/RD related to hemorrhage, thrombosis and infection. The list of codes was selected by French clinicians. An incident ITP patient was defined as any patient who had never had an ICD10 code "D69.3" on the calendar year preceding the inclusion. Hospital stays with at least one of the 2 CCAM codes for splenectomy (FFFC001 "Total splenectomy by laparoscopy", FFFA001 "Total splenectomy by laparotomy") were extracted. For each stay, a disease related group (DRG) code (€, 2016) was calculated according to the French health service perspective. Costs of extra-DRG drugs were not accounted for. **RESULTS:** The incidence of ITP was stable over time with 3,600-3,900 patients/year. The incident number of hospital stays for ITP was also stable over time (12,000-14,000 stays). The number of splenectomized patients has decreased by 37% since 2007 (152 patients were splenectomized in 2015 vs. 241 in 2007). The average hospital cost of ITP patients varied from 13,429€ to 14,446€ per splenectomized patient and from 3,459€ to 3,599€ per non-splenectomized patient. **CONCLUSIONS:** This study suggests that hospitalization costs for hemorrhage, thrombosis and infection are higher in the group of splenectomized patients. A cost-effectiveness analysis from a broader perspective (in and out patients) should be conducted.
**PSY38: COST IMPACT OF A NOVEL PROPHYLACTIC TREATMENT FOR HAEMOPHILIA A PATIENTS WITH INHIBITORS IN THE UK**

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**OBJECTIVES:** To demonstrate the impact of a novel prophylactic treatment on the uncertainty of drug treatment costs in patients with Haemophilia A with inhibitors. For patients with inhibitors, the only haemostatic options currently available are bypassing agents (BPA). The haemostatic effect of BPA in PWHA with inhibitors is suboptimal, leading to a higher number of bleeds compared to patients without inhibitors. **METHODS:** Average per person annual BPA drug treatment costs were estimated using four sources of data. BPA on demand dosages and bleeding rates were taken from HAVEN 1, a pivotal Phase III study designed to evaluate the efficacy, safety, and pharmacokinetics of once weekly emicizumab prophylaxis compared with no prophylaxis. BPA prophylaxis dosing was obtained from a non-interventional study (NIS) BH29768. Average weights of patients were obtained from the UK National Haemophilia Database (NHD). List prices were used for drug costs. Deterministic sensitivity analyses were conducted to determine the range of BPA costs. **RESULTS:** Estimated annual per patient BPA costs in the 40+ age groups were £1,329,514 for prophylactic use and for on demand £433,065. Variability in annual bleed rates and BPA dosing resulted in a range in BPA costs of +/- 26.9% for prophylactic and +/- 67.7% for on demand bypassing agents. The reduction in the number of bleeds with emicizumab reduces the uncertainty in annual bypassing agent drug costs to a range of just +/- 4%. **CONCLUSIONS:** An effective, widely used and fixed dose prophylactic treatment for PWHA patients with inhibitors has the potential to greatly reduce the uncertainty in predicting drug treatment costs which in the UK account for over 95% of the total treatment costs. This should aid in budget planning when, for patients who experience a large number of bleeds, annual BPA treatment costs can easily broach £500,000 with on demand or over £1,250,00 for prophylaxis.

**PSY39: COST-MINIMIZATION ANALYSIS OF 10% INTRAVENOUS IMMUNOGLOBULIN IN TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN CHILDREN IN THE RUSSIAN FEDERATION**

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**OBJECTIVES:** To conduct cost-minimization analysis of 10% liquid intravenous immunoglobulin (IVIG) compared with IVIGs of 5% concentration in treatment of primary immunodeficiencies (PID) in children in Russia for 1-year period. **METHODS:** A cost-minimization model was developed in Excel 2013 to simulate the direct and indirect costs for 1-year period. Costs included ones for treatment course with IVIGs and IVIG administration, expenditures of infections’ treatment, ones associated with storage and transportation of IVIG, disability pensions and payment for sick leave in connection with caring for a sick child. The following sources were used for calculations: epidemiological data from Ministry of health reports, database of tenders for purchase of medicines, prescribing Information for the drugs, Federal statistical monitoring in the sphere of payment of labour of social workers, tariffs for payment of medical care in stationary conditions on completed cases, requirements of sanitary-epidemiological rules, wholesale prices on refrigerated equipment, the duration of the absence of children in educational institution because of PID according to Stein et al.,2009. **RESULTS:** According to the cost-minimization analysis, 10% IVIG (Switzerland) therapy (552,618 rubles/9,690 $) is the least costly by the end of the 1 year per 1 patient. Therapy with 5% IVIG (Italy) costs over £1,250,00 for prophylaxis. **CONCLUSIONS:** The treatment of primary immunodeficiencies with 10% liquid intravenous immunoglobulin (Switzerland) is a cost saving option compared with treatment with 5% IVIGs in children in Russia for 1-year period.

**PSY40: ECONOMIC EVALUATION OF 10% INTRAVENOUS IMMUNOGLOBULIN IN TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN ADULTS IN THE RUSSIAN FEDERATION**

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**OBJECTIVES:** To conduct cost-minimization analysis of 10% liquid intravenous immunoglobulin (IVIG) compared with IVIGs of 5% concentration in treatment of primary immunodeficiencies (PID) in adults in Russia for 1-year period. **METHODS:** A cost-minimization model was developed in Excel 2013 to simulate the direct and indirect costs for 1-year period. Costs included ones for treatment course with IVIGs and IVIG administration, expenditures of infections’ treatment, ones associated with storage and transportation of IVIG, disability pensions and payments for sick leave due to illness of the patient, GDP loss due to disability. Differences in costs are explained by the various duration of IVIG administration, the differences in the average price per 1 g IVIG and storage conditions. **RESULTS:** According to the cost-minimization analysis, 10% IVIG (Switzerland) therapy (1,507,564 rubles/26,435 $) is the least costly by the end of the 1st year per 1 patient. Therapy with 5% IVIG (Italy) costs
OBJECTIVES: Haemophilia A is a genetic disorder characterized by deficiency in factor VIII (FVIII), how frequently a person bleeds and its severity depends on how much FVIII is in the plasma. Consequently, severe Haemophilia A is a lifelong condition that requires treatment with exogenous FVIII. Reduction of bleeding and chronic joint disease is achieved by prophylactic treatment. Several recombinant FVIII products (BAY 81-8973 and BIIB-031) have been recently approved introducing new dose frequency intervals. The aim of this study is to compare prophylactic treatments costs of recombinant FVIII products. METHODS: The annual costs have been calculated according to the different prophylactic doses of recombinant FVIII products, based on the Summary of Product Characteristics (SmPCs), for adults and adolescents aged 12 and over, with an average weight of 70kg. The number of units of FVIII is expressed in International Units (IU). Prophylactic treatment with BAY 81-8973 (20-40 IU/kg, 2-3 times weekly) was compared to prophylactic treatment with BIIB-031 (50 IU/kg, every 3-5 days) and rAHF-PFM (20-40 IU/kg, intervals of 2-3 days). The analysis was conducted from the Spanish National Health System perspective in a 1-year time horizon. Costs were based on the price per IU established in the reference price group in 2017 Euro (€). RESULTS: Over the time horizon evaluated, average prophylaxis cost per year was estimated at €180,739.10 with BAY 81-8973 treatment, compared with €211,441.58 for BIIB-031 and €211,441.58 for rAHF-PFM. CONCLUSIONS: The analysis conducted in this study concludes that the estimated annual prophylactic treatment of severe haemophilia A with BAY 81-8973 could be less expensive than other recombinant FVIII product at the same price per IU.

OBJECTIVES: Autosomal dominant polycystic kidney disease (ADPKD) is the leading heritable cause of end-stage renal disease (ESRD) in the U.S. and Europe. Approximately 50% of patients progress to ESRD and require dialysis by the fourth and sixth decades of life, which eventually leads to the need for renal transplantation. Very little is known about the burden of renal transplant for ADPKD patients. METHODS: An ADPKD (ICD-9-CM: 753.12,753.13) beneficiary cohort (i.e. those who received renal transplantation [ICD-9-CM: 55.69.V42.0]) was selected from the 2011-2014 Medicare Limited Data Set. Beneficiaries were indexed at date of first renal transplant. Healthcare utilization (i.e., outpatient [OP], office [OV], emergency department [ED], inpatient [IP] visits) and costs were measured in 12-months pre- and post-transplant periods. Beneficiaries were stratified by age to adjust for variability in disease progression (≤44, 45-54, 55-64, ≥65 years). Patient characteristics, pre- and post-transplant utilization and costs were displayed by age group for comparison using Student-t tests, chi-square tests and ANOVA. RESULTS: The study sample consisted of 562 beneficiaries (males [55.16%], females [77.98%]) of which 9.4% were aged ≤44 years, 22.4% 45-54, 30.1% 55-64, and 38.1% ≥65. Average Charlson Comorbidity Index (CCI) score increased (p=0.0016) with age (≤44: 2.13 [0.39], 45-54: 2.39 [0.66], 55-64: 2.59 [0.86], ≥65: 2.84 [1.50]). Healthcare utilization other than OP (i.e., OV, ED, IP) increased (p<0.0001) within all age groups. Total healthcare costs decreased (p<0.0001) within age groups with exception of those ≤44. CONCLUSIONS: In this study, Medicare ADPKD transplant patients experienced an increase in healthcare utilization, but a decrease in total healthcare costs between pre- and post-transplant periods. The observed decrease in costs may have occurred because immunosuppression costs were assumed to be equal regardless of age at transplant. Further evaluation is needed to determine what procedures and care encounters differ between the pre- and post-transplant periods and how long this trend continues.
OBJECTIVES: EPAG and ROMI are commonly used second line (2L) ITP treatments, however, there are limited published data on resource utilization and cost burden experienced by patients on these treatments in real world settings. We examined resource use and costs in ITP patients treated with EPAG and ROMI. METHODS: This study used a syndicated electronic medical records network containing records for inpatient/outpatient services and procedures, disease diagnoses, AEs, prescription drugs and labs for over 29 million patients from 26 US hospital institutions. Adult patients diagnosed with primary ITP and treated with EPAG or ROMI were matched on age, prior steroid treatment, history of HBV/HCV/ HIV, malignancy, severe aplastic anemia, myelodysplastic syndrome, myelofibrosis and splenectomy. Resource use for treatment, administration, adverse events, rescue medication, platelet transfusion and routine care were collected over 12 months following treatment initiation. Unit costs obtained from various public sources were applied to calculate the annual total cost per treatment. 95% confidence intervals (CIs) were calculated for each resource use, except the drug costs, and used to calculate the CIs for the total costs. RESULTS: 1,030 patients were identified: EPAG (650), ROMI (380). Treatment and administration costs were lower for EPAG vs. ROMI: EPAG $62,202, ROMI $84,396. All other costs were also lower for EPAG vs. ROMI: rescue medication/ transfusion: EPAG $1,220 ($877-$1,639) vs. ROMI $1,906 ($1,362-$2,579), AEs: EPAG $4,927 ($3,748-$6,346) vs. ROMI $7,399 ($5,367-$9,916) and routine care costs: EPAG $3,283 ($2,927-$3,825) vs. ROMI $4,731 ($3,986-$5,526), the latter mainly driven by hospitalization costs. Total annual costs of treatment were lower for EPAG vs. ROMI: EPAG: $71,632 ($69,753-$74,012) vs. ROMI: $98,432 ($95,112-$102,418). CONCLUSIONS: This retrospective RWE study reports annual economic burden of ITP treatment. Total annual costs of treatment were significantly lower for EPAG vs. ROMI. Study limitations include reliance on electronic medical records with limited longitudinal data.

PSY45: REAL-WORLD RESOURCE USE AND COSTS OF CARCINOID HEART DISEASE IN PATIENTS WITH NEUROENDOCRINE TUMORS: A RETROSPECTIVE SWEDISH STUDY

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OBJECTIVES: Carcinoid syndrome (CS) is a rare condition developing in ~5% of patients diagnosed with gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Patients with CS may also develop carcinoid heart disease (CHD), which can lead to complications such as atrial fibrillation and right-sided heart failure, which is life-threatening. We conducted an observational, retrospective registry study to quantify the real-world costs and healthcare resource use (HRU) of CHD in patients with GEP-NETs and CS. METHODS: Data was collected from national Swedish healthcare registers from 01 July 2005–31 December 2013 for patients who were diagnosed with GEP-NETs, CS, and used somatostatin analogs (SSAs). HRU (surgeries, medical interventions, examinations, imaging, outpatient visits, hospitalizations, and CS- or CHD-related drugs) was collected and costed in euros (2015 rate) from date of CS diagnosis until death or end of follow-up. RESULTS: 312 patients were included in the analysis, of which 20 (6.4%) were also diagnosed with CHD. There was a general trend of higher HRU for CHD patients, who also tended to use a higher dose of SSAs. The mean cost per patient per year of CHD was 6,700€ (24,000€ including SSAs) in comparison with 2,100€ (16,700€ including SSAs) in patients without CHD, representing an increase of 4,600€ (7,200€ including SSAs). This cost increase in patients with CHD was driven mainly by SSAs (2,600€), valve replacement surgery (2,000€), and echocardiography (900€). CONCLUSIONS: Though the study was conducted retrospectively in a small sample size (n=20/312) as a result of the rarity of CHD, the data nevertheless showed that the financial burden of patients with CHD was higher than in patients with GEP-NETs and CS without CHD. Innovations in the available treatment options to prevent CHD should be explored to minimize the economic burden and impact of the disease on patients’ lives.

PSY46: REAL-WORLD RESOURCE USE AND COSTS OF TREATING CONTROLLED AND UNCONTROLLED CARCINOID SYNDROME: A RETROSPECTIVE SWEDISH STUDY

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OBJECTIVES: Carcinoid syndrome (CS) is characterized by a spectrum of symptoms secondary to gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including flushing and diarrhea. Many patients with CS experience uncontrolled symptoms despite treatment with somatostatin analogs (SSAs). There is a lack of treatment pattern data and consensus around treatment approaches. As authorities are increasingly requiring high-quality real-world evidence to inform decision-making, we conducted a nationwide registry study to gain knowledge of clinical practice, and quantify healthcare resource use (HRU) and costs in uncontrolled CS. METHODS: Data were collected
from Swedish healthcare registers from July 2005–December 2013. Swedish data were chosen for their exhaustiveness, comprehensiveness, and precision of linkage between registers. HRU (surgeries, medical interventions, examinations, imaging, outpatient visits, hospitalizations, CS-related drugs) was collected and costed in euros (2015 rate), comparing the 8 months before/after patients became uncontrolled in their CS. **RESULTS:** 33% (n=103/312) of patients diagnosed with metastatic GEP-NETs and CS, and using SSAs experienced dose escalation, suggestive of uncontrolled CS symptoms. 64 patients total met the inclusion criteria. The total cost of all resources was 15,500€/patient during the 8-month period of controlled CS, rising to 21,700€/patient during the 8-month period of uncontrolled CS, an increase of ~40% (6,200€/patient, 95% CI: 3,186–9,192€). There was a general trend of HRU and cost increases during uncontrolled CS, driven mainly by SSA use, which may have been off-label for a subset of patients (2,100€/patient), tumor-related medical interventions (2,000€/patient) and tumor-related examinations (1,100€/patient). **CONCLUSIONS:** Though the study was conducted retrospectively in a small sample as a result of the rarity of the disease, the data nevertheless showed greater cost of uncontrolled CS in comparison to controlled CS. The debilitating effects of CS on patients’ quality of life and the expense of the current armamentarium could lead to increased HRU and costs.

**PSY47: ECONOMIC IMPACT OF MODERATE AND SEVERE NEUROTROPHIC KERATITIS IN ITALY**


**OBJECTIVES:** Neurotrophic keratitis (NK) is a rare corneal degenerative disease caused by impaired corneal innervation. Available research suggests Italian incidence and prevalence rates below 1.6/10,000 (Sacchetti and Lambiase, 2014). There is general paucity of evidence and no published economic studies of NK in the local or international literature. This is a first attempt to assess the economic impact of moderate (persistent epithelial defect, PED) and severe (corneal ulcer, CU) NK from the national health system (NHS) and societal perspectives in Italy (cost year 2017). **METHODS:** Treatment algorithm and health resource use were estimated in a survey of 9 large national referral centres, specialized in corneal conditions, across Italy. Centre representatives reported information from local clinical practice; national ambulatory and inpatient tariffs were applied to units of service, and AIFA published prices to pharmaceuticals. Mean annual per patient cost was derived as average cost weighted by proportion of patients on each respective treatment and length of treatment. Societal perspective included patients’ out-of-pocket payments and societal remuneration for eye functional loss, as a consequence of NK. **RESULTS:** Estimated mean annual cost of treatment for the Italian NHS was €5,167 and €10,885 per PED and CU NK patient, respectively. Costs were largely driven by costs of visits, ambulatory and hospital interventions such as temporary/permanent tarsorrhaphy, amniotic-membrane transplant, conjunctival flap and corneal transplant. Estimated mean annual cost from the societal perspective was €5,788 and €11,730 per PED and CU NK patients. This included cost of out-of-pocket payments for artificial tears, antibiotic and corticosteroid drops, therapeutic contact lenses and estimated mean remuneration per functional eye loss. **CONCLUSIONS:** Mean annual cost of NK in the Italian setting increases by twofold with disease severity. Further research is warranted to provide more insight especially into indirect costs.

**PSY48: A SYSTEMATIC LITERATURE REVIEW ON QUALITY OF LIFE AND ECONOMIC BURDEN OF PSORIASIS IN THE ASIA-PACIFIC REGION**

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**OBJECTIVES:** A number of studies have shown substantial burden of psoriasis in western countries, while the humanistic and economic burden of psoriasis in Asia-Pacific Region remains largely unknown. This study aimed to systematically review published literature on quality of life (QoL) and economic burden of psoriasis in the Asia-Pacific (AP) region. **METHODS:** Searching strategy were performed in both English and Chinese electronic databases for literature published between January 2000 and June 2017, with the name of 10 selected countries or regions: Australia, China, Hong Kong, Japan, Korea, Malaysia, Philippines, Singapore, Taiwan, and Thailand. Abstracts were retrieved to select studies evaluating QoL and economic burden for psoriasis disease in Asia-Pacific region. All local currencies were converted to USD using newly-published exchange rate. **RESULTS:** A total of 346 studies were retrieved, of which 7 studies assessed the economic burden of psoriasis and 57 informed on QoL. Almost all the studies (95%) were conducted in Australia, China, Japan, Malaysia and Taiwan. Most studies were cross-sectional through patient survey. The annual direct cost per patient ranged between USD306 and USD1917 in these countries/regions in AP region. Nevertheless, the component of cost and clinical characteristics of patient population were highly diversified among these studies. One study in Taiwan also showed that annual work productivity loss per patient was USD205 for moderate-to-severe psoriasis. QoL were commonly measured by Dermatology Life Quality
Index (DLQI) and demonstrated a large to extremely large impairment due to psoriasis (DLQI score = 6~30). EQ-5D was rarely reported in these studies. **CONCLUSIONS:** This review demonstrated that psoriasis imposes a large burden in AP region, however unbalanced research outcomes were observed among those countries/regions. There is still a need for more comprehensive studies on QoL and costs in Asia-Pacific region to inform and support decision-making for best allocation of resources.

**PSY49: LIFE EXPECTANCY AND COSTS OF TRANSTHYRETIN FAMILIAL AMYLOID POLYNEUROPATHY**

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**OBJECTIVES:** To estimate the mean life-years and healthcare cost of transthyretin familial amyloid polyneuropathy (TTR-FAP), a rare and life-threatening neurodegenerative disease, using data from the largest and oldest Portuguese patient’s cluster. **METHODS:** A stochastic Markov model was specified to predict life-years (LY) and associated costs (€) of TTR-FAP patients’ over their lifetime. The model tracks transitions of patients between three disease stages (Coutinho stages 1, 2 and 3) and death. Transition probabilities between disease stages were based on published results on natural history stage duration making use of an exponential distribution. Natural history overall survival (OS) was captured by the Kaplan-Meier survival estimates from the Portuguese TTR-FAP referral centers. Stage costs were elicited through a panel of Portuguese experts with extensive clinical experience. A societal perspective was adopted. Indirect costs were not included. **RESULTS:** If untreated, TTR-FAP patients have a decreased mean life-expectancy after diagnosis of 12.72 years associated with mean healthcare costs of 125 645€ per patient. **CONCLUSIONS:** TTR-FAP disease induces impressive healthcare costs and a reduced life expectancy. These results can contribute to the economic assessment of new healthcare interventions, as data in this rare disease is sparse. Real-world registries can contribute to augment comprehensive knowledge on this rare disease and to enhanced better informed decisions in the near future.

**PSY50: BURDEN OF DIABETES MELLITUS IN PATIENTS WITH ACMEGALY TREATED WITH SECOND-LINE PHARMACOTHERAPY IN SPAIN**

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**OBJECTIVES:** To evaluate the burden of diabetes mellitus (DM) in adult patients with acromegaly treated with second-line pharmacotherapy, from the perspective of the Spanish National Health System (NHS). **METHODS:** A Markov model was developed which included three states (normal glucose metabolism, diabetes mellitus and death) with time horizons of 1, 2 and 5 years. The evolution of a hypothetical cohort of patients with acromegaly requiring second-line pharmacological treatment after somatostatin analogues therapy was analyzed. Direct healthcare costs regarding acromegaly management, diabetes management and drugs costs, (€2017) were obtained from Spanish sources. The transition probabilities between health states were obtained from published clinical trials, epidemiological and real world studies. Deterministic and probabilistic sensitivity analyses were undertaken. **RESULTS:** Compared to pasireotide, pegvisomant, increased the likelihood of glucose normalization and reduced the likelihood of DM. Consequently, in a cohort of 1,000 patients with acromegaly, treatment with pegvisomant compared to pasireotide would prevent 243, 413 and 678 cases of DM after 1, 2 and 5 years, respectively, and would reduce mortality by 0.2% after 5 years of treatment, considering published evidence from clinical trials and real world studies. This would result in €1.54 million savings for the NHS in 5 years. These health benefits would be obtained with a slightly higher cost per patient treated with pegvisomant, from an extra 3.3% at first year to 1.3% in the fifth year. After 5 years of treatment, the probability that pegvisomant generated savings versus pasireotide would be 52.8%. **CONCLUSIONS:** The favorable effects of pegvisomant on glucose metabolism would allow a considerable number of cases of DM to be avoided compared to pasireotide, with a slightly higher cost, in Spain.

**PSY51: SOCIETAL COST PATTERNS BY SPINE SURGICAL OUTCOME GROUPS AND PATIENTS TREATED WITH SPINAL CORD STIMULATION FOLLOWING SPINE SURGERY**

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OBJECTIVES: To identify patients with different outcomes of lumbar spine surgery in terms of pain relief and patients who are subsequently treated with spinal cord stimulation (SCS) and describe the patterns of societal costs and quality of life (QoL) in these groups. METHODS: Patients who underwent elective lumbar spine surgery during 2000–2012 were identified in the Swedish spine register Swespine (n=7,227). Patients with persistent pain and subsequently treated with SCS ("to-be SCS patients") were identified in the Swedish national patient register (n=236). Outcomes of spine surgery were defined using Global Assessment (GA) of back/leg pain reported 2 years post-surgery. GA level 1 (pain disappeared) and 2 (much improved) were categorised as “successful”; 3 (somewhat improved) as “undetermined”; 4 (unchanged) and 5 (worsened) as “persistent pain”. To-be SCS patients were not analysed by GA-level. Costs (healthcare resources and indirect costs) were calculated 3 years before/after surgery, for each outcome group and to-be SCS patients. QoL was estimated using EQ-5D reported at baseline and year 5 post-surgery. RESULTS: Most patients had successful outcome (73%). In all groups, costs increased gradually leading up to surgery and peaked in the month after surgery. Three years pre-surgery, mean monthly total cost was in the successful group: €531; undetermined: €882; persistent pain: €891; and to-be SCS patients: €1,153. Three years post-surgery, the corresponding cost was €509, €1,105, €1,269 and €3,346, respectively. The groups with persistent pain, undetermined outcome and to-be SCS patients had worse baseline QoL (0.26, 0.33, 0.20, respectively) and worse QoL post-surgery (0.46, 0.62, 0.24), compared with the successful group (baseline: 0.34, post-surgery 0.82). CONCLUSIONS: There was an apparent association between outcome, costs and post-surgery QoL. Patients with undetermined outcome, persistent pain and to-be-SCS patients had less QoL improvement post-surgery and higher costs both before and after surgery compared with the successful group.

**PSY52: DIRECT COSTS OF INFLAMMATORY BOWEL DISEASES THERAPY IN POLAND - NATIONWIDE DATABASE ANALYSIS**

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OBJECTIVES: Inflammatory bowel disease (IBD) constitute a significant burden for both patients and the society. The aim of our study was to assess the total direct costs of IBD in Poland. METHODS: Information on drugs, dietary supplements, medical devices, outpatient and inpatient services utilized by 60,472 IBD patients from Poland for the years 2012-2014 were collected from databases of the National Health Fund (NHF), the payer for medical services in Poland. Nonparametric Pearson chi2 test and Kruskal-Wallis H test with Bonferroni correction for multiple hypothesis testing were used to compare expenditures or treatment utilization by year, patient's age and IBD diagnosis. RESULTS: Expenditures from public payer's budget among IBD patients were from PLN289.57 million (€69 million) in 2012, PLN305.55 million (€72.75 million) in 2013 and PLN276.54 million (€65.84 million) in 2014. The cost of inpatient and outpatient services accumulated of around half of total expenditures. The main component of public payer’s expenditures was associated with surgical and medical procedures, including biologic treatment. The utilization of pharmacotherapies differed by age and diagnosis (adjusted for multiplicity p value < 0.001). Biologics, steroids and immunomodulatory drugs were significantly more often used by patients with Crohn disease (CD) then patients with ulcerative colitis (UC). However, consumption of aminosalicylates was more common among UC patients. The use of biologics was the highest among young patients with IBD and the lowest among the oldest patients (0.1% in patients 65+ years). CONCLUSIONS: Direct cost of IBD in Poland impose a significant burden for NHF with around €70 million annually. Moreover, the study revealed that the treatment pattern and drug utilization depends on patient's age and diagnosis ("stronger" drugs were more often incorporated into treatment of younger patients and patients with CD).

**PSY53: ASSESSING THE REAL-WORLD HOSPITAL ECONOMIC BURDEN OF SPINAL MUSCULAR ATROPHY (SMA) IN FRANCE**

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OBJECTIVES: To assess the hospital economic burden of SMA for patients with Infantile and other inherited SMA in France. METHODS: The PMSI (Programme de Médicalisation des Systèmes d’Information), a comprehensive national database of French hospital stays, was used to identify SMA patients in 2014 and 2015 with ICD-10 codes: G120 for infantile spinal muscular atrophy, Type I and G121 for other inherited SMA. Patients’ annual costs in acute care, home hospitalizations and rehabilitation care were estimated during the 2015 year, according to the National Health Insurance (NHI) perspective using respective Diagnosis Related Groups (DRGs) and corresponding tariffs (€2016). RESULTS: 183 patients with infantile SMA and 732 with other inherited SMA were identified. At identification time, the median age was 3 years, ranging from 0 to 19 for infantile SMA patients, and 21 years, ranging
from 0 to 85 for other inherited SMA patients. Both populations were mainly managed with acute care and most frequently for nervous system or respiratory issues. Based on hospital stays observed in 2015, the overall annual cost of hospitalization was estimated at €1.8 million for patients with infantile SMA and €5.3 million for patients with other inherited SMA. The average hospital cost for infantile SMA patient was €13,400, ranging from €226 to €111,200. 48% of this cost was due to acute care, 45% to rehabilitation care and 7% to home stays. For other inherited SMA patients, the average hospital cost was €8,900 ranging from €157 to €279,600. 56% of this cost was due to acute care, 38% to rehabilitation care and 6% to home stays. **CONCLUSIONS:** Studying hospitalization data for SMA patients in France provides a better understanding of the economic burden of SMA. If acute care is at the heart of the patient management, the economic burden is balanced between acute care and rehabilitation care.

**PSY54: COSTS ASSOCIATED WITH TRANSTHYRETIN FAMILIAL AMYLOID POLYNEUROPATHY PROGRESSION**

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**OBJECTIVES:** This research sets out to estimate the annual healthcare resource use and costs associated with the management of transthyretin familial amyloid polyneuropathy (TTR-FAP) per disease clinical stage. Rare disease costs may be difficult to assess and are often disregarded in decision making but are warranted. **METHODS:** Healthcare resource use associated with the management of transthyretin familial amyloid polyneuropathy was elicited through a panel of Portuguese experts with extensive clinical experience in TTR-FAP referral centres. A two-stage modified Delphi technique was adopted – on 1st round a questionnaire was applied and on the 2nd round a consensus meeting was implemented. The resources analysed covered medical visits, laboratory tests, imaging examinations, hospitalizations, medication, complications (e.g. dialysis), physical and rehabilitation sessions, medical devices (e.g. pacemaker) and mobility aids (e.g. crutches) and other daily-life supports. Unit costs were extracted from Portuguese official sources, wherever possible. Healthcare stage costs were obtained using weighted healthcare resource use and unit costs. A societal perspective was adopted. Disease-modifying oral treatment, liver transplant (with immunosuppressive regimens) and indirect costs were not included. **RESULTS:** We can estimate that average annual healthcare costs are 4 859 €, 9 062 € and 12 425€ among patient stages 1, 2 and 3, respectively. **CONCLUSIONS:** TTR-FAP patients have increased associated costs as disease progresses. These results can contribute to the economic assessment of new and existing healthcare interventions, as data is sparse to inform decision making. Real-world registries are important to gain comprehensive knowledge on rare diseases and to document healthcare resource utilization.

**PSY55: HEALTHCARE INSURANCE SPENDING AT YEAR 2 BETWEEN TREATMENT GROUPS FOLLOWING DIAGNOSIS OF NONTUBERCULAR MYCOBACTERIAL LUNG DISEASE IN THE US**

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**OBJECTIVES:** The study compared healthcare insurance spending between treatment groups in patients with nontuberculous mycobacterial lung disease (NTMLD) from a US national managed care claims database. **METHODS:** Patient (N=1039) pharmacy claims at year 1 following NTMLD diagnosis were classified into 3 treatment groups including triple combo (macrolide + ethambutol + rifamycin ± other drugs) (G1), other antibiotics for NTMLD (G2), and no treatment (G3). Healthcare insurance spending at year 2 was compared between treatments with adjustment for lung infection due to mycobacterium abscessus and cystic fibrosis, and for Charlson Comorbidity Index (CCI) during the 12 months prior to NTMLD diagnosis (baseline). Insurance spending was measured by allowed payment amounts and converted to Resource-Based Relative Value Scale (described elsewhere). **RESULTS:** Mean age was 66, 66 and 73 years with 65%, 70% and 66% women in G1 (n=353), G2 (n=388) and G3 (n=298) respectively. At baseline, there was no difference on CCI (CCI=2) between treatment groups. However, comorbidity distribution differed prominently in asthma (22.1%, 26.3% and 11.4%), arrhythmia (19.3%, 19.3% and 27.2%), acute lung infection (26.3%, 19.3% and 27.2%), and tuberculosis (9.3%, 8.2% and 5.4%), and in immunosuppressant use (51%, 51.5% and 25.2%). Mean (median) baseline total insurance payment was $32950($18067) in G1, $44507($18405) in G2, and $25555($10576) in G3. At year 2, CCI stayed almost unchanged and total payments were $26906($11638), $38130($13995) and $19449($7682), respectively. Compared to G2, adjusted total insurance payment was lower in G1 (6-$49838, 95%CI: -86576 to -13101, p=0.008) and G3 (6-$83567, 95%CI: -131471 to -35663, p<0.001); but no
statistically significant difference was found between G1 and G3. **CONCLUSIONS:** Healthcare insurance spending was higher in patients with NTMLD and treated with drug regimens other than ATS/IDSA recommended triple therapy. Spending in patient comorbidity subgroups will be further investigated.

**PSY56: ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE (HRQOL), AND COSTS OF TREATMENT IN CHRONIC MYELOGENIC LEUKEMIA (CML) IN BULGARIA**

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**OBJECTIVES:** To evaluate the health related quality of life (HRQoL) and costs of treating CML in a hospital setting in Bulgaria. **METHODS:** Prospective, observational, 1 year lasting study of real life therapy of 42 hospitalized patients in Alexandrovska university hospital in Sofia. HRQoL was evaluated with SF-36 questionnaire. Costs data were collected from clinic and hospital pharmacy’s electronic program. Descriptive statistic and t-test analysis was also performed. The point of view is that o the hospital and patients for 1 year time. **RESULTS:** 42 patients enrolled form the Haematology clinic in Alexandrovska were distributed according to gender (19 females, 23 males) and represent 71.19% of all treated from CML in the clinic. 2 patients started treatment in December, 1 patient discontinued treatment before the researched period, because of comorbidity with costs= 0EUR, but its medical results were also tracked. HRQoL varied among the CML patient population 23.15 and 94.78 out of 100 points (SD 69.24). 32 patients (76.19%) showed HRQoL over 50. The high values measured in parameter “health compared to last year” – 72.62, suggested that patients benefit from the applied therapy. The only parameter which average value is less than 50 – 47.5 is “vitality, energy or fatigue”. The other parameters’ values is around 64. Costs were between 13 609.77 EUR and 45 064.10EUR per year (SD 4724.85 EUR). **CONCLUSIONS:** Although the therapy is very expensive it provides suggests good control of this considered as a malignant disease and relatively high quality of life of CML patient population.

**PSY57: GERMAN SITUATION OF TREATMENT WITH BIOLOGICAL AGENTS AMONG PATIENTS WITH PSORIASIS BASED ON A CLAIMS DATA ANALYSIS**

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**OBJECTIVES:** Psoriasis (PsO) is not curable; however, for many people treatment will help to control the disease. 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. 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 PsO (ICD-10 code L40, -), and start / maintenance / switch of treatment with PsO 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 PsO are adalimumab and apremilast, however, at a low level of share of prescriptions. Adalimumab and etanercept are administered mostly to patients already on treatment (in 2015 adalimumab 40.4 % vs. etanercept 26.6 %). The total costs of the included 2’041 patients add up to € 36 874’827 in 2015. The total number of patients who had hospital admissions and the total treatment costs including all individual cost items grew yearly on average between 1.7% and 14.5 % (2012 – 2015). Hospitalization per patient declined slightly from 0.8 to 0.7. **CONCLUSIONS:** Adalimumab, apremilast and etanercept are those biological agents mainly used for treating PsO. All cost items grew steadily over the last 4 years. Total costs in 2015 were € 36.9 million (on average € 18’067 per patient).

**PSY58: ECONOMIC EVALUATION OF A PATIENT SUPPORT PROGRAMME ABBVIE CARE 2.0 IMMUNOLOGY**

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**OBJECTIVES:** To assess the impact on resources consumption and health outcomes of the patient support programme (PSP) Abbvie Care 2.0 Immunology in Spain. **METHODS:** A cost-consequence analysis was designed in
Excel to estimate differences following the implementation of Abbvie Care 2.0 in patients with immune-mediated chronic diseases along a 1-year time horizon. The hospital perspective was used to collect inputs related to health outcomes and resource consumption in 2 different situations: without and with PSP implementation, for each patient group; rheumatic (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis), dermatologic (psoriasis, hidradenitis suppurativa) and gastrointestinal (ulcerative colitis, Crohn’s disease). The collected resources included annual number of hospital professional visits (clinician, nurse and pharmacist) and average visit duration, annual number of emergency visits and disease-related hospital admissions. Health outcomes comprised adherence, persistence, activation (measured with PAM-10 questionnaire) and programme satisfaction for patients and professionals. An expert panel of pharmacists from 6 public hospitals validated and collected data. Unitary costs (€, 2017) for resources derived from local databases. RESULTS: For an hypothetical cohort of patients (41.7% rheumatic, 24.0% dermatologic and 34.4% gastrointestinal immunologic diseases), the PSP implementation was associated to reduction in routine visits to physician (-13.1%), hospital pharmacy (-33.4%) and specialized nursery (-9.4%) as well as visit duration (-5.6%, -6.4% and -10.9%, respectively) Additional incidence-related visits decreased also in annual number -5.3% (physician), -12.1% (pharmacy), -14.5% (nurse), and duration, which joined to reduction in emergency visits (-59.1%) and hospital admissions (-84.5%) were associated to average cost-savings of €3,578.25 patient/year. Abbvie Care 2.0 implementation increased drug adherence (1.6%) and 6-months persistence (10.3%) and patient activation (2.8% of PAM-10 Total score improvement). The average PSP-satisfaction reported-scores reached 9.66/10 for patients and 8/10 for professionals. CONCLUSIONS: Abbvie Care 2.0 contributes to reduce burden of hospital visits, being associated to cost-savings and improvement in health outcomes with high satisfaction-levels scores.

PSY59: COST EFFECTIVENESS OF OPTIFAST® LCD AS COMPARED WITH LIRAGLUTIDE 3 MG AND “NO INTERVENTION” IN SWITZERLAND

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OBJECTIVES: Obesity is associated with high direct and indirect costs related to increased healthcare utilization and loss of productivity. Optifast® is a clinically-proven total diet replacement Low Calorie Diet for obesity management. In the context of a medically supervised weight management program, Optifast achieves a significant and durable weight loss at a rate of ≈ 1 kg per week. This health economic model aims to demonstrate potential cost savings of Optifast® in Switzerland, as compared to “no intervention” and pharmacotherapy with liraglutide 3 mg. Payers’ and employers’ perspectives are taken into account. METHODS: An event-driven decision analytic model estimated the cost-effectiveness of 1-year Optifast® program over 10 years period in Switzerland. The analysis was performed for the broad population of obese persons (BMI > 30 kg/m2) treated with Optifast® vs liraglutide 3 mg and vs “no intervention”. The model includes the risk of complications related to increased BMI; data sources include published literature, clinical trials, official Swiss price/tariff lists and national population statistics. The primary perspective is that of the Swiss payer and employer; costs are in 2016 CHF. RESULTS: Optifast® leads to cost savings for payers (CHF 5,623) and employers (CHF 30,307) over the same time period by reducing the cost of obesity complications. Compared to liraglutide 3 mg, Optifast® leads to additional cost savings for payers (CHF 9,732) and employers (CHF 14,187) over the same time period. Scenario analyses show additional cost savings in patients with severe obesity (BMI>40 kg/m2), with T2 diabetes mellitus. CONCLUSIONS: Reimbursing Optifast® leads to meaningful cost savings for Swiss payers and employers as compared with liraglutide 3 mg and with “no intervention” in obese patients. Similar results could be expected in matching healthcare settings of other countries.

PSY60: SECUKINUMAB AS A MORE EFFICIENT ALTERNATIVE FOR THE TREATMENT OF ANKYLOSING SPONDYLITIS: A COST PER RESPONDER ANALYSIS VERSUS ADALIMUMAB AND GOLIMUMAB FROM A PERUVIAN PERSPECTIVE FOR PRIVATE AND PUBLIC HEALTH SCHEMES

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OBJECTIVES: The objective of this analysis was to compare the cost per responder based on the Assessment of Spondyloarthritis International Society (ASAS) outcomes at 24 weeks of treatment of ankylosing spondylitis (AS) with secukinumab relative to adalimumab and golimumab from a third payer perspective. METHODS: The cost per responder for each treatment was estimated by dividing the drug acquisition cost with its response rate. Drug costs were estimated in US dollars (USD) from public sources: DIGEMID and SEACE for private and public health schemes, respectively. Response rates were used from a previous matching-adjusted indirect comparison (MAIC) based on the data from MEASURE1-2, ATLAS and GO-RAISE clinical trials of secukinumab, adalimumab and golimumab, respectively. MAIC analysis matched several patient characteristic such as age, gender distribution, Bath Ankylosing Spondylitis Functional Index (BASFI), C-reactive protein (CRP) and TNF-naïve proportion at the
RESULTS: Response rates were significantly higher for secukinumab compared to adalimumab and golimumab at 24 weeks in the MAIC. Private health scheme costs per ASAS20 responder were USD12.259 vs USD30.004, cost per ASAS40 responder were USD14.616 vs USD38.420, costs per ASAS5/6 responder were USD28.519 vs USD68.488 for secukinumab vs adalimumab, respectively. For secukinumab versus golimumab, costs per ASAS20 responder were USD11.923 vs USD18.677, cost per ASAS40 responder were USD14.362 vs USD23.658, whereas, costs per ASAS5/6 responder were USD26.153 vs USD40.556, respectively. Additional analysis for Public health scheme present similar results for both comparisons. Sensitivity analyses for ASAS response rates and cost per responder showed similar results, confirming the validity of the main analysis.

CONCLUSIONS: The cost per responder for all ASAS outcomes were consistently lower for secukinumab versus all comparators, showing the dominance of secukinumab versus adalimumab and golimumab. These findings indicate that it is more efficient to treat AS patients with secukinumab versus adalimumab and golimumab in the Peruvian context.

PSY62: A COST EFFECTIVENESS ANALYSIS OF OBINUTUZUMAB IN THE MANAGEMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA IN GREECE

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OBJECTIVES: The objective of this study was to estimate the cost-effectiveness of obinutuzumab in combination with chlorambucil in first line treatment of chronic lymphocytic leukemia (CLL) in Greece, in patients unsuitable for full-dose fludarabine therapy. METHODS: A three-state Markov model was locally adapted to reflect the treatment pathway and resource use within the Greek health care setting. The model compared obinutuzumab + chlorambucil (GClb) versus rituximab + chlorambucil (RClb), chlorambucil monotherapy (Clb), ofatumumab + chlorambucil (OClb) and rituximab + bendamustine (RBenda). Patient demographics and clinical data were taken from the CLL11 clinical trial and indirect analysis. Data on resource use were elicited from an expert panel of 6 hematologists with the Delphi technique. Unit costs were taken from officially published Greek sources (Ministry of Health, Social Insurance Funds). Utility data were taken from a published UK study. Only direct costs were considered in the analysis and the cost base year was 2016. The time horizon was lifetime and the perspective adopted was the societal. Future costs and outcomes were discounted at 3.5%. Probabilistic sensitivity analysis (PSA) was performed to test robustness of model results. RESULTS: GClb was associated with higher mean costs (€24,874) but also with higher life years (LYs -5.70) and quality adjusted life years (QALYs) 3.95 versus all comparators. The incremental cost effectiveness ratio (ICER) of GClb versus RClb was estimated at €15,679 per LY and €16,614 per QALY gained. The
PSY63: SYSTEMATIC REVIEW OF THE COST-EFFECTIVENESS OF MEDICINES FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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OBJECTIVES: Idiopathic Pulmonary Fibrosis (IPF) is a rare, progressive disease of unknown aetiology with a median survival of 3 years. To date, nintedanib and pirfenidone are the only antifibrotic agents indicated for the treatment of IPF in Western countries. The aim of this study is to conduct a systematic review of the literature on the cost-effectiveness of these two medicines. METHODS: Search strings with “nintedanib”, “pirfenidone”, “cost-effectiveness”, “cost-utility”, “idiopathic pulmonary fibrosis” and “health technology assessment” terms were entered in PubMed, ISPOR presentations database, EMBASE, ScienceDirect, Cochrane CENTRAL, BIOSIS, Tufts CEA registry, the UK National Institute for Health Research Health Technology Assessment Database, Web of Science and Google. Relevant abstracts, publications and articles in English were collected from inception to June 2017. RESULTS: A total of 12 publications were included in the review. Five studies were conducted in the UK setting, 2 in Canada and Italy, 1 in France, Ireland and Spain. In 10 studies, the perspective was that of the National Health Service. Ten studies used a Markov model while 1 other study used a microsimulation model. When compared to best supportive care (BSC), neither nintedanib nor pirfenidone had an incremental cost-effectiveness ratio inferior to €30,000 in any studies except in one which aimed to assess the impact of different models. Seven studies compared nintedanib to pirfenidone. Six of them showed economic dominance of nintedanib over pirfenidone (less costs, more quality-adjusted life years [QALY]), while one showed that pirfenidone was a cost-effective strategy (more QALYs but more costs) compared to nintedanib. CONCLUSIONS: Overall, the cost-effectiveness of IPF treatments has been well studied. Nintedanib and pirfenidone have demonstrated important clinical benefits for patients with IPF. Due the lack of alternative treatment, nintedanib and pirfenidone are rarely cost-effective versus BSC. When compared together, nintedanib dominates pirfenidone in most analyses (less costs, more QALYs).

PSY64: THE COMPARATIVE PHARMACOECONOMIC ANALYSIS OF USING DIFFERENT AGONISTS OF THE THROMBOPOIETIN RECEPTOR IN ADULT PATIENTS WITH CHRONIC IDIOPATHIC THROMBOCYTOPENIC PURPURA IN ACTUAL PRACTICE IN RUSSIA

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OBJECTIVES: To perform cost-effectiveness analysis of using different thrombopoietin (TPO) receptor agonists - romiplostim and eltrombopag - in adult patients with chronic idiopathic thrombocytopenic purpura (ITP) taking into account compliance in the management of them in actual practice in Russia. METHODS: MS Excel based model of medical care patients with chronic ITP has been developed based on the research hypothesis that the level of patient compliance in certain categories can affect the effectiveness of long-term therapy with different TPO receptor agonists - romiplostim 250 mcg SC once weekly and eltrombopag 50 mg per os once daily. To evaluate the real clinical practice of patients with chronic ITP in Russia interview of experts was conducted. Direct medical costs including drugs, injections, therapy monitoring (CBC, platelet count), rescue treatment, bleeding treatment (grade 3, 4 with the WHO bleeding scale), outpatient visits were calculated for 1 patient for 1 year. The overall platelet response was included into the model as the effectiveness criteria. RESULTS: A survey of experts showed that the using of romiplostim is associated with a higher compliance in patients with a chronic ITP, therefore with a higher efficacy of treatment. The total costs of treatment per patient with chronic ITP within 1 year were $67,468 with romiplostim and $30,975 with eltrombopag. However, taking into account a possible low level of compliance of patients in certain categories in real clinical practice in Russia the cost-effectiveness ratio for romiplostim amounted to $81,287/1 case effectively treatment compared with $110,625/1 case of effective treatment for eltrombopag. The difference amounted to $29,338 in favor of the romiplostim (rate for June 2017). CONCLUSIONS: Using of romiplostim in the treatment of adult patients with chronic ITP was effective and economically justified treatment option in real clinical practice in Russia in patients with low compliance.

PSY65: ASSESSING COST-EFFECTIVENESS AND KEY VALUE DRIVERS OF ADJUVANT TRIGLYCERIDE LOWERING THERAPY IN MANAGEMENT OF PATIENTS WITH A RARE GENETIC SYNDROME

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OBJECTIVES: This research focused on a rare genetic disease in which the body does not break down fat (lipids) correctly. The current standard of care (SoC) is diet; however, patients receive off-label adjuvant triglyceride (TG) lowering treatments. There is limited literature on the long-term clinical and cost-effectiveness of adding TG lowering therapy in the management of these patients. The objective of this work was to develop a modelling framework that would adequately capture the range of benefits and costs associated with adjuvant TG lowering therapy in the management of patients with this disease. METHODS: A decision analytic, Markov model was developed to evaluate the cost-utility of current SoC (diet) compared to TG lowering therapies (including fibrates and statins) for patient management. The model included five health states: high risk TG level, low risk TG level, acute metabolic morbidity (event — tunnel state), post-high risk TG level, and post-low risk TG level. A cycle length of 3 months, and the perspective of the UK healthcare system were used. Clinical outcomes, costs, and utilities were obtained from publicly available sources and through discussions with clinical experts. RESULTS: The model structure adequately captured the treatment pathway for patients with the disease and the unique range of benefits, including potential quality of life improvements, as well as the differences in costs that accrue with different treatment options. The major value drivers for the TG lowering therapy included quality of life, cost of therapy, and relative treatment efficacy. CONCLUSIONS: Based on these findings, it is feasible to model the lifelong benefits that accumulate with adjuvant TG lowering therapy and compare overall benefits and costs to current SoC.

PSY66: IDENTIFYING EVIDENCE ON THE COST-EFFECTIVENESS OF TREATMENTS AND COSTS/RESOURCE USE AND QUALITY OF LIFE OF PATIENTS WITH FOLLICULAR LYMPHOMA AND MARGINAL ZONE LYMPHOMA: SYSTEMATIC REVIEWS

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OBJECTIVES: Systematic reviews were conducted to identify evidence on the cost-effectiveness of treatments, costs/resource use, and health-related-quality-of-life (HRQoL) of patients with follicular lymphoma (FL) or marginal zone lymphoma (MZL). METHODS: Key electronic databases, relevant conference proceedings, and publically available information from health technology assessment bodies were searched between March-April 2017. RESULTS: Twenty-three economic evaluations investigated patients with FL; one investigated patients with FL and MZL. Five costs/resource use and four HRQoL studies were identified in FL, none in MZL. Most models used a Markov approach from a healthcare provider perspective. US studies investigating patients with FL reported an incremental cost-effectiveness ratio (ICER) of $28,565/QALY for first-line rituximab-CVP versus CVP, and $43,000/QALY for second-line obinutuzumab plus bendamustine (OBZ+BEN) followed by OBZ maintenance versus BEN. In the UK studies, ICERs were £7,720-10,834/QALY for first-line rituximab + chemotherapy versus chemotherapy, £27,988/QALY for second-line OBZ+BEN+OBZ maintenance versus BEN, and £62,653/QALY for second-line idelalisib versus chemotherapy and/or rituximab. Mean lifetime costs in first-line patients ranged from £108,000 (rituximab) to £130,300 (rituximab-CHOP) in the US and from £2,185 (watch-and-wait) to £17,054 (chemotherapy) in the UK. In another US study investigating previously-treated patients, 12-month cumulative costs were higher in patients with progression than without ($30,890 vs. $8,704). HRQoL studies used FACT-Lym or EORTC-QLQ-C30 questionnaires. In a multinational study, a greater proportion of rituximab-refractory patients receiving OBZ+BEN+OBZ maintenance reported a meaningful improvement (≥2 point increase) in the total FACT-Lym scores compared to patients receiving BEN 4-12 months after treatment. In the UK total FACT-Lym scores were higher for newly-diagnosed patients compared to patients with progression (136.04 vs. 109.7). CONCLUSIONS: The majority of cost-effectiveness studies identified were in the relapsed/refractory or maintenance settings. The limited data on cost/resource use and HRQoL suggest that patients with progressive disease incur higher costs and experience poorer HRQoL than stable patients.

PSY67: EVALUATING THE ADDITION TO FORMULARY OF BELIMUMAB FOR THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS: A COST-EFFECTIVENESS MODEL

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OBJECTIVES: Systemic lupus erythematosus (SLE) is a chronic, multisystem autoimmune disease that causes potentially irreversible organ damage. A previous cost-effectiveness model (CEM) evaluating intravenous belimumab in SLE was a patient microsimulation model with a series of risk equations describing disease activity and survival models to depict time to organ damage. This model was substantially revised to use a semi-Markov model that still
captures the complexity of SLE and analyses subcutaneous belimumab. METHODS: Post hoc regression analyses of the intravenous belimumab US long-term extension study (BEL112233) and the Toronto Lupus Cohort were conducted to identify drivers of utilities, disease progression and SLE-related mortality (HO-15-15879/206347). Costs were based on LUCIC (Systemic Lupus Erythematosus Cost of Care in Canada; 114745). Results demonstrated that the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI) and the presence of cardiovascular damage were sufficient to capture organ damage effects. Thus, health states were defined by treatment, SDI score and presence/absence of cardiovascular damage. The model uses a 1-year cycle length to analyse over a modifiable lifetime time horizon. Patient distribution at time=0 and Year 1 outcomes are based on source clinical trials. Thereafter, disease activity measured by adjusted mean SLEDAI (AMS), flares, and probability of organ damage progression are modelled separately for each health state and dynamically updated each cycle. Health state costs and utilities are based on multivariate regression analyses that increment payoffs for each cycle. RESULTS: A new CEM framework was developed within a Markov model, which further allowed incorporation of AMS, flares and organ damage progression in SLE. Total costs and outcomes were similar to the previous CEM. CONCLUSIONS: This modelling study has simplified clinical assumptions of SLE to produce a Markov model that may be used by additional stakeholders due to its increased transparency and shorter run time. Study funded by GSK.

**PSY66: COST-UTILITY ANALYSIS OF BIOLOGICAL THERAPIES IN PSORIASIS USING REAL WORLD EVIDENCE**

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OBJECTIVES: To assess the cost-utility of biological therapies in the treatment of adults with moderate-to-severe psoriasis, using evidence from real-world data. METHODS: A Markov model was developed to compare different sequences of biological therapies and apremilast for the management of adult psoriasis patients with inadequate response to conventional disease-modifying anti-rheumatic drugs (cDMARD-IR). Efficacy and safety data were derived from published network meta-analyses. The drug survival data in the model was derived from the DERMIO registry. Benefits were measured in quality adjusted life years (QALYs) and were derived from published EQ-5D data from the BADBIR registry (Iskandar et al, 2017). Dermatology Quality of Life Index (DLQI) data were also reported, and we estimated alternative utility values by mapping DLQI to EQ-5D using several published mapping algorithms. Health care resource use and costs were calculated based on data from published literature and public UK sources. The base case analysis included treatments for which survival data was available (adalimumab, etanercept, infliximab, ustekinumab), with the remaining therapies tested in scenario analyses using different survival and quality of life assumptions. Parameters related to efficacy, cost and utility were tested in sensitivity analysis. RESULTS: Base case results estimated that sequences with ustekinumab as first-line therapy had significantly better overall drug survival than all other biologics as first-line treatment for psoriasis, and were therefore more cost-effective. Scenario analysis with newer therapies suggested that apremilast, secukinumab and ixekizumab would require significantly better first-line drug survival, quality of life improvements and/or reduced pricing to achieve similar cost-effectiveness. The model was sensitive to the assumptions of drug survival as well as the different utility mapping algorithms. CONCLUSIONS: The results of this analysis with real-world drug survival data suggest that ustekinumab represents a more cost-effective treatment than other biologics as a first-line treatment for cDMARD-IR patients with psoriasis.

**PSY69: COST-EFFECTIVENESS ANALYSIS OF OBETICHOLIC ACID FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) PATIENTS WITH INADEQUATE RESPONSE OR INTOLERANCE TO URSDODEOXYCHOLIC ACID (UDCA) IN FRANCE**

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OBJECTIVES: Obeticholic acid (OCA) is a novel, rationally designed drug targeting the farnesoid X receptor. Efficacy and safety have been demonstrated in POISE, a phase III clinical trial comparing OCA regimens to placebo. OCA has been reported to significantly decrease alkaline phosphatase (ALP) and bilirubin compared to placebo thus having the potential to reduce the risk of progressing to end-stage liver disease (ESLD). This analysis evaluated the cost-effectiveness of OCA titration in PBC patients with inadequate response or intolerance to UDCA in France. METHODS: A Markov-model followed a cohort of 10,000 patients over lifetime. The model has two components: the liver disease component defining the PBC risk of progression based on ALP and bilirubin biomarkers; and the clinical endpoint component depicting progression through ESLD, including decompensated cirrhosis, liver transplantations and liver-related mortality. OCA titration (5 to 10mg) in combination with UDCA was compared to UDCA for patients with inadequate response. OCA titration monotherapy was compared to no treatment for patients intolerant to UDCA. Main input parameters were estimated from POISE, the Global PBC Study Group...
and length of stay. Costs showed that LOS and cost per day in hospital ward were estimated to range from €570,373 to €426,358, corresponding to potential savings of €144,015. Sensitivity analysis demonstrated robustness of the model undertaken. The model was adapted to a Health Insurance perspective. One-way sensitivity analyses (OWSA) were undertaken. Results from the model suggest that peri-operative IDA treatment with FCM reduces the overall costs in a cohort of 100 patients from €570,373 to €426,358, corresponding to potential savings of €144,015. Sensitivity analysis showed that LOS and cost per day in hospital ward were the main cost drivers. CONCLUSIONS: From the collective perspective, treatment with OCA titration regimens can improve the health outcomes of PBC patients who currently do not have any alternative therapy and remain a cost-effective use of healthcare resource.

**PSY70: MODELLING FOR RARE DISEASES: CASE OF CANAKINUMAB IN PERIODIC FEVER SYNDROMES IN FRANCE**

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**OBJECTIVES:** Canakinumab, an interleukin-1 inhibitor is indicated in periodic fever syndromes (PFS), including familial Mediterranean fever resistant to colchicine, mevalonate kinase deficiency, tumour necrosis factor receptor associated periodic syndrome, in adults, adolescents and children aged 2 years and older. Through the example of canakinumab in France, the objective was to evaluate the challenges related to modelling rare diseases. METHODS: No model in PFS was identified in the literature. Clinical inputs regarding the progression of the disease and its management were obtained through clinicians’ interviews and questionnaires. Among complications associated with amyloidosis, only renal complications were included due to lack of data. Transition probabilities for amyloidosis complications were obtained from a UK study including PFS patients. While efficacy and utility data came from the phase III CLUSTER study (no stratification by age group was possible due to low sample sizes), safety data were obtained from the Beta-Confident registry, and long-term persistence data were obtained from the French ENVOL observational study. All-cause, amyloidosis and end stage renal disease (ESRD) related-mortality were accounted for. RESULTS: The model combined a 16-week decision tree evaluating response and remission in patients with canakinumab by dosage, spontaneous response, non-response, amyloidosis, ESRD and death. Three age-group cohorts were used to better account for the disease management in children. Canakinumab was associated with a higher number of life years and QALYs, although the utility data was uncertain. Canakinumab had a lower number of flares, which also resulted into a reduction in caregiver time. CONCLUSIONS: Modelling rare diseases is associated with high uncertainty, linked to low sample sizes, few long-term real world data, and requires relying on clinician inputs. Therefore, budget impact analysis is useful to discuss the financial resources Health Insurance will have to support.

**PSY71: COST SAVINGS OF PERIOPERATIVE ANEMIA TREATMENT WITH FERRIC CARBOXYMALTOSE IN COLORECTAL CANCER SURGERY PATIENTS**

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**OBJECTIVES:** Pre-operative anemia, commonly associated with iron deficiency (IDA), occurs in approximately 30% of patients undergoing surgery. Perioperative administration of ferric carboxymaltose (FCM) was previously shown to reduce the need for red blood cell concentrate (RBC), surgical complications, mortality and the hospital length of stay (LOS) in patients with preoperative IDA. The objective of this study is to model the cost impact of peri-operative IDA treatment with FCM vs. usual care prior to colorectal cancer surgery in the French health care setting. METHODS: The model used is based on the results of a RCT by Froessler et al. comparing FCM vs. usual care in abdominal surgery mostly colorectal cancer surgery patients (73% in FCM group and 85% in usual care group). Reported reduction in RBC transfusion (12.5% vs. 31.5%) and LOS (6 days vs. 9) were used as clinical metrics of the model. Cost parameters for hospitalization are based on the French Diagnostic-Related Groups (DRG) and for hospital activity on the French national hospitalizations database (PMSI). DRG were identified based on the CIM-10 diagnosis for colorectal cancer (C18). The study sample was extrapolated to a cohort size of 100 patients. The model was adapted to a Health Insurance perspective. One-way sensitivity analyses (OWSA) were undertaken. RESULTS: A total of 20,485 hospital stays for CRC resection were extracted from the PMSI database. Results from the model suggests that peri-operative IDA treatment with FCM reduces the overall costs in a cohort of 100 patients from €570,373 to €426,358, corresponding to potential savings of €144,015. Sensitivity analysis showed that LOS and cost per day in hospital ward were the main cost drivers. CONCLUSIONS: Peri-operative IDA treatment with FCM in CRC surgery could lead to significant cost savings based on a reduction in blood transfusion and length of stay.
PSY72: COST-UTILITY OF IDELALISIB IN COMBINATION WITH RITUXIMAB IN RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: The aim of this study was to evaluate the cost-utility of idelalisib in combination with rituximab (IR) versus rituximab (R) monotherapy in the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL), from the Spanish National Health perspective (NHS).

METHODS: A partitioned survival model of area under the curve with three mutually exclusive health states [progression-free survival (PFS), disease progression and death] was developed to estimate the quality-adjusted life years (QALY) gained with IR or R. The initial cohort included patients with CLL receiving a second line (2L) or subsequent line (+2L) of treatment with IR or R. Costs and benefits were estimated at fixed time points (cycle length of 1 week) for a lifetime horizon (30 years).

Survival data were based on the results of the pivotal CLL clinical trial comparing IR vs R (Furman 2014) and external sources. Direct healthcare costs (list drug acquisition, administration and monitoring, adverse events, and clinical management of CLL; €, 2016) were considered in the model. Costs and health outcomes were discounted at a rate of 3% per year. Deterministic and probabilistic sensitivity analyses (SA) were performed to evaluate model robustness.

RESULTS: For a lifetime horizon, 2L IR treatment yielded more efficacy than R (4.965 vs 1.818 QALY).

Total IR costs were €118,254 versus €23,874 with R. The incremental cost-utility ratio was €29,985/QALY gained with IR versus R. The model was sensitive to changes in time horizon and PFS distribution adjustment. In the probabilistic SA, IR was cost-effective in 84% of samples using a frequently referenced threshold of €45,000/QALY gained in Spain.

CONCLUSIONS: Compared with R, IR increases survival of previously treated adult patients (who have received at least one prior therapy) and is a cost-effective treatment, from the perspective of the Spanish NHS.

PSY73: IMPACT OF METABOLIC SURGERY ON COST AND LONG-TERM HEALTH OUTCOME: A COST-EFFECTIVENESS APPROACH

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OBJECTIVES: The increase of obesity has become a major public-health concern. Morbid obesity is associated with comorbidities, reduced quality-of-life and death. Metabolic surgery (MS) is the most effective treatment against obesity. The aim of this study was to evaluate the costs and outcomes of MS, based on hospital-records (2014) of two Austrian specialized centers. MS was compared with no-surgery in patients with a BMI ≥30 kg/m². At baseline 39.4% of patients exhibit diabetes, 77.9% CVD, 35.3% hyperlipidemia and 35% are depressed.

METHODS: MS was documented retrospectively over one year follow-up to collect resource utilization data of 177 patients (21 Roux-en-Y Gastric bypass, 21 Sleeve Gastrectomy and 135 One Anastomosis Gastric bypass). A cohort-simulation-model was developed to simulate the long-term consequences of diabetes including diabetic-complications, CVD, hyperlipidemia, depression, myocardial-infarction and stroke over a 20 year time-horizon. The model includes thirteen health-states to describe the long-term follow-up. Probabilities and utilities were derived from literature. Direct medical-costs from published sources were used and expressed in 2017€ from the payer’s perspective. QALYs, LYS and total costs were discounted at 5% p.a. Monte-Carlo simulation accounted for uncertainty.

RESULTS: MS leads to costs of 37,501 € per patient and 9.88 QALYs (14.72LY) over a 20 year time-horizon. No MS is associated with 60,482 € and 7 QALYs (14.22LY). Total cost saving for MS amounts to 22,981 € per patient and a QALY gain of 2.88.

Operated persons exhibit cost-savings for complications of 31,165 €, which offsets procedure costs including reoperations (10,080 €). Over 20 years MS is able to save -656 patient-years with diabetes (-3.7 per patient), -608 patient-years with CVD (-3.4 per patient), -161 patient-years with hyperlipidemia (-0.90 per patient) and -157 patient-years with depression (-0.89) per patient.

CONCLUSIONS: MS is associated with substantial savings in long-term health-care costs, expected health-benefits and reduced onset of complications. MS significantly increases the quality-of-life.

PSY74: COST-EFFECTIVENESS OF BARIATRIC SURGERY COMPARED TO CONVENTIONAL TREATMENT FROM A SOCIETAL PERSPECTIVE IN GERMANY, FRANCE, ITALY AND THE UK

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**OBJECTIVES:** Obesity and diabetes are growing epidemics in European countries. Bariatric surgery is recommended for the treatment of patients with moderate or morbid obesity, particularly in patients who also have type 2 diabetes mellitus (T2DM). The objective was to investigate the cost-effectiveness of bariatric surgery in patients with morbid obesity or moderate obesity with obesity-related comorbidities; T2DM patients with BMI≥35; T2DM patients with BMI≥30,<35; and all patients with mild obesity, from the societal perspective in Germany, France, Italy and the UK. **METHODS:** A Markov model with a cohort of 1,000 patients was used to evaluate the cost-effectiveness of bariatric surgery compared to conventional treatment (CT) over a 20-year time horizon. Model inputs were derived from the literature informed the complex nature of obesity and its associated comorbidities, including T2DM, stroke, myocardial infarction, cancer, knee pain and obstructive sleep apnoea. Up-to-date healthcare costs from the four countries were applied. Productivity loss calculations were included to account for differences in employment rates and overall work impairment between bariatric surgery and CT. **RESULTS:** In the T2DM population with BMI≥35, 47%-1/4% of patients were in T2DM remission at year 10/20 following bariatric surgery, compared to 10%-4% of patients treated with CT. In the morbidly obese population, the cumulative number of patient-years with T2DM was 46-57% lower and there were 32-42% fewer new T2DM cases with bariatric surgery compared to CT over 20 years. Bariatric surgery dominated CT from the societal perspective in all countries and populations, except in the UK T2DM population with BMI≥30,<35, where the ICER was £559/QALY. Probabilistic sensitivity analyses showed the model results to be robust to uncertainty. **CONCLUSIONS:** Bariatric surgery is highly cost-effective in Germany, France, Italy and the UK. Full implementation of existing clinical guidelines would reduce the burden of obesity and T2DM and generate economic benefits for society.

**PSY75: COST-EFFECTIVENESS ANALYSIS OF SECOND-LINE PHARMACOLOGICAL TREATMENTS OF ACROMEGALY IN SPAIN**

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**OBJECTIVES:** To estimate the cost-effectiveness of second line pharmacological treatments in patients with acromegaly resistant to somatostatin analogues (SSA) from the perspective of the Spanish National Health System (NHS). **METHODS:** A Markov model was constructed to analyze the cost-effectiveness of pegvisomant and pasireotide in SSA-resistant acromegaly, simulating the progression of the disease in a cohort of patients from the beginning of treatment to death. The model allowed the estimation of the quality-adjusted life-years (QALYs) from the perspective of the Spanish NHS. Treatment with pegvisomant or pasireotide was analyzed and compared to somatostatin analogues (SSA) retreatment. Efficacy data was obtained from clinical trials and the utilities were sourced from the literature. The direct health costs were calculated based on published Spanish data (€2016). A univariate sensitivity analysis was performed to evaluate the influence on cost-effectiveness of the most relevant variables, together with a probabilistic sensitivity analysis to assess the robustness of the results. **RESULTS:** The Incremental Cost Effectiveness Ratio (ICER) of pegvisomant vs. SSA was €93,070/QALY. The ICER of pasireotide vs. SSA was €555,600/QALY. ICER was mainly driven by the incremental efficacy (4.41 QALYs for pegvisomant vs. AAS and 0.71 QALYs for pasireotide vs. AAS), with a similar increase in costs (€410,000 for pegvisomant vs. AAS and €396,000 for pasireotide vs. AAS). Using lanreotide instead of octreotide and reducing the discount rate decreased the ICER in both cases. In contrast, increasing pegvisomant and pasireotide doses and reducing the time horizon lead to an increase in the ICER. **CONCLUSIONS:** The ICER of pasireotide compared to SSA was six times higher than the ICER of pegvisomant compared to SSA. Therefore, pegvisomant is the most cost-effective second line alternative in the treatment of acromegaly in SSA-resistant patients for the Spanish NHS.

**PSY76: PRODUCTIVITY COSTS RELATED TO BORTEZOMIB AND CARFILZOMIB ADMINISTRATION FOR MULTIPLE MYELOMA IN FINLAND**

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**OBJECTIVES:** Bortezomib and carfilzomib treatments for multiple myeloma (MM) require drug administration visits at hospital. Commonly, an escort (e.g. caregiver, relative, friend) accompanies patient during such hospital outpatient visit. These outpatient visits occur frequently, but patient’s or escort’s productivity costs (PCs) related to these visits have not been published. PCs are important for both individual and societal perspectives and relevant for burden of illness or cost-effectiveness analyses. This study estimated potential absenteeism-based PCs related to bortezomib and carfilzomib administration in Finland. **METHODS:** PCs were estimated conservatively based on time lost due to drug administration during outpatient visit. Number of visits and their lengths per treatment cycle were defined based on treatment protocols and local practices. Cycles of three weeks and four administrations for bortezomib, and four...
weeks and six administrations for carfilzomib were used. Travel times to and from hospital were estimated based on the results of a spatial health care accessibility analysis with 1x1km population density resolution, location of university and central hospitals, and the geometry of the road and street network in Finland. **RESULTS:** PCs per employed patient were 91€/visit and 337€/cycle for bortezomib, and 146€/visit and 882€/cycle for carfilzomib. When considering the employment rate of MM patients, average patient’s PCs were 316€/visit and 126€/cycle for bortezomib, and 50€/visit and 302€/cycle for carfilzomib. With escort’s PCs included, average PCs increased to 50€/visit and 201€/cycle for bortezomib, and 81€/visit and 484€/cycle for carfilzomib. PCs per person attributable to travelling were 28€/visit. **CONCLUSIONS:** PCs related to bortezomib and carfilzomib administration for MM were estimated to be significant. In addition, travelling time to and from hospital forms a significant proportion of total PCs, at least in sparsely populated areas such as Finland. Therefore, novel oral medications including ixazomib have significant potential in reducing absenteeism-based PCs during the treatment of MM.

**PSY77:** HEALTH CARE RESOURCE USE (HCRU) DUE TO BLEEDING RELATED EPISODES (BRE) IN PATIENTS WITH IMMUNE THROMBOCYTOPENIC PURPURA (ITP) RECEIVING ELTROMBOPAG (EPAG), ROMIPLOSTIM (ROMI), OR RITUXIMAB (RITUX): REAL WORLD EVIDENCE (RWE) FROM 27 US INSTITUTIONS

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**OBJECTIVES:** Study objective was to assess the HCRU rates due to BREs in ITP patients. **METHODS:** A syndicated electronic medical record network containing data on inpatient and outpatient services and procedures, diagnoses, prescriptions, and labs for over 29 million patients from 27 US hospitals was queried. Adult patients (≥18) diagnosed with primary ITP and treated with EPAG, ROMI, or RITUX currently and steroids previously were included. Patients with secondary ITP were excluded. Patients were divided into three groups based on type of BREs since initiating treatment: no BREs, BREs without platelet transfusion (PT) (mild) and BREs with PT (severe). BREs were identified as actual bleeding events and/or uses of rescue therapy (intravenous immunoglobulin or steroids, or platelet transfusion) using a combination of diagnosis, procedure, and medication codes. Mean rates of HCRU across three groups were compared using Z-tests (two-sided α=0.05). **RESULTS:** 570 ITP patients treated with EPAG, ROMI, or RITUX were identified: no BREs (320), mild BREs (220) severe BREs (50). Age and gender were similar across the groups. HCRU was significantly higher in patients with BREs vs. without: ER visits (29%, 52%, 60%), hospitalizations (26%, 48%, 60%) and office visits (45%, 67%, 60%), no BRE, mild BRE, severe BRE, respectively (all p<0.05). The rates of diagnostic procedures were also significantly higher in patients with BREs vs. no BREs. ER visits, hospitalizations and diagnostic procedures were higher while office visits were lower in patients with severe vs. mild BREs, although not statistically significant. **CONCLUSIONS:** This retrospective RWE study emphasized the significantly higher HCRU in patients with BREs as compared to patients without BREs. Severe BREs add additional burden of hospitalizations and emergency room visits, which may potentially lead to substantial financial burden.

**PSY78:** RESOURCE UTILISATION AND COSTS ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA MORPHINE FOR POST-OPERATIVE PAIN MANAGEMENT IN A TEACHING HOSPITAL SETTING IN IRELAND

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**OBJECTIVES:** Information regarding resource utilisation, hospital logistics, and costs associated with intravenous patient-controlled analgesia (IV PCA) morphine treatment is limited. In this prospective study, conducted between March 2016 and June 2016 in The Adelaide and Meath, incorporating The National Children’s Hospital (AMNCH), Tallaght, these aspects of treatment with IV PCA-morphine were examined. **METHODS:** Information about IV PCA morphine related staff time and resource use were recorded for patients (n = 25) who had undergone elective surgery. The nature of IV PCA-morphine complications, e.g. problems with drugs or pumps, were also recorded. The unit cost of each staff member and resource used for an episode of treatment with IV PCA-morphine were derived from national and local sources. The time required by staff and resource costs was calculated to generate a per-patient cost estimate of an episode of treatment with IV PCA-morphine. **RESULTS:** An episode of IV PCA-morphine treatment lasted on average 1.7 days and had a mean cost of €148.20. This cost was made up of staff time (68%), pump costs (1.1%) and consumable costs (29.6%). The mean time spent by staff on IV PCA-morphine treatment tasks over the course of treatment in the recovery room and on the ward was 124 minutes (Recovery room (39 minutes), Ward (85 minutes)). Patients enrolled into this study were 56% male, with an ASA health classification of I or II (92%). 60% were on a concomitant medication prior to their procedure, and 20% required additional analgesic treatment during recovery. **CONCLUSIONS:** Substantial staff time and costs are associated with IV PCA-morphine treatment. In the light of these costs, exploration of the potential availability of less costly alternatives are recommended.
PSY79: DETERMINING THE SHARES OF THE COST OF ANESTHESIA AND INTENSIVE CARE MEDICINE IN STATIONARY AND STATIONARY PART AND THEIR DEVELOPMENT SINCE 2006 IN GERMANY

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**OBJECTIVES:** The G-DRG system defines the anesthesia and intensive care medicine as its own cost centers and recorded financial expenses very differentiated. Thus, it is possible to calculate the total cost of the two areas, even for individual interventions. The analysis should demonstrate the cost and determine changes over time since 2006. **METHODS:** The cost matrixes from the German DRG-Institute per identified DRG were weighted with the calculated cases for Germany. Used were the G-DRG Reportbrowser 2006-2015, the Calculationbrowser 2013/2015, and Microsoft Excel and Access (version 2013). **RESULTS:** In 2015 calculations for 13.633.491 hospital cases were identified. Anesthesia accounted for 5.3%, the intensive care for 12.7% of total costs. Anesthesia are the 26.2% of the theater costs. The cost of anesthesia has risen from 2006 to 2015 to 31.7%, the intensive care medicine by 97.8%. Physicians account for 42.9% in anesthesia and 20.4% of ICU costs. Medical technical service accounts for 27.9% and 0.8%, nurse care 0.0% and 40.3%, pharmaceuticals 2.6% and 6.5%. From 2008 to 2015, the costs for physicians in anesthesia rose by 4.0% per year, in ICU by 7.9%, ICU-nurse-care by 5.1%. The medical technical service increased by 3.4% (A) decreased in ICU by 3.9%. Medical infrastructure costs rose by 3.2% (A) and 9.8% (I). Drugs rose only about 1.1% (A) and 1.9% (I). **CONCLUSIONS:** The cost of anesthesia and intensive care medicine are quite accurate and differentiated measured in Germany. These can be used for capacity planning and comparisons. Approximately 26% of theater cost is driven by anesthesia. The ICU-expenses have risen far more in the last decade as for anesthesia. The main increase is for infrastructure before the pay for physicians. Drug costs have only a very small and relatively decreasing share in both areas.

**SYSTEMIC DISORDERS/CONDITIONS - Patient-Reported Outcomes & Patient Preference Studies**

PSY80: IMPACT OF LOW ADHERENCE ON COST-EFFECTIVENESS OF THE BIOLOGICAL TREATMENT OF PSORIASIS (PSO) AND PSORIATIC ARTHRITIS (PSA) IN SLOVENIA

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**OBJECTIVES:** To evaluate the impact of low adherence in patients with psoriasis (PsO) and psoriatic arthritis (PsA) treated with biological therapy (adalimumab) in Slovenia. **METHODS:** Flexible Markov state transition cohort models were adapted using locally-specific data separately for each indication taking into account the complexity of treatment pathways in PsO and PsA. Health states within both models were assessed either on the basis of Psoriasis Area Severity Index for PsO or Psoriatic Arthritis Response Criteria and Health Assessment Questionnaire for PsA. Adalimumab was compared with best supportive care (BSC) following the design of clinical trials and requirement that the cost-effectiveness of adalimumab is appraised in a conservative manner. **RESULTS:** In patients suffering from PsO, the treatment with adalimumab when compared to BSC resulted in ICER of €11.005 per QALY for full (100%) adherence, and €62.711 per QALY for real-life (50%) adherence. In patients suffering from PsA resulting ICER was €16.313 per QALY for full (100%) adherence and €37.865 per QALY for real-life (50%) adherence. Even the adherence that is often deemed satisfactory (75%) had pronounced effect on cost-effectiveness of treatment with adalimumab when compared to BSC (ICER of €33.954 per QALY for PsO and €26.948 per QALY for PsA). The sensitivity analysis showed robustness of findings in both groups of patients. **CONCLUSIONS:** Our pharmacoeconomic analysis indicates that cost-effectiveness is markedly altered by low adherence to the treatment with adalimumab in patients suffering from PsO and PsA. The findings of our study have potential implications for introduction of adherence-enhancing interventions.

PSY81: COMPLIANCE AND TREATMENT SATISFACTION WITH BIOLOGICAL TREATMENTS FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA)

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OBJECTIVES: To examine caregivers’ treatment satisfaction and adherence with biologic treatments for SJIA. METHODS: Within an international, non-interventional study to assess the burden of SJIA, a tailored questionnaire was developed to capture caregiver’s satisfaction with their child’s current and past biological treatment experience for SJIA. Caregiver’s satisfaction at the time of completing the questionnaire was assessed based on their perception of the efficacy, safety and convenience of each treatment and their child’s adherence to it. RESULTS: Anakinra (N=41 [32%]), canakinumab (N=29 [48%]) and tocilizumab (N=31 [48%]) were the three biologics captured. Respondents answered based on all treatment experience, regardless of current treatment. Caregivers perceived treatment satisfaction with canakinumab was consistently high and equal to or higher than caregivers’ satisfaction with anakinra or tocilizumab. Significantly more caregivers were not stressed or anxious when their child received canakinumab (48%), and thought that canakinumab was convenient (69%), caused no burden to them (38%) and demonstrated complete improvement in symptoms (48%). In contrast, anakinra and tocilizumab were reported to be inconvenient by 58% and 48%, caused moderate to extreme burden in 64% and 71%, respectively, and anakinra had a high ‘no improvement of symptoms’ rate (24%). Overall, 41% of caregivers thought their child was not stressed or anxious receiving canakinumab compared to anakinra (12%) and tocilizumab (35%). Complete treatment compliance as follows: canakinumab (96%), anakinra (85%) and tocilizumab (81%). The main reasons for missing treatment were due to ‘forgetting to give’ or ‘forgetting to take the treatment’ in the anakinra group (17%) or the treatment was found to be ‘inconvenient for practical reasons’ in the tocilizumab group (9.8%). CONCLUSIONS: According to caregivers, biologic treatment completely improved SJIA symptoms in 48% of children on canakinumab or tocilizumab and 32% on anakinra. Canakinumab treatment was associated with higher treatment satisfaction and adherence compared to tocilizumab and anakinra for SJIA.

PSY82: EQ-5D-5L UTILITY VALUES FOR SPANISH PATIENTS WITH PAINFUL CHRONIC OSTEOARTHRITIS, LOW-BACK-PAIN OR CANCER PAIN

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OBJECTIVES: Utility is a measure used in pharmaco-economic studies to calculate the gain of Quality-Adjusted Life Years. Painful chronic osteoarthritis (PCOA), chronic-low-back-pain (CLBP) or cancer pain (CP) are among the most prevalent health conditions resulting in seeking medical advice. The objective was to fit equations allowing to estimate the age and sex adjusted utility value of the EQ-5D-5L according with the severity of pain for patients with PCOA, CLBP or CP in Spain. METHODS: The year 2011/2012 National Health Survey, which includes the EQ-5D-5L questionnaire and self-reported health conditions, was used. Data from individuals, both gender, above 18 years-old, who self-reported OA, CLBP or cancer as diagnosed by a physician were analysed. The Spanish raw utility values were extracted from the website of EuroQol group. Linear regression models were fitted to estimate adjusted utility value from EQ-5D-5L separately by sex. Severity of pain was assessed by means of the pain item of the EQ-5D-5L. Age and number of comorbidities were used as covariates. RESULTS: 5,012 records with OA [68.3±13.5 years-old (mean±SD), 72.3% women] 4,565 with CLBP [59.1±17.0 years-old, 64.9% women] and 739 with cancer [66.3±14.4 years-old, 60.1% women] were analysed. Equations fitted for OA were, respectively for men [adjusted R2=0.52, F=500.2 (p<0.001)] and women [adjusted R2=0.55, F=1,485.8 (p<0.001)]; UEQ-5D-5L= 1.351-0.156(EQ-5D-5Litem pain score)-0.002(age[years])-0.018(number-of-comorbidities), and UEQ-5D-5L= 1.535-0.169(EQ-5D-5Litem pain score)-0.005(age[years])-0.013(number-of-comorbidities). For CLBP were, respectively for men [adjusted R2=0.60, F=807.8 (p<0.001)] and women [adjusted R2=0.59, F=1,397.8 (p<0.001)]; UEQ-5D-5L= 1.240-0.147(EQ-5D-5Litem pain score)-0.001(age[years])-0.018(number-of-comorbidities), and UEQ-5D-5L= 1.377-0.160(EQ-5D-5Litem pain score)-0.003(age[years])-0.013(number-of-comorbidities). For cancer subjects were, respectively for men [adjusted R2=0.57, F=129.1 (p<0.001)] and women [adjusted R2=0.64, F=264.1 (p<0.001)]; UEQ-5D-5L= 1.346-0.174(EQ-5D-5Litem pain score)-0.002(age[years])-0.016(number-of-comorbidities), and UEQ-5D-5L= 1.466-0.175(EQ-5D-5Litem pain score)-0.004(age[years])-0.011(number-of-comorbidities). CONCLUSIONS: This work provides equations allowing to estimate the age and number of comorbidities adjusted utility value of subjects with PCOA, CLBP or CP according to severity of pain and sex in Spain.

PSY83: DEVELOPMENT AND UTILITY VALUATION OF HEALTH STATES FOR HAEMOPHILIA AND RELATED COMPLICATIONS IN EUROPE AND IN THE USA

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OBJECTIVES: This study aimed to quantify the impact of congenital haemophilia severity and selected haemophilia-related complications on health-related quality of life (HRQoL), expressed as health utilities, using a Time Trade-Off (TTO) valuation approach in Europe and the USA. METHODS: Nine health state descriptions were developed based on literature review and interviews with haematologists and individuals with haemophilia. Three descriptions
characterised the impact of mild, moderate and severe haemophilia. Six descriptions characterised disease-related complications added to the moderate description (arthroscopic synovectomy; prosthetic joint replacement, chronic pain, spontaneous bleed, traumatic bleed, and end-stage joint disease). Pilot-testing was performed with five to six adults from the general public in the UK, France, Germany, Italy, Sweden and the USA to confirm the understanding and appropriateness of the descriptions. TTO interviews with a 10-year trade-off period and a 100-point visual analogue scale rating exercise were conducted with 100 adults from the general public in each country. RESULTS: The TTO valuation led to consistent findings across countries. Utility values obtained for the health states corresponding to mild, moderate and severe haemophilia demonstrated a decline in HRQoL corresponding with the increase in severity. The mean utility value for the mild health state was 0.80 ranging from 0.86 (Sweden) to 0.73 (Italy), for the moderate health state 0.73 ranging from 0.76 (Germany/Sweden) to 0.68 (Italy), and for the severe health state 0.67 ranging from 0.71 (Germany) to 0.64 (UK). The most severe disutility related to the addition of a haemophilia-related complication was associated with the burden of end-stage joint disease with a mean disutility of 0.28 ranging from 0.23 in Italy to 0.36 in the UK. CONCLUSIONS: This study underlines how French, Italian, German, Swedish, US and UK populations value haemophilia-related health states and stresses the importance of minimising disease impact and avoidance of associated complications.

**PSY84: ESTIMATION OF THE HEALTH-RELATED QUALITY OF LIFE BENEFITS OF TREATMENT FOR SPINAL MUSCULAR ATROPHY (SMA)**

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OBJECTIVES: Spinal muscular atrophy (SMA) is a rare autosomal recessive neuromuscular disease that causes progressive proximal muscle weakness and paralysis. Recently nusinersen became the first treatment approved for patients with SMA. This study was designed to address gaps in the evidence regarding the impact on health-related quality of life (HRQoL). These data are required for assessing cost-effectiveness of treatments, but capturing this in rare paediatric diseases is challenging. METHODS: Case histories were developed to match the definition of states in a decision model designed to measure the cost-effectiveness of nusinersen for the treatment of SMA type 1 and 2. The case studies were developed from a review of the literature focusing on HRQoL impact, and interviews with five clinical experts in SMA. Following this, five clinical experts provided a proxy assessment of the case studies using the EQ-5D-Y and PedsQL-NMM (baseline states only). RESULTS: The experts who took part in the valuation interviews had an average of 14 years experience working with SMA patients. The SMA type 1 utilities ranged from -0.37 (requires ventilation) to 0.72 (reclassified as type 3), with quite substantial differences between some states. Most type 1 states had a utility score below zero indicating a state worse than dead. The SMA type 2 utilities ranged from -0.13 (worsened) to 0.77 (stands/walks unaided). The results showed an incremental increase of 0.03 moving from baseline (0.04) to mild improvement (0.07), and from mild to moderate improvement (0.10), and a large increase in utility values for the standing/walking states (0.53 and 0.77). CONCLUSIONS: The utility scores obtained in this study highlight the very substantial burden experienced by SMA patients. Despite the limitations in the methods used, this study produced data with face validity and is a useful starting point for understanding the burden of SMA type 1 and 2.

**PSY85: SOCIALEl PREFERENCES FOR FUNDING ORPHAN DRUGS IN THE UK: AN APPLICATION OF VALUE BASED PRICING USING DISCRETE CHOICE EXPERIMENT METHODS**

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OBJECTIVES: Orphan drugs tend to be expensive and many may not provide value for money by standard measures of cost-effectiveness. Their general availability by the National Health Service (NHS) suggests that special criteria apply to rare diseases for OD reimbursement. The aim of the present study is to identify characteristics that may influence policy and to determine a value based price (VBP) for orphan drugs based on public preferences. METHODS: Participants (n=2000) who completed a discrete choice experiment (DCE) made choices between hypothetical drugs described by varying disease and drug characteristics. The coefficients from the DCE were used to estimate a utility model based on reimbursement evidence and thus the VBP of evaluated orphan drugs. RESULTS: Rarity -0.888 (95% CI -0.9439, -0.8323) and the availability of other drug treatments -0.0756 (95% CI -0.1511, -0.0272) was unlikely to influence the general populations decision when determining which treatment the NHS should provide. However, the results showed a strong preference of the general public to fund drugs that had large treatment benefits 0.8536 (95% CI 0.8044 to 0.9027) and improvements to every day life 0.6589 (95% CI 0.6261, 0.6918), regardless of the prevalence of the disease. According to the utility model, 6 of 12 NHS approved orphan drugs passed the reimbursement preference threshold of the general population. Respondents would not prefer NHS funding for 5 of the remainder (VBP <£0 per patient per year), while one would be acceptable with a 9-fold reduction in the list price. CONCLUSIONS: Estimation of the VBP suggests that the treatment benefit of a drug is
the primary driver when determining the value of a drug. Based on our model, there does seem to be a preference from the general population to fund high cost treatments regardless of disease prevalence.

**PSY86: SOCIETAL PREFERENCES FOR FUNDING ORPHAN DRUGS IN THE UK: A PERSON TRADE OFF STUDY**

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**OBJECTIVES**: Orphan drugs for rare diseases tend to be high cost treatments. Current practice by UK health technology assessment organisations suggests that rarity in itself may be justification for exceeding standard thresholds of cost effectiveness. This study aims to examine whether or not there is support among the UK general public for prioritising treatments of patients with rare diseases. **METHODS**: Using PTO design, the preferences of 1000 people for allocating fixed funds between a drug treatment for patients with rare versus common diseases were determined. Further samples (n=500 each) were asked to allocate funding between a drug treatment for rare disease and i) increase waiting list or ii) reduced NHS staffing. Costs and treatment benefits were varied in each scenario. **RESULTS**: The general population generally preferred to distribute funds equally between patients with a common disease and those with a rare disease. Distribution of preferences for treating patients with: (i) rare, (ii) common disease, or (iii) equal allocation of funds, were: 32%, 14%, 54%. When cost of rare disease treatment increased, we observed less support for treating rare disease patients (19%, 54%, 27%). However, this was reversed if the drug also offered greater treatment benefits (71%, 50%, 44%). When asked to trade off between the alternative framing scenarios, respondents preferred not increasing waiting lists (45%, 9%, 46%, equal cost scenario) to fund treatments for rare diseases. However, respondents preferred replacing vacant NHS staff posts when treatment cost increased (31.2%, 34.4%, 34.4%). **CONCLUSIONS**: There is little support among the UK general public for prioritising treatments on the basis of disease rarity alone; although there was a preference observed when treatment benefit was greater, despite the increase in cost. This suggests that there may be a preference for funding high cost treatments for rare disease patients but only if treatment benefit was high.

**PSY87: THE BURDEN OF ALBINISM: CREATION OF A QUESTIONNAIRE**

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**OBJECTIVES**: No specific tool currently exists for assessing the burden placed upon persons suffering from albinism. FIMARAD (Rare Diseases in Dermatology) group began an initiative to create a specific questionnaire. **METHODS**: The questionnaire was devised using standardized methodology for developing and validating QoL questionnaires: according to the following chronological structure: 3 phases/ conceptual-development-validation. A multidisciplinary working group was assembled, including PRO’experts, dermatologists and representatives of the Genespoir association. Validated questionnaires SF12), MetraPVC, Body-Image-States-Scale(BISS) and Daily-Life -Quality-Index(DLQI) were also administered in order to ensure external validity. **RESULTS**: Based on an initial verbatim report, the workgroup compiled a list of items, which were transcribed and reformulated into questions. In this phase, 65 items were defined, reorganized and regrouped according to content, then reduced to 24. This questionnaire was proposed to 87 subjects with albinism during the development phase. 63 responded. During the validation phase, Principal Component Analysis (PCA) was conducted on the 24 items, which allowed the questionnaire to be reduced to 20 questions [Q]. The standardized regression coefficients were all greater than 0.5 on their corresponding factors. Based on their normalized regression coefficients, each group of questions was linked to one of the following four dimensions: “living with the disease”(8Q), “daily life”(3Q), “resignation”(3Q), and “fear of the future”(6Q). To verify external validity, the correlation coefficients of the questionnaire were also calculated with the following validated questionnaires: SF12, Metra-PVC, BISS, and DLQI. Strong correlation was found and so external validity was confirmed **CONCLUSIONS**: This questionnaire represents the first specific assessment tool for evaluating the burden of albinism. It is easy to use and relatively quick to complete, which will allow the burden over time to be evaluated with a reproducible questionnaire. To ensure that this questionnaire can be used by as many people as possible, cultural and linguistic validation in US English was conducted with the original French version.

**PSY88: EXPLORING CONCURRENT VALIDITY OF THE CLN2 CLINICAL RATING SCALE: COMPARISON TO PEDSQL USING MIXED EFFECTS MODELLING AND DATA FROM A PHASE 1/2 SINGLE-ARM TRIAL**

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OBJECTIVES: Neuronal Ceroid Lipofuscinosis type 2 (CLN2) disease is a rare, autosomal recessive disorder typically manifesting in late-infantile children. The disease results in progressive language loss, movement disorders, pain, dementia, vision loss and ultimately death at 8–12 years of age. The 0–6 point Motor-Language CLN2 Clinical Rating Scale was the primary endpoint in the pivotal cerliponase alfa trial for the treatment of CLN2 disease. This analysis aimed to concurrently validate this disease-specific functional rating scale by examining its relationship to the Paediatric Quality of Life Inventory (PedsQL) tool, for which a minimal clinically important difference of 4.5 has been established.1 METHODS: Data from the phase 1/2 single-arm trial of 23 CLN2 patients treated with cerliponase alfa for a minimum of 97 weeks were used in this analysis (NCT01907087). To determine the relationship between the clinician-reported CLN2 Clinical Rating Scale total score and the proxy-reported PedsQL score at both the total and domain level, simple linear regression followed by mixed effects analyses (to account for within-subject correlation) were conducted. RESULTS: For the simple and mixed effects analyses, there was very strong evidence of a positive correlation between the PedsQL total score and the CLN2 Clinical Rating Scale total score (p<0.001; simple regression adjusted R-squared=0.27; mixed effects CLN2 Clinical Rating Scale parameter estimate [95% confidence interval (CI)]: 5.06 [2.66, 7.44]). It appears this relationship was primarily driven by the PedsQL Physical domain (p<0.001; simple regression adjusted R-squared=0.42; mixed effects CLN2 Clinical Rating Scale parameter estimate [95% CI]: 10.41 [7.21, 13.54]). CONCLUSIONS: These results provide evidence of concurrent validity between the CLN2 Clinical Rating Scale and PedsQL score, in particular, with respect to physical function. This relationship suggests a 1-point change on the CLN2 Clinical Rating Scale may be meaningful to patients. REFERENCES: 1. Varni J. et al., Expert Rev Pharmacoecon Outcomes Res., 2005.

PSY89: AN EFFECTIVE TABLET PROGRAM FOR COLLECTING PAIN DATA FROM PATIENTS

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OBJECTIVES: To show how a simple tablet program can be successfully used with minimal supervision and instruction to collect pain data from patients. METHODS: The data collection method was an Android application, designed to be run on a tablet. There was a tutorial to explain how to enter data, and a nurse was present to activate the survey and support the patient, if necessary. The application displayed a timer and prompted the patient to report their pain level at each time point, and within a set window, using a sliding scale (0–10). Patient data were stored on an internal database within the application and subsequently uploaded to a local database server. RESULTS: The primary objective of the study was to determine the time to onset of significant pain relief in patients applying ibuprofen gel, ibuprofen gel with levomenthol, or diclofenac gel to treat soft tissue injuries. Significant pain relief was defined as a reduction of 2 points on an 11 point numeric rating scale (NRS) for pain. One patient was affected by a bug in the data collection system, but the problem was discovered and resolved before the next patient was scheduled. The remaining 181 patients used the tablets to input data on their pain levels at 17 time points over a 2 hour period following gel application, allowing the primary study objective to be assessed. Excluding the patient affected by the bug, who was not assessed, only thirteen patients had some missing time point data and there were only 18 missing data points from a total of 3,077 (0.6%). CONCLUSIONS: The tablet program was easy to use, resulting in high completion rates. Electronic prompting meant that data could be reliably collected at precise time points, and patients could input data themselves, which reduced labour costs.

PSY90: BURDEN OF ARTHRITIC MANIFESTATIONS ON PSORIATIC PATIENTS - SUB-ANALYSIS OF PESSOA, A PATIENT REPORTED OUTCOMES STUDY IN PORTUGAL

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OBJECTIVES: Psoriasis (PsO) and psoriatic arthritis (PsA) is a chronic inflammatory disorder, presenting several types of manifestations with significant impact on quality of life (QoL). This analysis aimed to characterize PsO patients with and without comorbid PsA, and evaluate the disease impact on QoL. METHODS: PsESSOa was a cross-sectional study in 564 adult Portuguese patients with PsO. Data was collected through an electronic questionnaire entered directly by patients (Jun-Jul2016). Comparisons were executed between PsA patients (patients with PsO and PsA) and patients with PsO only. RESULTS: 126 patients (22.4%) reported PsA. 63.5% (n=80) were females, mean(SD) age 47.2±12.9 years. Most common type of psoriasis was plaque psoriasis (67.5%). Based on patient reported Body Surface Area, 67.8% had moderate to severe psoriasis. Comparing to other patients, PsA patients presented higher prevalence of depression/ anxiety (37.7% vs 21.9%; p=0.002) and hypertension (30.2% vs 16.6%; p=0.001). The majority of patients were seen by dermatologist in both groups (54.4% in PsA group vs 64.0%) although more patients in PsA group were followed by rheumatologist (23.0% vs 9.8%). Patients with PsA reported higher monthly medication/ health product cost (56€ vs 36€) and more frequent physician
appointments (66% vs 40% with visiting interval < 6 months). EQ-5D-3L results showed that PsA patients had worse scores in anxiety/depression dimension (62.6% were moderately anxious or depressed; 9.3% extremely anxious or depressed) and in pain/discomfort dimension (60.7% had moderate pain or discomfort; 14.9% had extreme pain or discomfort). PsA patients also had a significant worse overall EQ-5D-3L VAS score (59.4 vs 70.6; p<0.001). CONCLUSIONS: This sub-analysis reinforces the humanistic burden of PsA in patients with PsO diagnosis. PsA patients had higher prevalence of comorbidities and health resource use. Patients’ perspective should increasingly be integrated in clinical practice to improve disease awareness and obtain more real-life outcomes evaluation.

**PSY91: HEALTH-RELATED QUALITY OF LIFE AND PHARMACOTHERAPY COSTS STUDY FOR PATIENTS WITH RARE ENDOCRINE DISEASES IN BULGARIA – A PILOT STUDY**

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OBJECTIVES: The goal is to calculate the pharmacotherapy cost and quality of life of Bulgarian patients with rare endocrine diseases. METHODS: An ambispective study among hospitalized patients with acromegaly and Cushing syndrome was conducted at the University Endocrinology Hospital for Active Treatment of, Sofia. A bottom up approach was applied to calculate the average monthly pharmacotherapy costs per person for the period 2015-2016. The quality-of-life survey was accessed through SF-36. Descriptive statistics, correlation analysis and non-parametric Mann Whitney test were applied using STATISTICA Version 13. RESULTS: The total number of included patients with acromegaly was 22 and 5 with Cushing syndrome. The patients over 50 years of age prevail in both groups – 68% and 80%, respectively. The pharmacotherapy for patients with acromegaly includes Sandostatin (72%) and Sandostatin+Pegvisomant (13.6%). The average monthly costs for acromegaly patients are 2 351.42 BGN (SD=1943.06) whereas Pasireotide therapy costs 6 465.65 BGN, at the ex-change rate of 1BGN=1.95Euro. The average quality of life did not differ significantly (P = .065) between the acromegaly and Cushing syndrome groups = 54.77 (SD=16,885) vs. 34.76 (SD=12,229), respectively. The men with acromegaly have higher values for physiological functions in comparison with the women (80.48 vs. 43.06). Acromegaly patients have statistically significantly higher values for vitality, energy or fatigue (53.26 vs. 46.8) and for general health perception (54.54 vs. 37). A negative low correlation between average costs and the average quality of life for acromegaly patients was defined – the higher the costs, the lower the quality of life (r=-0.134). CONCLUSIONS: The quality of life for patients with rare endocrine diseases is low especially regarding vitality, energy or fatigue and general health. The direct medical costs are significant and negatively correlated with the quality of life.

**PSY92: DISEASE-SPECIFIC PATIENT-REPORTED OUTCOME INSTRUMENTS IN SICKLE CELL DISEASE: A SYSTEMATIC LITERATURE REVIEW**

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OBJECTIVES: The US Food and Drug Administration (FDA) convened patient-focused drug development meetings to identify those symptoms/effects of sickle cell disease (SCD) on daily living, which are most important to patients. Drug developers are now expected to present direct evidence of the benefit of SCD therapies on these symptoms/effects. Such evidence has to be generated by measuring standardised patient-reported outcomes (PROs). This review aimed to identify and summarize published data on available SCD-specific PRO instruments. METHODS: MEDLINE® and EMBASE® databases were searched to identify studies assessing SCD-specific PROs, published in English and in the last 15 years. RESULTS: The literature search identified 26 studies (sample size, N=12 to N=561) assessing 13 SCD-specific PRO instruments. Most studies were conducted in the US (22 studies) followed by the UK (3 studies). Equal number of studies (13 studies) included either adult or paediatric (<18 years) patients. Of the identified instruments, nine were used in adults and four in children or adolescents. The Pediatric Quality of Life Inventory™ Sickle Cell Disease Module (PedsQL-SCD) was most frequently used (8 studies), followed by the Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me; 4 studies) and the Sickle Cell Pain Burden Interview-Youth (SCPBI-Y; 3 studies). Pain was the most frequently assessed concept, included in eight of the 13 identified instruments. Other key symptoms/concepts assessed included cognition, fatigue, functional ability, self-efficacy, sleep, stiffness, emotional and social impairment/stigma, and quality of life. Eight instruments were developed in the last 5 years. Validation studies were available for 10 instruments. CONCLUSIONS: Several SCD-specific PRO instruments are available for selection as endpoint in clinical studies to demonstrate the effectiveness of innovative interventions in target population. Many scales are recently developed and their utility in clinical studies is yet to be ascertained.

**PSY93: VALIDITY OF CHANGE IN RECALL PERIOD FOR THE NORFOLK QOL PATIENT REPORTED OUTCOME (PRO) MEASURE**
OBJECTIVES: Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP) is a rare degenerative disease with a progression pattern similar to that observed in diabetic neuropathy (Vinik et al., 2014). The Norfolk QOL-DN was developed to capture patients’ perceptions of the effects of diabetic neuropathy and has been validated in TTR-FAP patients. Based on regulatory feedback the recall period of the measure was changed from 4- to 1-week. The objective of this research was to determine the validity and acceptability of the one-week recall period. METHODS: Individual qualitative telephone interviews were conducted with patients diagnosed with TTR-FAP. Interviews were conducted by trained interviewers between May 2016 and June 2016. At the start of the interview, subjects completed the Norfolk QOL-DN while “thinking aloud,” or talking about the questionnaire instructions and items and their response to them. Participants were also asked questions about the ease of completing the Norfolk QOL-DN, focusing on the relevance of the one-week recall period. Interviews were audio-recorded and transcribed and analysed using qualitative thematic and content analysis. RESULTS: Twenty participants were interviewed; 55% male; mean age 61.1 years. No participants had significant difficulties understanding how to answer the Norfolk QOL-DN questions using a one-week recall period. All participants had experienced at least one of the symptoms covered by the instrument in the past week. The most prevalent type of symptom was neuropathy-related. All participants experienced at least one neuropathy symptom within the one-week time period. Generic functioning and HRQoL items were somewhat less sensitive as participants had adjusted their lives to their disability, not because they had problems with the recall period. CONCLUSIONS: Participants in this study were able to understand and respond to the Norfolk QOL-DN items using the one-week recall period. Additional work exploring the item relevance and performance within TTR FAP would add to the rigour of this measure within this population.

PSY94: THE IMPACT OF SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) ON A CAREGIVER’S PRODUCTIVITY AND THE CHILD’S SCHOOLING


OBJECTIVES: To evaluate the impact of SJIA on the caregiver’s work productivity and the child’s schooling. METHODS: As part of an international study to assess the burden of SJIA on the caregiver and patient, from a caregiver’s perspective, caregiver’s work productivity (using the work productivity and activity impairment questionnaire (WPAI)) and impact on patients schooling (using tailored questions) were assessed. Caregivers indicated change in work commitments due to their child’s SJIA and how frequently it caused them to miss work or for their child or siblings to miss school. RESULTS: Sixty-one biologic treated patients participated (12 anakinra, 25 canakinumab, 24 tocilizumab). Mean age at diagnosis and survey completion was 6.4 and 11.3 years, respectively. 77% of caregivers were employed (full or part time), however 36% had reduced their number of working hours or stopped working due to their child’s SJIA. SJIA related appointments were the main cause of a caregiver missing work, in the past two months (57%). Employed caregivers had missed a mean 2.8 hours of work in the past seven days due to their child’s SJIA, equating to approximately 25 working days annually. Caregiver’s mean absenteeism score based on WPAI, was 10% and mean presenteeism score (reduced on-the-job effectiveness) was 11%, equivalent to a productivity loss of 27.5 work days. In the two months prior to survey completion, a mean 2.9 school days were missed by patients due to their SJIA. Assuming a 5-day school week and 36 school weeks per year, this equated to 10% yearly schooling loss. SJIA caused patients’ siblings to miss a mean 0.3 days of school in the past two months. CONCLUSIONS: SJIA families experience reduced school and work productivity. There is a need for effective therapeutic interventions which are not burdensome and limit disruption on SJIA families’ lives.

PSY96: THE IMPACT OF OBESITY AND DEPRIVATION ON HRQOL GAINS FOLLOWING HIP AND KNEE REPLACEMENTS

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OBJECTIVES: Obesity and deprivation have been shown to negatively impact HRQoL. This research aimed to
PSY97: HEALTH RELATED QUALITY OF LIFE FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) PATIENTS AND CAREGIVERS ON BIOLOGIC THERAPY, FROM A CAREGIVER’S PERSPECTIVE.


OBJECTIVES: To evaluate the impact of SJIA on patient and caregiver health related quality of life (HRQoL), from the caregiver’s perspective, based on an international, non-interventional study. METHODS: This study assessed the physical, mental and stress impact associated with SJIA on the caregiver and patient, from the caregiver’s perspective, using the following validated outcome measures: Child Health Questionnaire Parent-Form 50 (CHQ-PF50) for the child and 36-Item Short-Form Health Survey (SF-36v2) for the caregiver. The physical and mental component scores were compared to US population norms. Eligible patients had received biologic treatment for ≥2 months. RESULTS: Sixty-one biologic treated children were included. The mean (±SD: standard deviation) CHQ PF-50 physical (PhS) and psychosocial (PsS) summary scores in children with SJIA compared to the US normative population were significantly lower, by a large (>0.8 SD) and moderately large (>0.5 SD) effect size, (PhS: 40.0±18.2 vs. 53.0±8.8; PsS: 46.6±11.3 vs. 51.2±9.1), respectively. Caregivers displayed a mean SF-36v2 physical component score higher than a normative US population, although their mean mental component score was significantly lower than the US normative population, by a small effect size (>0.3 SD), (MCS 46.2±10.7 vs. 50.0±10). The most frequent and high cause of stress for SJIA caregivers were: ‘worry about the long-term impact of their child’s SJIA’ (45%); ‘uncertainty about the future of their child, family and themselves, due to their child’s SJIA’ (28%); ‘uncertainty about their child’s ability to become fully independent as an adult’ (27%) and ‘feeling helpless about their child’s SJIA’ (24%). CONCLUSIONS: SJIA has a significant impact on both the child and caregivers’ HRQoL. SJIA patients’ physical HRQoL was severely impaired and their psychosocial health impaired to a small degree. Caregivers were physically healthy but displayed mental HRQoL impairment.

PSY98: A PREDICTIVE MODEL TO INCLUDE UNCERTAINTY IN MEAN HEALTH UTILITIES ESTIMATION: IMPACT OF SOCIAL CLASS, BODY MASS INDEX AND CHRONIC DISEASES.


OBJECTIVES: Including second order uncertainty for utility values when building cost-effectiveness modelling is challenging due to its odds distribution. Our approach enables including uncertainty related to the effect of sociodemographic characteristics or chronic conditions on mean utilities included as input in different models. METHODS: In Spain, the EQ-5D-5L was incorporated in the National Health Survey carried out between...
OBJECTIVES: Light chain (AL) amyloidosis is a rare disease characterized by misfolded protein deposits in tissues and vital organs. This study examines whether health-related quality of life (HRQoL) is associated with the work productivity and impairment of patients with AL amyloidosis. METHODS: An online survey was administered to patients with AL amyloidosis (N = 341) from the United States, Europe, and other countries to assess HRQoL and work impairment. The Work Productivity and Activity Impairment: Specific Health Problem (WPAI:SHP) questionnaire was used to assess disease-related Absenteeism; Presenteeism (i.e., impairment at work); and Productivity Loss (i.e., overall work impairment) among employed patients (n=108). Employed patients were classified into two groups ("No Impact" = 0% or "Impact" > 0%) based on their scores for each WPAI scale. HRQoL was assessed with the SF-36v2® Health Survey Physical and Mental Component Summary Scores (PCS, MCS), and the Medical Outcomes Study (MOS) Sleep Scale-6R. Cross-sectional associations between HRQoL and the dichotomous WPAI impact measures were analyzed using separate multivariable logistic models. Odds ratios were interpreted in terms of 5 point decrements in HRQoL scores. RESULTS: Based on multivariable models, HRQoL scores were associated with all WPAI outcomes (p < 0.05). While associations between PCS and each WPAI outcome were fairly similar (ORs ranged from 1.80 to 1.90), MCS was more closely related to Presenteeism (OR=2.19) than Absenteeism (OR=1.28). Five-point lower MCS and Sleep Index scores more than doubled the odds of Productivity Loss (OR=2.16 and 2.28, respectively); whereas, a five-point lower PCS score had a slightly lower impact (80% greater odds of Productivity Loss, OR=1.85). CONCLUSIONS: Physical and mental impairments, as well as sleep problems, are associated with loss of overall work productivity. HRQoL measures are good indicators for understanding the impact of AL amyloidosis on patients’ work productivity and impairment.

OBJECTIVES: Light chain (AL) amyloidosis is a serious, complex disease that is associated with a high degree of humanistic burden and morbidity. We investigated whether health-related quality of life (HRQoL) was prospectively associated with rates of emergency room (ER) visits and hospitalization, independent of other patient characteristics. METHODS: The analysis sample included patients with AL amyloidosis (n=184) from the United States, Europe, and other countries who completed three online surveys (i.e. initial, six month and twelve month follow-up) in a non-interventional, longitudinal online study. Negative binomial regression models were used to examine the association between baseline HRQoL scores (SF-36v2® Health Survey physical and mental component (PCS, MCS) summary scores) and the number (cumulative counts across both follow-ups) of ER visits and hospitalizations. Incident rate ratios (IRR) were interpreted in terms of 5 point decrements in HRQoL scores. RESULTS: A five-point lower PCS score was associated with a 54% greater rate of ER visits (p < 0.001) and a 35% greater rate of hospitalizations (p < 0.001). A five-point lower MCS score was associated with a 29% greater rate of ER visits (p < 0.001) and a 34% greater rate of hospitalizations (p < 0.001). CONCLUSIONS: Both physical and mental HRQoL impairment were significantly associated with increased rates of ER visits and hospitalizations, independent of other patient characteristics. Scores from patient-reported HRQoL surveys may serve as a proxy for disease severity and prognosis for the prediction of future ER visits and hospitalizations. Elucidating the magnitude of
healthcare resource utilization in AL amyloidosis provides clinicians, scientists, and regulators an understanding of the burden of disease that these patients experience.

**PSY101: RARE DISEASES, ARE CAREGIVERS JUST AS AFFECTED AS PATIENTS?**

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**OBJECTIVES:** Research on rare diseases from the patient perspective is limited; however, research into the impact on parental caregivers of affected individuals is even more limited. The aim of this study was to gather evidence to explore the impact of caring for an individual with a rare disease. **METHODS:** An informal literature review was conducted to identify studies exploring the impact of caring for somebody with a rare disease. Evidence from these studies was used to establish an overview of the impact of living with an individual(s) with a rare disease. **RESULTS:** The published studies represented input from caregivers of patients with over 100 rare diseases. Common themes emerged across the disease areas representing multiple domains of quality of life (QoL). Caregivers reported considerable emotional impacts including anxiety, depression and feelings of guilt associated with hereditary diseases. Social impacts for caregivers included reduced social participation, limited social support networks, and affected relationships with partners, other children and family members. Caregivers also reported experiencing limited expert disease knowledge from healthcare professionals. The reduced ability to work was a common area of concern for caregivers as were the financial impacts associated with caring for an individual with a rare disease. Caregivers own physical health is impacted due to the care needs of their child. As well as the direct impact to the caregiver; caregiver burden contributes to the overall cost of an individual’s disease. Estimates within the literature of the monetary impact of caring for an individual with a rare disease ranges up 31% of the total cost of illness. **CONCLUSIONS:** Caring for an individual with a rare disease represents considerable personal impact. The associated societal costs contribute to the overall cost of illness. This information is important when considering the benefits of new treatments but also the cost and value of these treatments.

**PSY102: MEASURING QUALITY OF LIFE IN INFANTS AND CHILDREN WITH SPINAL MUSCULAR ATROPHY: A SYSTEMATIC LITERATURE REVIEW**

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**OBJECTIVES:** SMA is a rare, hereditary, autosomal recessive neuromuscular disorder that in its most severe forms impacts infants and children. Once symptomatic, it is characterized clinically by a distinct inability to achieve motor milestones, such as the ability to lift the head, sit, stand, or walk. The disease presentation varies widely in both age of onset and severity of symptoms. As standard of care evolves, appropriate tools must be available to accurately capture changes in quality of life (QOL) to improve treatment. QOL measurement in very young infants presents a particular challenge. Therefore, this review aims to highlight commonly used measurement tools and identifies future research opportunities for QOL measurement in SMA. **METHODS:** This review focused on the various tools used to measure QOL in children <18 years of age with formally diagnosed SMA (Type I, II or III). An assessment of the measurement tools was undertaken based on a set of criteria relating to validity and perspective. **RESULTS:** The review identified a range of generic and therapy specific QOL measurement tools. The PedsQL was the most commonly utilized tool to measure QOL in children; this included the generic and neuromuscular modules. No disease specific tool to capture QOL in children with SMA was identified. Additionally, no measurement tools exist for very young infants (i.e. under 12 months) with SMA Type 1. **CONCLUSIONS:** Evolving standards of care will lead to increased interest by stakeholders, not least HTA bodies/payers, on the methods used to measure quality of life in infants and children across all types of SMA. The evolving natural history of SMA requires an approach which captures the SMA disease continuum within and across SMA disease phenotypology. Generic tools may not adequately capture QOL changes in SMA. Further research is required to explore the scope for a disease focused approach.

**SYSTEMIC DISORDERS/CONDITIONS - Health Care Use & Policy Studies**

**PSY104: REGIONAL VARIATIONS IN APPRAISAL AND UPTAKE OF NEW TREATMENTS FOR ULTRA RARE DISEASES IN THE UK: A CASE STUDY OF ATALUREN FOR NONSENSE MUTATION DUCHENNE MUSCULAR DYSTROPHY (nMDD)**

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**OBJECTIVES:** NICE Highly Specialised Technology guidance only applies to England, which represents 80% of the
UK population. We describe regional variations in gaining reimbursement for the estimated 70 nmDMD UK patients eligible for ataluren. METHODS: We review the appraisal processes used to evaluate the clinical and cost-effectiveness of ataluren and the associated timelines to reimbursement and patient access. RESULTS: Applications for reimbursement were made to England, Scotland, Wales, Northern Ireland (NI) and the Isle of Man. Detailed dossiers were submitted to NICE and SMC following different templates and requirements. EMA conditional marketing authorisation was granted in July 2014. Over a year later, the first patient received NHS-funded ataluren in Scotland via an Individual Patient Treatment Request. Individual funding requests elsewhere in the UK were unsuccessful. Following patient and political lobbying over a 13-month review, final positive NICE guidance for England was published under the conditions of a multi-stakeholder 5-year Managed Access Agreement between PTC, NICE, NHS England, the NorthStar clinician network, and the patient associations Muscular Dystrophy UK and Action Duchenne. NI and Wales endorsed NICE guidance under a patient access scheme (PAS). Despite negative SMC guidance following a shorter 5-month appraisal process, patient and political lobbying contributed to ataluren being reimbursed in Scotland with a PAS. CONCLUSIONS: Market access in the UK does not start and stop at NICE or SMC. Through the different formal submission processes, patient and political lobbying were instrumental in achieving reimbursement outcomes across the UK. Many regions do not have fit-for-purpose processes for assessing products for ultra-rare conditions, as recognised by the recent Montgomery review in Scotland. The decision-making power of NICE and SMC in reviewing high-cost first-in-class ultra-orphan treatments is no longer clear in a regulatory and reimbursement environment where EMA assesses safety and efficacy whilst the NHS assesses willingness to pay.

**PSY105: DIAGNOSIS OF PATIENTS WITH DUCHEENNE MUSCULAR DYSTROPHY (DMD): RESULTS FROM A GLOBAL SURVEY OF HEALTHCARE PROVIDERS FROM NINE COUNTRIES**

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OBJECTIVES: Evaluate the practice patterns associated with diagnosis of DMD in routine clinical practice settings across nine countries. METHODS: A quantitative survey was implemented in May 2017 in the U.S, Europe5 (Germany/France/Italy/Spain/UK), Turkey, Colombia, and Brazil among specialists treating a minimum threshold of DMD patients; physicians must have been in practice between 2-35yrs and spend >=25% of time in direct patient care. Fifty-minute survey (in local language) captured physician/site characteristics, dynamics of patient diagnostics, genetic testing, besides perceptions of early intervention and disease management, as well as specific DMD treatment attributes and stakeholder interactions. Descriptive statistics were computed. RESULTS: Preliminary analysis included 170 physicians (pediatric neurologist:51.8%; neuromuscular specialist:28.2%; adult neurologist:12.4%; duration in practice:16.5yrs; US:24.7%, Europe5:45.3%, Turkey:7.6%, Colombia:3.8%, Brazil:13.5%); 80.6% and 80.0% of physicians were affiliated with muscle centers and hospitals, respectively. Mean number of DMD patients in each practice:43.0; >90% were managed jointly by multiple healthcare providers (HCPs). In respective clinical practices, 72.0% of patients were diagnosed by the physicians themselves who were participating in this study and the rest by other specialties/HCP counterparts. Mean patient age when family first began noticing symptoms: 34.7months (SD:24.1months), when physician first became aware of these symptoms: 42.3months (SD:27.9months), and when DMD diagnosis was confirmed: 53.9months (SD:30.3months). 67.1% of patients received genetic testing to diagnose DMD: 82.3% and 58.2% received serum CK testing and muscle biopsy, respectively. Top3 reasons for not doing genetic testing were: reliance on results from other tests (e.g. serum CK, muscle biopsy), lack of reimbursement or insurance coverage, and family unwilling or uninterested. CONCLUSIONS: There is delay between the time parents of DMD patients first become aware of symptoms and when the DMD diagnosis is confirmed. One-third of the patients did not receive genetic testing for various reasons. Implications of these practice patterns on patient management and outcomes warrants scrutiny.

**PSY106: RISK FACTORS AND DIAGNOSIS OF NONTUBERCULOUS MYCOBACTERIAL LUNG DISEASE (NTMLD) IN INCIDENT COHORTS OF BRONCHIECTASIS (BE) AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN A NATIONAL US MANAGED CARE INSURANCE PLAN.**

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OBJECTIVES: NTMLD is rare, but representation in individuals with BE or COPD is increased. This study evaluated the risks and factors that may impact occurrence of NTMLD in patients with incident BE or COPD. METHODS: Individuals from a US care plan with claims (2008-2015) for BE (n=15,238) or COPD (n=562,136), were retained. They had 12 months (baseline) of coverage and a BE (no previous COPD or NTMLD) or COPD (no previous BE or NTMLD) claim. NTMLD was defined as ≥2 medical claims ≥30 days apart. NTMLD incidence was estimated using Poisson regression; time to NTMLD from first BE or COPD claim was estimated using Cox regression. RESULTS: Mean age (64 vs. 58 years), percentage of women (63% vs. 55%), and comorbidity were
higher for BE than COPD. Baseline claims for asthma, cancer, cystic fibrosis, gastroesophageal reflux disease (GERD), valve disease, hyperlipidemia, hypertension, immunosuppressant use, organ transplant, pneumonia, and rheumatoid disease were more numerous for BE. Claims for current tobacco use were more for COPD. NTMLD diagnosis rate for BE vs. COPD was 9.13 vs. 0.24/1000 person-years. Adjusted risk of NTMLD was 28× higher for BE (P<0.001). NTMLD risk increased 50% for every additional 20 years of age in both cohorts and was associated with female gender, aspergillosis, cystic fibrosis, immunosuppressant use, immune system disorder, moderate or severe liver disease, and tuberculosis. Congestive heart failure (CHF), dementia, diabetes, hypertension, obesity, and current tobacco use were associated with a lower rate of NTMLD diagnosis in the BE cohort. CONCLUSIONS: NTMLD risk in the incident BE cohort was 28× that in the COPD cohort. Multiple factors are related to increased NTMLD risk after diagnosis of BE or COPD. A combination of BE and CHF, GERD, or valve disease was associated with lower rates of NTMLD diagnosis, possibly due to a masking effect.

PSY107: ACHIEVING KEY OBJECTIVES IN RARE DISEASES HEALTHCARE POLICY IN SPAIN: CONTRIBUTION FROM A DRAVET SYNDROME WORKING GROUP

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OBJECTIVES: Elucidate main unmet needs for Dravet Syndrome (DS) in Spain, and propose actions that could contribute to meeting key healthcare (HC) objectives from the Spanish National Strategy for Rare Diseases (RRDD). METHODS: Literature review from international (i.e. Pubmed, Google Scholar and Cochrane) and national (i.e. Medes) sources. Information obtained was complemented and validated through interviews with 8 Spanish experts in DS management and later used to establish a two round-consultation Delphi study including 19 specialists (9 neuro-paediatricians, 9 neurologists/epileptologists and 1 primary care physician) from 17 different centres spread across 7 regions. Validation of results via an Advisory Board meeting including 10 specialists (7 neuro-paediatricians and 3 neurologists/epileptologists) in DS in Spain. RESULTS: Key needs for DS in Spain were identified as: 1) Robust epidemiological data; 2) Consensus for patient diagnosis and management; 3) Training of HC professionals; 4) Agility for genetic testing; 5) Better disease awareness; 6) Disease continuum management (paediatric to adulthood) and 7) Availability of more effective treatments. Actions were proposed, including: 1) Performing an epidemiological study; 2) Generate a national consensus paper later incorporated at regional and hospital level; 3) Establish a validated training programme for PC and ER paediatricians to improve prognosis and outcomes; 4) Revisit timely access to and results from genetic testing; 5) Develop a disease severity model including quality of life aspects; 6) Impulse a best practice framework for patient derivation and 7) Continue efforts in development, approval and timely access to new treatments. CONCLUSIONS: Identified priorities are fully aligned with the 7 strategic lines within the Spanish NHS Strategic Plan for RRDD. Execution of proposed actions by DS experts can effectively contribute to the achievement of specific objectives identified in the RRDD Strategy Follow-up Report, all of which have been reported as “initiated” or “partially completed” to date.

PSY108: MANAGEMENT OF DUCHEINNE MUSCULAR DYSTROPHY (DMD): RESULTS FROM A GLOBAL SURVEY OF HEALTHCARE PROVIDERS FROM NINE COUNTRIES

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OBJECTIVES: Assess the physician perception and dynamics of management of patients with DMD. METHODS: A quantitative survey was implemented in May 2017 in the U.S, Europe (Germany/France/Italy/Spain/UK), Turkey, Colombia, Brazil among specialists treating a minimum threshold of DMD patients; physicians must have been in practice between 2-35yrs and spent >=25% of time in direct patient care. Fifty-minute survey (in local languages) captured physicians/site characteristics, perceptions of early intervention and disease management, as well as the dynamics of patient diagnostics, genetic testing, specific DMD treatment attributes and stakeholder interactions. Descriptive statistics were computed. RESULTS: Preliminary analysis included 170 physicians (pediatric neurologist: 51.8%; neuromuscular specialist: 28.2%; adult neurologist: 12.4%; US: 24.7%, Europe5: 45.3%, Turkey: 7.6%, Colombia: 8.8%, Brazil: 13.5%) completing the survey. Mean number of DMD patients in practice: 43.0, mean number of patients personally managed within previous12mo: 26.9; 80.6% & 80.0% physicians were affiliated with muscle centers and hospitals, respectively. Physicians used diverse pathways to treat DMD patients (not mutually-exclusive): Physical therapy/rehabilitation (92.9%), pulmonary/respiratory care (92.4%), orthopedic/orthotics (86.5%), prescription medications (84.1%), symptom management/supportive care (82.9%), cardiac care (81.8%), scoliosis management (60.0%), nutritional/vitamins (76.5%), psychological (74.1%), palliative care (48.2%). Key physician perceptions of DMD management (rated >=5 on a likert scale of 1(strongly-disagree)-7(strongly-agree)): preserving functionality at all stages of disease is key (91.2%), delaying loss of ambulation is a meaningful outcome (90.6%), pressing need for earlier detection of DMD (87.7%) and earlier start of treatment (86.5%), early diagnosis/treatment could meaningfully delay irreversible muscle damage (84.5%); 84.1% discussed genetic-test results with patients;
68.8%, 57.7% and 42.9% reported using timed function tests, 6-minute walk test and north star ambulatory assessment to measure disease progression, respectively. **CONCLUSIONS:** This cohort of physicians highlighted the diversity in DMD disease management. Majority of physicians highlighted the importance of early DMD diagnosis/treatment, preserving functionality and delay loss of ambulation.

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**PSY110:** **ECONOMIC EVALUATION AND COST-EFFECTIVENESS THRESHOLD IN PRACTICE OF DECISION-MAKING ON ORPHAN DRUG REIMBURSEMENT IN POLAND**

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**OBJECTIVES:** Use of economic evaluations and cost-effectiveness thresholds for orphan drugs raise concerns and discussions worldwide. Orphan drugs undergo a full pharmacoeconomic evaluation and assessment in Poland. The goal of this study was to find out how important the reimbursement criterion of cost-effectiveness threshold (3xGDP per capita for QALY/LYG gained) is in case of orphan drugs in Poland. **METHODS:** Documents published by the Agency for Health Technology Assessment and Tariff System (AHTAPol) and Minister of Health (MoH), pertaining to all orphan drugs considered for reimbursement between 2015 and 2016, were analysed. Inferences from published sources were used when ICUR values (cost-effectiveness indicators) were not disclosed due to confidentiality. **RESULTS:** ICUR value was calculated in 30 cases out of 32 orphan drug reimbursement applications. Positive recommendations of AHTAPol’s President (RAP) were issued for 30% of cost-ineffective cases. Negative RAP were issued for 13% of cost-effective cases. Positive MoH’s reimbursement decisions were issued for 33% of cost-ineffective cases, while 17% of cost-effective cases did not receive positive MoH reimbursement decisions. Risk sharing schemes (RSS) were proposed in 22 applications, of which 13 cases assessed by AHTAPol’s President were found as insufficient. For 10 applications, RSS were not proposed (for 7 of them AHTAPol’s President suggested necessity of RSS). The main reasons for negative RAP in cost-effective cases included lack of evidence of clinical effectiveness and uncertainty of estimations. The main reasons for positive RAP in cost-ineffective cases included limited therapeutic options, the only therapy available and proven clinical-effectiveness. **CONCLUSIONS:** Despite existence of formal cost-effectiveness threshold and no special formal approach to reimbursement of orphan drugs, results of pharmacoeconomic analysis do not determine final reimbursement decisions in Poland. Cost-effectiveness cannot be considered as a crucial criterion in decision-making on orphan drug reimbursement in Poland.

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**PSY110:** **APPLICATION OF MULTI-CRITERIA DECISION ANALYSIS (MCDA) TO DETERMINE THE VALUE OF TREATMENTS FOR THE MODERATE TO SEVERE PLACQUE PSORIASIS IN SPAIN.**

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**OBJECTIVES:** To evaluate the value of a new treatment of moderate-severe plaque psoriasis, Ixekizumab, compared to the main therapeutic alternatives through MCDA. **METHODS:** Available evidence of Ixekizumab as well as its therapeutic alternatives in the same indication: Evaluations of the Hospital Genesis Group, guidelines of clinical practice, public document of European evaluation (EPAR) and other evaluations for Societies and Institutions in Spain. EVIDEM framework weighted by a total of 45 national and regional evaluators in Spain was used. Evidence Matrix were scored by a panel of 5 experts; 2 hospital pharmacists, 1 regional payer, 1 psoriasis expert and 1 patient representative. **RESULTS:** Moderate-severe plaque psoriasis was perceived as a disease of moderate severity, affecting a large population size and with some unmet needs. In case of comparative efficacy/effectiveness (PASI90 and PASI100) and patient-perceived health (including posology and quality of life) Ixekizumab was perceived as a value option in front of its comparators. Comparative safety and tolerability was perceived as similar for all the alternatives. Regarding, the therapeutic benefit, Ixekizumab was considered as a drug able to add value. The proposed cost of Ixekizumab, other medical costs, and also of non-medical costs, in general, were considered as positive. The global value contribution of Ixekizumab, compared with its comparators were: secukinumab (0.36), ustekinumab (0.38), etanercept (0.44) and adalimumab (0.45). **CONCLUSIONS:** The MCDA has demonstrated that it is a useful tool to compare the value of the several treatments in Psoriasis. Ixekizumab would be perceived as a valuable option in the treatment of moderate-severe plaque psoriasis compared with current alternative treatment. The main contribution of value would be based on its therapeutic benefit and efficacy (measured in terms of a response to PASI90 and PASI100 and maintenance of a long term), also valued because the easy posology and quality of life data.

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**PSY111:** **THE PRACTICE OF DECISION-MAKING OF PUBLIC HEALTH AUTHORITIES IN POLAND ON REIMBURSEMENT OF ORPHAN DRUGS**
**PSY112: ACCESS AND REIMBURSEMENT FOR EMERGING NEUROPATHIC PAIN AGENTS IN THE EU5: AVOIDING THE STING OF LOW-COST COMPETITION AND TIGHTENING BUDGETS**

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**OBJECTIVES:** This research examines access and reimbursement challenges for emerging neuropathic pain (NP) agents in the EU5 (France, Germany, Italy, Spain, UK) given rising disease prevalence, long-available and low-priced analogesics, and growing generic presence in key drug classes. METHODS: Across the EU5, 259 GPs and pain specialists were surveyed regarding their prescribing for NP, while 15 payers who influence reimbursement were interviewed. RESULTS: Interviewed payers demand staunch demonstration of clear clinical benefits from emerging NP therapies, specifying robust efficacy and/or safety improvements over existing standards of care (SOC). Similarly, the largest percentage of surveyed physicians across countries (25-46%) identify efficacy benefit versus SOC as their main driver for prescribing new drugs, followed by safety/tolerability advantages. Notably, payers interviewed consider the profile of emerging antiepileptic mirogabalin not sufficiently differentiated from that of pregabalin (Lyrica), warning that if superior efficacy is not proven, premium pricing and advantageous positioning cannot be justified. This is especially pertinent as our research also reveals that despite ongoing patent protection of pregabalin in NP, availability of generic pregabalin for non-NP indications represents a pricing and uptake barrier for new NP brands given off-label generic use in several EU5 markets. Yet, surveyed physicians’ estimated uptake of mirogabalin is 29-42%, with expected use relatively early in the treatment algorithm. This likely reflects the imprecise nature of prescribing owing to the complex pathology of NP. In addition, physicians cite NP-subtype-specific labeling as an uptake lever, reflecting interviewed payer consensus, which pinpoints NP-subtype-specific labelling as financially advantageous given the smaller patient population versus drugs with a broad pain label. CONCLUSIONS: Optimal access and reimbursement are achievable for emerging NP agents that showcase superiority over SOC. Targeting NP/NP subtypes specifically would curry favor among payers due to reduced budgetary impact, and could encourage uptake over more-broadly labelled alternatives which may not target key mechanisms underlying neuropathy.

**PSY113: A REVIEW OF METHODOLOGY AND RESPONSE TO IQWIG REPORT “TREATMENT OF HAEMOPHILIA PATIENTS”**

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**OBJECTIVES:** In May 2015, the German Institute for Quality and Efficiency in Health Care (IQWiG) published an assessment of treatment for haemophilia patients. The aims of the report were: 1) to map current evidence pertaining to long-term factor treatment of patients with severe haemophilia (SH); 2) to conduct a benefit assessment of prophylactic versus on-demand treatment strategy in the continuous treatment of patients with SH, with morbidity and health-related quality of life (HRQoL) as specified endpoints; and 3) to investigate the extent to which guidelines for
the continuous treatment of patients with SH in Germany are based on current evidence. METHODS: A critical review of the report scope and methodology, with an analysis of pre-existing data from an observational burden of illness study in Germany and other European countries (CHESS), in order to showcase the utility of ‘real world’ data in healthcare policy design. RESULTS: The report and supporting research were comprehensive yet limiting in their exclusion of studies undertaken outside of a clinical trial setting. Several endpoints could not be evaluated due to insufficient evidence. Outcomes associated with primary (lifelong) and secondary prophylaxis (PPX/SPX) regimens were not differentiated, despite studied differences in outcomes between the two approaches. Neither patient factors (e.g. bleeding phenotype) nor treatment factors (e.g. trough levels) were considered in the assessment. In contrast to the report’s conclusions, patients receiving PPX within CHESS reported significantly higher HRQOL, lower bleed frequency, fewer areas of chronic synovitis, and reduced pain versus on-demand and SPX. CONCLUSIONS: The IQWiG report methodology provides a limited approach, particularly in the evaluation of treatments for rare diseases, as reflected in the assessment of prophylaxis and on-demand treatment in SH. A more pragmatic approach to evidence collation, in which the idiosyncrasies of this rare disease may be effectively captured, is recommended for future evaluations.

**PSY114: TIME TO ACCESS: TOO FAST, TOO SLOW, OR JUST RIGHT? AN EVOLVING PUBLIC REIMBURSEMENT LANDSCAPE OF DRUGS FOR RARE DISEASES IN CANADA**

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OBJECTIVES: The Canadian public reimbursement landscape has evolved rapidly over the years. One of the major developments was the introduction of the pan-Canadian Pharmaceutical Alliance (pCPA) in 2010. The pCPA conducts joint federal/provincial/territorial negotiations for brand name drugs in Canada to achieve greater value for publicly funded drug programs and patients. The other development is an increasing number of drugs for rare diseases (DRDs) are entering the market. The objective of this study is to determine the impact of the pCPA on the time to reimbursement by Canadian public drug plans on all drugs and DRDs. METHODS: All data were obtained from publically available and proprietary sources. Key metrics included time from regulatory approval to initiation of health technology assessment (HTA), time from HTA submission to recommendation, time from HTA recommendation to pCPA negotiation, time from pCPA negotiation to completion, and time from HTA recommendation to public reimbursement. The later was compared to that of prior to pCPA (i.e., 2004-2009). RESULTS: Time from regulatory approval to initiation of HTA assessment for all drugs have decreased gradually since 2008 but was uneven for DRDs. The length of the HTA process (from submission to recommendation) was consistent over time with the exception of 2014 and 2015 in which record number of submissions were received. The time from HTA recommendation to pCPA negotiation was comparable for all drugs and DRDs. However, DRDs took approximately 1 month longer compared to all drugs to complete pCPA negotiation. Furthermore, across Canada, the time from HTA recommendation to public plan reimbursement for all drugs increased by almost one-third (more than 3 months) when pCPA negotiation was involved. DRDs took an additional one and a half-month to achieve public reimbursement. CONCLUSIONS: pCPA has substantially lengthened the time to reimbursement of important medications in Canada, with DRDs particularly affected.

**PSY115: HOW SHOULD WE VALUE ORPHAN DRUGS? SUGGESTIONS FROM A LARGE PUBLIC OPINION SURVEY**

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OBJECTIVES: While many authors suggested using a multi-criteria approach for orphan drug assessment and proposed a list of determinants of orphan drug value, studies on social preferences regarding these determinants remain limited. The current study aimed at identifying preferences of the French general population regarding a number of determinants in a discrete choice experiment. METHODS: The list of attributes was formed based on a literature search and was refined through expert interviews, a focus group, and a pilot study. The final list included nine attributes: disease disability and mortality, number of patients, availability of alternative treatments, treatment impact on disease disability and survival, treatment safety, uncertainty around therapeutic effect, and annual treatment cost per patient. Participants were presented with 12 questions containing two drugs profiles described according to the attributes and were asked to choose one (or none) treatment. The questionnaire was distributed using a web platform. A conditional logit model was used for statistical analyses and included all attributes and a dummy variable corresponding to a choice of none treatment. An interaction between the number of patients and per patient cost was tested. RESULTS: A total of 958 persons participated in the study. The highest estimate weight was observed for treatment impact (p<0.0001) on survival and uncertainty around therapeutic effect (p<0.0001). Participants were also sensitive to the availability of alternative treatments (p=0.0014), treatment safety (p<0.0001) and impact on disability (p<0.0001), disease mortality (p<0.0001). Participant preferred more prevalent diseases
study was to perform multicriteria decision analysis (MCDA) to evaluate various aspects of a medicament providing of

OBJECTIVES: Technologies, Moscow National

Krysanova V1, Krysanov I2, Ermakova V1, Sechenov University, Moscow, Russia, Institute of Medical and Social Technologies, Moscow National University of Food Production, Moscow, Russia

OBJECTIVES: Orphan diseases such as Huntington's disease (HD), a progressive neurodegenerative disorder, have significant impact on patients and their families, as well as the healthcare systems and societies. The main aim of this study was to perform multicriteria decision analysis (MCDA) to evaluate various aspects of a medicament providing of

( p<0.0001). Although the interaction between the number of patients and per patient cost was significant ( p<0.0001), the trend in preferences toward lower per patient costs was not observed. CONCLUSIONS: The society does not seem to support drugs for less prevalent diseases and to be aware about drug pricing in general. Should special measures for orphan drugs be introduced, education on their necessity is needed.

PSY116: ORPHAN DRUGS IN FRANCE: KEY MARKET ACCESS INCENTIVES

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OBJECTIVES: In Europe, an orphan disease is defined by a prevalence of less than 5 in 10 000 inhabitants which represent a maximum target population of 30 000 patients in France. Economic incentives are set up by authorities to encourage pharmaceutical development in rare disease treatments. This analysis aims at exploring French stakeholders’ policy toward orphan drugs on both Transparency Committee (TC) assessment and pricing decisions. METHODS: All non-oncologic orphan drugs listed between 2006 and 2016 were identified. TC opinion (study design, comparator, target population) and price evolution were analyzed for each drug. First, results were compared to data for all drugs assessed in 2015, when available. Then, orphan drugs were clustered in two periods of time (2006-2010 and 2011-2016) in order to describe variations on assessment and price lifecycle. RESULTS: 53 orphan drugs were analyzed on two main items: HTA assessment and price evolution. 40% of orphan drugs received an ASMR I to III (high to moderate improved clinical benefit) from TC from 2006 to 2016 versus 3% among drugs of all types (2015). From 2006 to 2010, the rate of ASMR I to III among orphan drugs reached 57% versus 29% between 2011 and 2016. Application process time for orphan drugs from publication of TC opinion to price release is similar between the two periods. First price reduction for orphan drugs occurred in average 4.7 years after price release regardless of ASMR level. In general, 5 years price stability is known to be granted only for products with ASMR I to III. CONCLUSIONS: In France, orphan drugs seem to benefit from a more favorable market access vis-a-vis drugs of all types regarding price evolution and HTA assessment. However, a strengthening of TC doctrine seems to emerge in the 5 past years despite similar level of demonstration.

PSY117: CRITICAL ASSESSMENT OF ATMP MARKET ACCESS OUTCOMES ON A NATIONAL-LEVEL ACROSS EU5 COUNTRIES

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OBJECTIVES: Advanced therapy medical products (ATMPs) pose specific pricing, reimbursement and market access considerations. The aim of this research is to review ATMP assessments by EU HTA bodies to understand key drivers for securing adoption. METHODS: HTA websites from France (HAS), Germany (IQWiG/G-BA), Italy (AIFA and regions), Spain (MSSSI and regions) and the UK (NICE, SMC) were searched. Targeted reviews of journal publications, policy documents and grey literature were also performed. RESULTS: Provenge was withdrawn from the EU in May 2015, ChondroCelect in 2016 and Glybera is due to be withdrawn in October 2017. At HTA-level, in Germany, Glybera, Holoclar, Imlygic and Strimvelis all went through the AMNOG process. Glybera gained an ‘unquantifiable’ benefit as submitted clinical data were not supportive of medical benefit. Reimbursement was later gained through insurers following reclassification to a tissue engineered product (TEP), putting Glybera outside of the AMNOG process. Imlygic obtained an ‘unquantifiable’ outcome as the G-BA considered the choice of comparator (GM-CSF) to be wrong. Strimvelis is still being assessed. ChondroCelect, Glybera and Holoclar were assessed by HAS; ChondroCelect was rejected because of a lack of demonstrated efficacy in clinically recognized trial outcomes. Glybera was awarded an ‘insufficient’ ASMR because of uncertainties around short to medium term safety, and the inability to re-administer after initial treatment. Holoclar achieved an ASMR IV for minor added benefit in a condition with high unmet need. CONCLUSIONS: Comments from HAS on the lack of recognizable clinical outcomes, and reclassification of Glybera in Germany to a TEP, demonstrates that national HTA process are not yet adapted to the early clinical datasets and novel outcome measures that ATMPs utilise. These products require new approaches to assessing value, and so strong value stories that educate on ATMPs being the solution for burdensome conditions, will be key to future success.

PSY118: THE MULTICRITERIA DECISION ANALYSIS OF USING TETRABENAZINE FOR PATIENTS WITH HUNTINGTON'S DISEASE IN RUSSIA

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OBJECTIVES: Orphan diseases such as Huntington’s disease (HD), a progressive neurodegenerative disorder, have significant impact on patients and their families, as well as the healthcare systems and societies. The main aim of this study was to perform multicriteria decision analysis (MCDA) to evaluate various aspects of a medicament providing of

p<0.0001). Although the interaction between the number of patients and per patient cost was significant (p<0.0001), the trend in preferences toward lower per patient costs was not observed. CONCLUSIONS: The society does not seem to support drugs for less prevalent diseases and to be aware about drug pricing in general. Should special measures for orphan drugs be introduced, education on their necessity is needed.
tetabenzine (TBZ) for patients with HD. METHODS: Analysis of the published clinical trials was conducted to evaluate efficacy and safety of using TBZ for patients with HD. The initial list of value attributes (5 - impact of rare disease and 5 - impact of the drug) was identified from a literature review and expert’s survey. Further experts assigned relative weights to the attributes in 2 groups (the rating scale ranged from 1 (less important) to 5 (most importantly)). Then experts rated TBZ against each attribute (the rating scale ranged from 1 (worst score) to 7 (best score)). In the end weighted score for each attribute was identified. RESULTS: Experts considered that the most important attributes are the impact of disease (scores 27.3 versus 24.7). In the both groups the most important attribute was evidence of treatment clinical efficacy and patient clinical outcome (scores 8.67 and 6.00). A total weighted score for attributes of the disease was 85.78, and for attributes of the impact of the drug — 78.67. CONCLUSIONS: All experts agreed to give slightly more weight to the attributes of the disease than to the impact of the drug. The present study was the first experience of conducting MCDA for HD. This analysis showed the importance of the different kinds of aspects in deciding on funding drug supply patients with HD.

**PSY119: TRANSITION FROM ORPHAN DISEASE TO FULL ASSESSMENT IN THE GERMAN AMNOG SYSTEM: KEY LEARNINGS FROM PIONEERS**

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OBJECTIVES: A specific feature of the German HTA process is the relevance of the orphan disease (OD) status. The additional medical benefit of orphan drugs, assessed by the German HTA body (G-BA, Federal Joint Committee) is already acknowledged by approval. Companies are not obliged to present head-to-head data against an appropriate comparator. However, if the revenue per annum exceeds 50 million euros or OD status is lost, reevaluation against an appropriate comparator is mandatory. The aim of this study is to reveal the consequences of reevaluation with regard to acceptance of study data, patient relevant endpoints and extent of additional benefit assigned by G-BA and IQWiG (Institute for Quality and Efficiency in Health Care), respectively. METHODS: A database containing all assessed AMNOG dossiers was screened for dossiers which have been assessed both under orphan and non-orphan conditions. Data on indication, size of target population, the comparator utilized in the company’s dossier, and outcome (added benefit) were collected and analyzed. RESULTS: Since 2011, five former OD drugs were reassessed: ruxolitinib (hematology), pomalidomid, ibrutinib, ramucirumab (oncology), and macitentan (cardiovascular disorders). In four cases, annual revenues had exceeded 50 million euros, and one drug was deprived of the OD designation (ramucirumab). Time between reevaluation ranged from 14 months (ibrutinib) to 32.5 months (macitentan). At initial assessment all drugs obtained an added benefit. After full evaluation four of the five compounds retained an added benefit at least in parts of the population. CONCLUSIONS: The transition from the assessment under OD to non-OD conditions pose a major challenge for companies as the existence of an added medical benefit is no longer preconditioned. Especially since clinical evidence for orphan diseases is limited, companies launching drugs likely to exceed the revenue limit or with uncertain OD status should be aware of the strict assessment criteria for non-orphan drugs.

**PSY120: MARKET SHARE AND SWITCHING DYNAMICS BETWEEN ETANERCEPT AND ITS BIOSIMILAR PRODUCT IN SWEDEN AND GERMANY: A REAL-WORLD PRELIMINARY ANALYSIS**

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OBJECTIVES: To describe the market share and switching dynamics between etanercept innovator (EtnI) and its biosimilar (EtnBS) assessed for rheumatic diseases, in Germany and Sweden. METHODS: Patients receiving rheumatologists’ prescriptions for EtnI and EtnBS in November 2015-March 217 were retrospectively identified using the Swedish Prescription Registry (100% of retail biologic prescriptions) and the QuintilesIMS® German Longitudinal Prescriptions database (LRx, 60% of the German statutory health insurance market). In each country, the monthly proportion of patients on EtnI and EtnBS was recorded. In addition, the monthly proportion of naïve patients and of those switching to EtnBS from prior EtnI or other biologic treatment were evaluated (12-month lookback period), along with the proportion of patients who switched back to EtnI or other biologics after starting EtnBS. RESULTS: Both in Germany and Sweden, the market share of EtnI constantly decreased and that of EtnBS constantly increased after EtnBS was launched. In the month of launch (Germany: February 2016; Sweden: April 2016), the proportion of patients who switched to EtnBS from any biologic treatment was ~100% in Germany and only 22% in Sweden. In the most recent 6 months, this proportion ranged from 41% to 49% in Germany and from 61% to 72% in Sweden. In both countries there was a similar proportion of patients with prior EtnI who switched back to the original EtnI (10% in Germany and 11% in Sweden) or any biologic agents (14% in both countries) after only 75 (Germany) and 55 (Sweden) days of treatment with EtnBS. CONCLUSIONS: Despite the observed differences in
market penetration, we found that both in Germany and Sweden there is a proportion of patients who switch back to the original biologic agent after being moved to EtNB5. Future studies should confirm these results and investigate the reasons for changing back to original biologics.

**PSY121: TREND IN HOSPITAL CASES OF ACQUIRED HEMOPHILIA A (AHA) 2010-2015 IN GERMANY**

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**OBJECTIVES:** Acquired hemophilia A (AHA) is a rare bleeding disorder, caused by autoantibodies against factor VIII. AHA may lead to spontaneous or trauma induced bleeds, treated with bypassing agents. Estimation of UK-incidence was 1.4 per million per year. No German data are available. Since 2010 a specific ICD-10-code for AHA exists. 2010 started major awareness campaigns by pharmaceutical industry. We examined the change in frequency of AHA coding. **METHODS:** Analysis of reports from German DRG-Institute, Statistical Office and hospitals for 2010-2015 for cases of AHA and treatments with high amounts of bypassing agents (APCC > 150.000 units, rFVIIa > 500 mg). Statistical analysis with Microsoft-Excel and Access version 2016. **RESULTS:** The number of cases with a main diagnosis of AHA (D68.31, ICD10-GM) increased from 29 (2010) to 142 (2015, +390%). The mean age of patients (73.4 +/- 15.9 years) and the gender distribution (58% male) remained stable over time. The average length of hospital stay of male patients (25.2 days) was significantly longer than for females (18.4 days). The number of cases with a secondary diagnosis of AHA increased from 186 (2010) to 491 (2015, +164%). The total number of cases in 2015 was 633 (~8 per mio. per year). The increase in cases was not associated with an equivalent growth in treatments with high doses of rFVIIa (108 in 2010, 127 in 2015; +18%) or APCC (66 in 2010, 75 in 2015; +14%). **CONCLUSIONS:** We found an increase in documented hospital cases with AHA from 2010 to 2015. The overall number exceeds the expectation based on previously reported incidence. This may reflect a growing awareness towards AHA and/or under-diagnosis in previous studies. The number of patients intensively treated with bypassing agents grew only little, suggesting that higher awareness may lead to earlier diagnosis and prevention of high costs due to bleeding.

**PSY122: REAL WORLD COMPARISON OF PERSISTENCE AND ADHERENCE AMONG BIOLOGIC NAÏVE PATIENTS INITIATING APREMILAST OR BIOLOGICS FOR THE TREATMENT OF PSORIASIS IN THE UNITED STATES**

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**OBJECTIVES:** To compare adherence and treatment persistence over 12 months among biologic naïve adults initiating apremilast or biologics for the treatment of psoriasis (PsO) in the United States. **METHODS:** Adult PsO patients initiating apremilast or biologics (index date) were identified in the January 2013 - June 2016 Truven Health MarketScan Research Databases. Patients were required to be apremilast/biologic naïve at index; 12 months of pre- and post-index continuous enrollment were required. Biologic users were matched up to 2:1 to apremilast users. Treatment persistence was defined as continuous treatment without (1) a >60-day gap in therapy, or (2) a switch to a different PsO treatment during the 12 month-post-index period. Patients were adherent if their medication possession ratio (MPR) was ≥80% while persistent on the index treatment. **RESULTS:** Matched samples of 703 PsO patients initiating apremilast and 1378 PsO patients initiating biologics were evaluated (mean age 49 years, approximately 50% female, mean Charlson score 0.4). Treatment persistence at 12 months was similar for PsO patients initiating apremilast compared to patients initiating biologics (44.4% vs 44.6%; p=0.914). Patients initiating apremilast were less likely to be non-persistent because of switching (6% vs 11%; p=0.003) and more likely to be non-persistent because of a >60-day gap in therapy (94% vs 89%; p=0.003) compared to patients initiating biologics. Persistence-based MPRs were similar for patients initiating apremilast compared to patients initiating biologics (0.86 vs 0.86; p=0.654) as were adherence rates (73% and 74%; p=0.516). **CONCLUSIONS:** Treatment persistence at 12 months and adherence were similar for biologic naïve PsO patients initiating apremilast or biologics in a large U.S. administrative claims database. Non-persistence due to switching was significantly lower for biologic naïve PsO patients initiating apremilast. Future research should describe the healthcare utilization and cost outcomes associated with these treatments.

**PSY123: A REAL WORD TREATMENT PATTERNS AND TRENDS IN PAINFUL DIABETIC NEUROPATHY AND POSTHERPATIC NEURALGIA**

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OBJECTIVES: The aim of this review is to identify treatment pattern and trends in real world, for painful diabetic neuropathy (PDN) and postherpatic neuralgia (PHN), and to compare them with the current recommended treatment guidelines in the US and UK. METHODS: A narrative review was conducted through searching Embase®, MEDLINE® and Cochrane from 2010 to March 2017. The data from the published studies were compared with clinical guidelines (International Association for the Study of Pain [IASP], European Federation of Neurological Societies [EFNS], National Institute for Health and Care Excellence (NICE) and Canadian guidelines). RESULTS: Of 1,566 citations reviewed, 8 relevant studies (PDN: 3 [US ]; PHN: 4 [3 US and 1 Canada ]; both PDN/PHN: 1 [UK ]) were identified. The included studies utilized data from claims/MarketScan/hospital databases. For PDN, anticonvulsants were the 1st line of choice in the US (48% to 66.6%) and antidepressants in UK (40%); commonest being gabapentin (45%; anticonvulsant) and amitriptyline (38.8%; antidepressant). This is in-line with treatment guidelines. Low adherence (~65- 69%) and high discontinuation (71.7-76.7%) rates were reported for anticonvulsants in the US. For PHN, opioids (49%) were commonly initiated as 1st line in the US (not in-line with guidelines) and antidepressants (39.4%) were commonly initiated as 1st line in the UK (in-line with treatment guidelines). Duration of PHN treatment with opioids (when used in 1st line) was shorter (4.6-28 days) compared to antidepressants (7.5-128 day). The discontinuation rates were high for patients who started with opioids (58%) or antidepressants/anticonvulsants/topicals (54%). CONCLUSIONS: In both the US and UK’s real-world settings, the management of PDN was in accordance with the recommended treatment guidelines. However, the management of PHN was in-line with recommended guidelines in UK, but not in the US (opioids were used as 1st line treatment).

PSY124: MARKET ACCESS OF NINTEDANIB FOR IDIOPATHIC PULMONARY FIBROSIS: A CROSS-COUNTRY REVIEW OF ACCESS CONDITIONS

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OBJECTIVES: Nintedanib (Ofev®) is used to treat adults with Idiopathic Pulmonary Fibrosis (IPF). IPF is a rare disease characterized by the formation of hard fibrous tissue in the lungs, causing persistent cough and severe shortness of breath. Despite treatment, IPF is typically progressive and median survival is 3 years from the time of diagnosis. Since its registration in 2015, nintedanib gained reimbursement in several countries. The aim is this study is to evaluate reimbursement restrictions of nintedanib across several EU Member States. METHODS: A comparative analysis of the reimbursement restrictions of nintedanib was performed across eight EU Member States: Belgium, Denmark, Finland, Greece, Luxembourg, the Netherlands, Portugal and Sweden. Information was gathered on the reimbursement restrictions, the existence of an HTA and the delay between registration and reimbursement. RESULTS: In five countries (DE, GR, LU, PO and SW), nintedanib is reimbursed for all adults with IPF (according to the label), i.e. without further reimbursement restrictions. In Finland, the reimbursement of nintedanib is restricted to patients with a Forced Vital Capacity (FVC) between 50% and 90%. In Belgium and the Netherlands there are strict and specific reimbursement criteria. For example, in Belgium, nintedanib is only reimbursed for non-smoking patients with an FVC above 50% and a DLco above 30%. Furthermore, only a very limited number of experts can prescribe nintedanib. The average delay between the EU registration and the approval for reimbursement amounted to 316 days (min: 127 days – max: 781 days). CONCLUSIONS: Access to nintedanib varies across EU Member States and significant delays in the reimbursement procedure prevent early access for patients. Some national authorities, such as Belgium, impose very strict access conditions. In light of the life-threatening nature of IPF, access restrictions need to be evidence based and should not exclude patients that could potentially benefit from treatment.

PSY125: COMPARISON OF LOW-DOSE LIRAGLUTIDE USE VERSUS OTHER GLP-1 RECEPTOR AGONISTS IN PATIENTS WITHOUT TYPE 2 DIABETES

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OBJECTIVES: The objective was to compare the use of low-dose liraglutide (1.2 and 1.8 mg, L-LD) in patients without a diagnosis for type 2 diabetes (T2D) to the other GLP-1 receptor agonists (GLP-1 RAs, albiglutide, dulaglutide, and exenatide). The hypothesis was that use of L-LD in patients without T2D was significantly greater than for the other marketed GLP-1 RAs in the post-approval period for high-dose liraglutide (3 mg, L-HD) which was approved for obesity in late 2014. METHODS: This cohort study included adult T2D patients with > 1 year of history in the Optum Humedica database and > 1 prescription for a GLP-1 RA between December 2014 and March 2016. Patients with insulin use, type 1 DM, and with prior prescriptions for L-LD and another GLP-1 RA were excluded. The proportions of patients with and without a diagnosis of T2D who were prescribed L-LD versus the other GLP-1 RAs and within each cohort were compared between the first and last months of the study period. RESULTS: A total of
11,245 L-LD patients and 4,134 patients taking the other GLP-1 RAs were identified. The proportion of patients with a prescription for L-LD and without a T2D diagnosis increased from 11.8% (57/485) in December 2014 to 37.5% (325/867) in March 2016 (p<0.0001). During this same period, the proportion of patients prescribed the other GLP-1 RAs without a T2D diagnosis decreased from 8.6% (13/152) to 4.5% (18/399) (p=0.10). The difference between groups in December 2014 was 3.2% (p=0.30) and in March 2016 was 33% (p<0.0001). CONCLUSIONS: Prescribing of L-LD (1.2 and 1.8 mg) in patients without T2D increased 3-fold in the 16 months after launch of L-HD (3 mg) and decreased for the other GLP-1 RAs. Increased payer scrutiny of the use of L-LD is warranted as part of a comprehensive evaluation of reimbursement policies for obesity treatments.

**PSY126: OPIOID UTILIZATION AND COST AMONG ELDERLY AND NON-ELDERLY MEDICARE BENEFICIARIES IN THE UNITED STATES: A STATE-LEVEL COMPARISON**

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**OBJECTIVES:** Medicare is a US federal health insurance program, available for people age 65+, younger people with disabilities and people with End Stage Renal Disease. This research aims to compare opioid utilization and cost among elderly and nonelderly Medicare beneficiaries by state. **METHODS:** This retrospective observational study used data from the de-identified 2015 Medicare Provider Utilization and Payment Data Public Use File, which includes prescription drug utilization and cost for 46 million elderly and 9 million non-elderly Medicare beneficiaries. Opioids were categorized based on Medicare’s Part D Overutilization and Monitoring System. By state, number of standardized 30-day prescriptions for opioids was divided by the total to arrive at percent of 30-day standardized prescriptions for opioids for elderly and non-elderly beneficiaries. The percent of costs spent on opioids was also calculated by state. Correlation coefficients were estimated to measure the strength of the association between opioid use and cost in the elderly and non-elderly. **RESULTS:** Percent of opioid prescriptions to total in the nonelderly ranged from 10.8% in Nevada to 5.0% in New York, and for the elderly from 4.1% in Alaska to 1.7% in New York. Similarly, the percent of costs spent on opioids ranged from 10.8% in Alaska to 3.3% in Hawaii in the nonelderly, and 4.2% in Alaska to 1.2% in New York for the elderly. The correlation was 0.84 (p<.001) between elderly and nonelderly for the percent of opioid prescriptions and 0.82 (p<.001) for the percent of costs spent on opioids. **CONCLUSIONS:** Opioid utilization was more than twice as high in nonelderly than in elderly Medicare beneficiaries. Future research is needed to determine whether there is overutilization in the nonelderly, particularly in states such as Nevada and Alaska, and to examine why states like New York have relatively limited use.

**PSY127: TREND ANALYSIS OF LISTING AND BUDGET IMPACT FOR ORPHAN DRUGS IN KOREA**

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**OBJECTIVES:** Orphan drugs refer to drugs used in rare diseases (~1 in 20,000 persons in Korea) and it is often difficult to be recommended in reimbursement due to lack of evidence. In recent years, some efforts have been made to improve the access of orphan drugs in Korea through P&R schemes such as economic evaluation exemption track. This study aims to estimate the historical trend of orphan drug listing and the annual budget impact of orphan drugs in Korea between 2010 and 2015 and future trend. **METHODS:** Reimbursement list of orphan drugs approved by Korean MFDS was derived to identify the number of orphan drugs situation annually from 2010 to 2015. HIRA claims data (2010–2015) was used to estimate the historical trend of the orphan drugs expenditure and total pharmaceutical expenditure respectively and also future trend analysis. **RESULTS:** Between 2010 and 2015, number of orphan drugs listed have been increased from 91 (88) to 117 (102). Regards to budget impact, expenditure for orphan drug summed up 86 billion KRW (73 million USD) in 2010 and increased to 229 billion KRW (195 million USD) in 2015, representing 0.687-1.646% of total Korean pharmaceutical expenditure. CAGR for orphan drugs (17.7%) are much bigger than those for total Korean pharmaceutical expenditure (1.8%). Assuming linearity, orphan drug expenditure will account for 1.9%–3.4% of total expenditure in the future (2016-2020). **CONCLUSIONS:** Although the number of available orphan drugs are increasing slightly and the budget impact for orphan drugs is quite very small compared to total pharmaceutical expenditure, budget impact of orphan drugs are increasing very fast annually. It seemed due to the impact of some policy to improve the access of orphan drugs in Korea. This study suggests that it might be needed to manage the budget impact of orphan drugs in the future, considering both access of drugs and financial sustainability.

**PSY128: HEALTH CARE RESOURCE UTILIZATION AMONG PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS IN BRAZIL**

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OBJECTIVES: To estimate the healthcare resource utilization (HRU) among moderate-to-severe plaque psoriasis patients in Brazil. METHODS: This was a cross-sectional, observational and multicenter study enrolling Brazilian patients with moderate-to-severe plaque psoriasis. Disease severity was assessed by physicians. Data were collected between December 2015 and November 2016 in 10 specialized centers. HRU was evaluated as the percentage of patients self-reporting their consumption of resources in the last 12 months. Resources consisted of drug treatment, phototherapy, alternative therapies, laboratory and imaging tests, hospitalization, outpatient visits, and emergency visits. Frequency and average consumption were analyzed. RESULTS: The study enrolled 188 patients; mean age at study visit was 48 (±13.1) years. Most of them were female (52.1%), Caucasian/white (68.6%). 30.5% (57/187) of patients reported being treated with biologic agents, 54% (101/187) with conventional systemic drugs and 95.7% (179/187) with topical therapy. 22.3% (42/188) subjects received at least one session of phototherapy and 16/188 patients (8.5%) reported the use of alternative therapies. Among patients who performed tests (n=159), 43.4% underwent imaging tests and 97.5% laboratory tests. Only 4 and 14 patients were hospitalized and needed emergency due to a cause related to psoriasis, respectively. Exacerbation was the main cause for both hospitalization (75.0%) and emergency (50.0%). Dermatologist was the most frequent specialty (98.9%, 178/180) among physicians, with a mean of 5.4 visits per year per patient. Among other healthcare professionals, psychologist was the most frequent (42.5%, 17/40) followed by nutritionist (40%, 16/40). CONCLUSIONS: These findings indicate that although most of moderate to severe psoriasis patients are being treated, only 30% are using biologic agent. Moreover, there is an important HRU among Brazilian moderate-to-severe plaque psoriasis patients, indicating room for improvement in the management of their disease and an economic burden for the society.

PSY129: REAL-WORLD HEALTH CARE EXPENDITURE IN HEMOPHILIA B PATIENTS USING STANDARD AND EXTENDED HALF-LIFE RECOMBINANT FACTOR IX PRODUCTS

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OBJECTIVES: Management of hemophilia B includes replacement of factor IX (FIX) by intravenous infusion. The recent introduction of extended half-life (EHL) FIX products has enabled comparison of health care expenditure and volumes of factor dispensed for hemophilia B patients using either nonacog alfa, a standard half-life (SHL) or eftrenonacog alfa, an EHL FIX product. METHODS: Data from a large, U.S. national specialty pharmacy database (April, 2015 to December, 2016) were used to identify direct expenditures and international units (IUs) dispensed for all patients who used nonacog alfa (SHL group) and/or eftrenonacog alfa (EHL group). The analysis was restricted to severe hemophilia B and prophylactic regimens only. Monthly averages were calculated for each patient considering the months in which the first and last prescriptions occurred, and intervening months. Descriptive statistics were used to analyze results. RESULTS: 151 patients meeting the above criteria were identified. The SHL group and EHL group comprised 101 and 75 patients, respectively; each group included 25 patients who had received both products during the study period. Median monthly average of FIX product dispensation was 26,050 IU (SHL) versus 15,412 IU (EHL) (p< 0.0001). Considerable variability was present in the range of monthly units dispensed in both groups (SHL, IQR 16,218 – 42,406 IU; EHL, IQR 10,897– 25,296IU). Median monthly expenditures were lower in the SHL group, 34,874 USD [IQR = 21,812-57,304] than in the EHL group, 45,673 USD [IQR = 31,621-74,505]; p=0.0031). CONCLUSIONS: Contemporary observations may be tailored through incorporation of clinical parameters into analyses of real-world claims data. This study suggests that contemporary SHL to EHL transitions incur a modest reduction in units dispensed and SHL to EHL transition is associated with increased expenditures. Further real world analyses incorporating larger numbers of patients should be explored.

PSY130: REAL-WORLD HEALTH CARE EXPENDITURE IN HEMOPHILIA A PATIENTS USING STANDARD AND EXTENDED HALF-LIFE RECOMBINANT FACTOR VIII PRODUCTS

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OBJECTIVES: Management of hemophilia A includes replacement of factor VIII (FVIII) by intravenous infusion. The recent introduction of extended half-life (EHL) FVIII products has enabled comparison of health care expenditure and volumes of factor dispensed for hemophilia A patients switching from a standard half-life (SHL) to EHL FVIII product. METHODS: The Truven Health MarketScan® Research US claims databases (Aug 1, 2014 to Jan 31, 2017) were used to identify direct expenditures and international units (IUs) dispensed for all patients who used SHL (SHL group) and/or EHL (EHL group). Data on patients who switched from an SHL to an EHL FVIII product were captured up to one year before and after the switch. Patients with at least 1 pre and post-calendar quarter of claims available were included in the switching analysis. RESULTS: Cross-sectional analysis: In the SHL group (N=415), Six distinct SHL FVIII products were dispensed, with two EHL FVIII products dispensed in the EHL group (N=91). Median FVIII...
product dispensation per calendar quarter was 46,409 IU (IQR, 12,760-87,670 IU) (SHL) versus 67,375 IU (IQR, 50,524-98,264 IU) (EHL). Median expenditures per calendar quarter were higher for EHL ($135,519; IQR, $100,320-186,557) than for SHL ($61,152; IQR, $18,593-115,845). Switching analysis: In the EHL group, 29 patients switched from one of three SHL FVIII products to one of two EHL FVIII products during the study period. Total median IU dispensation per calendar quarter increased following the switch from 58,598 IU (pre-switch, SHL) to 68,036 IU (post-switch, EHL; 16% increase). Factor-related expenditure also increased 84% ($76,553, SHL, versus $141,101, EHL).

CONCLUSIONS: This analysis suggests that switching from an SHL to an EHL product is associated with increased IU dispensation, expenditures and variability, including more EHL IU dispensed post-switch than SHL in quarters pre-switch. Further real world analyses incorporating larger numbers of patients should be explored.

PSY131: BIOSIMILAR DISCOUNTS ARE NOT SIMILAR: A COMPARISON OF THE PRICES AND DISCOUNTS OF ANTI-TNF BIOSIMILARS BETWEEN CANADA AND EUROPE

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OBJECTIVES: Pricing of biosimilars relative to originator biologics is a topic of international interest. The Organisation for Economic Co-operation and Development lists Canada as the second highest in pharmaceutical spending, only behind the United States. This study aimed to evaluate the differences in price discounts on biosimilars between Canada and select European countries. METHODS: Infliximab and etanercept biosimilars were used as examples, as these are the only anti-TNF biosimilars recommended for reimbursement by the Canadian Agency for Drugs and Technologies in Health. Prices for biosimilars and originator biologics were obtained from local drug formularies for the following geographies: Canada (Ontario), Northern Europe (Sweden, Norway, Denmark), Western Europe (United Kingdom, France, Switzerland), and Southern Europe (Italy, Spain, Portugal). T-tests were used to test the statistical significance of differences between regions. RESULTS: Of the ten countries evaluated, Canada ranked fourth in mean price of anti-TNF biosimilars at €578 (range: €435 - €800). The unit price of infliximab and etanercept reference biologics was higher in Canada (€654 and €1,076 respectively) compared to Western (€542 and €758) and Southern Europe (€556 and €994). The average price discount for anti-TNF biosimilars in Canada was 36%, the highest of all the regions examined: Northern Europe (22%, n=3; p=0.3804), Southern Europe (18%, n=4; p=0.0678), and Western Europe (13%, n=4; p=0.0237). CONCLUSIONS: The price of anti-TNF biosimilars is comparable between Canada and Europe. Canada’s higher prices on originator biologics makes it appear that the biosimilar price discount is greater in Canada than Europe. This study is limited to publically available data, and does not reflect discounts and prices seen in product listing and commercial agreements, or private tenders. Despite the low number of observations, the differences between discounts applied in Canada and Western Europe were found to be statistically significant.

PSY132: ACCESS TO MEDICINES FOR RARE DISEASES IN AUSTRALIA: THE CURRENT CLIMATE FOR REIMBURSEMENT

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OBJECTIVES: The challenges of developing evidence for the benefits of medicines in ultra-orphan conditions, along with the high cost per patient, results in greater complexity when seeking reimbursement. Treatment of rare diseases often requires public funding of medicines that are not proven to be cost-effective. Ultra-orphan drugs are funded in Australia on the Pharmaceutical Benefits Scheme (PBS) via Rule of Rescue (RoR) or funded outside the PBS on the Life Saving Drugs Program (LSDP) if relevant criteria are met. This review assesses the current environment for the funding of drugs on the LSDP since ‘substantial’ extension of survival became a requirement in 2010. METHODS: An internal database of Public Summary Documents (PSDs) published 2010-2016 were searched for ‘Life saving drug’ or ‘LSDP’ to identify submissions seeking funding on the LSDP. Manual searching supplemented the dataset. RESULTS: The PSD review identified 27 submissions for nine medicines in eight diseases. Of these, five medicines (55%) in four diseases have been listed on the LSDP despite requiring multiple submissions (average: 3.2) and in some cases, the PBAC indicating that the medicine did not meet the criteria. The main reason for rejection was due to uncertainty that the medicine would substantially increase life expectancy. Analysis of PSDs shows that only two agents showed a direct survival benefit based on non-randomised data. Other submissions used surrogate endpoints, modelled survival using case series or did not report survival data. Three medicines that had initially applied for LSDP were subsequently funded via the PBS. CONCLUSIONS: Despite the challenges for sponsors to meet tighter criteria of the LSDP and while the decision-making process can be sometimes unclear, medicines are likely to be funded when there is an acceptable level of evidence supporting an increase in survival. The LSDP provides an important pathway for access to drugs in Australia for rare, life-threatening diseases.

PSY133: UPDATE ON IMPACT OF THE ADDITIONAL BENEFIT EXTENT OF ORPHAN DRUGS ON PRICE NEGOTIATIONS IN THE GERMAN OUTPATIENT SECTOR
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**OBJECTIVES:** For orphan drugs an additional benefit is granted by market authorization of the EMA. [1] However, companies have to demonstrate the extent of this additional benefit as basis for subsequent reimbursement price negotiations by submitting a simplified dossier to the Federal Joint Committee. [2] The objective of this analysis was to assess whether the additional benefit extent of orphan drugs does impact the rebate size of the price negotiations. The hypothesis indicated an inversely proportional correlation between additional benefit extent and negotiated rebate size. **METHODS:** In a first step orphan substances affected by an early benefit assessment were identified within the German healthcare market. Correlation between additional benefit extent and rebate amount after negotiations was analyzed by Spearman correlation analysis. Data were collected from publicly available information of the Federal Joint Committee as well as price information from the German pharmacy pricing database LAUER-TAXE [3]. **RESULTS:** By May 2017, 99 [4] orphan drugs with active orphan drug designation were identified in the European Union. 40 [5] were currently distributed in the outpatient German healthcare market and underwent additional benefit extent assessment as well as price negotiations. Correlation between additional benefit extent and rebate size could only be identified if the category “not quantifiable additional benefit” was excluded. **CONCLUSIONS:** There is only limited correlation between the extent of additional benefit and rebate size for orphan drugs. This is mainly caused by a large rebate range for orphan drugs for which the additional benefit extent was not quantifiable. Further factors impacting the price negotiation were identified as: European comparison prices, treatment area, negotiation management and prevalence of indication. [1] European Medicines Agency, European Community, Regulation (EC) No 726/2004. [2] German courtesy translation: Gemeinsamer Bundesausschuss, Nutzenbewertung nach § 35a SGB V, 19.05.2017: https://www.gba.de/informationen/nutztenbewertung/. [3] LAUER-TAXE®, 19.05.2017. [4] European Medicines Agency, 19.05.2017 [5] Database Quintiles Commercial Germany GmbH 19.05.2017

**PSY134: NON-OPIOID ANALGESIC REIMBURSEMENT IN EUROPE: A COMPARATIVE STUDY**

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**OBJECTIVES:** The study had for objective to compare prices and reimbursement modalities of non-opioid analgesics (NOAs) in each European country to evaluate the future strategy of NOAs reimbursement. **METHODS:** A benchmark concerning NOAs reimbursement was conducted in April 2017. Seven European countries were included in the study: Belgium, France, Germany, Italy, the Netherlands, Spain and the United Kingdom. A survey was conducted in each country. Collected data were completed and compared to existing public data. **RESULTS:** The study showed that NOAs reimbursement in the 7 studied countries in fashions that differ from one country to another: apart from France, NOAs’ reimbursement rates depend on several variables which are related to the product (kind of analgesic, conditioning), the patient (income level, age, social status), and the disease (chronical or specific pathologies). The study also allowed to highlight that NOAs regulation and distribution are different in each country: some countries allow OTC NOA sale in supermarkets when in others it is permitted only in pharmacies. The benchmark underlines that: - In 4 out of 7 countries, aspirin is not reimbursed at all when prescribed as a pain drug - Ibuprofen is reimbursed in almost all countries but in specific conditions - Paracetamol is the most widely reimbursed drug, in regard of the data collected in all 7 countries. When focused on prices, German prices are higher than in other countries and Dutch prices appear to be the lowest. **CONCLUSIONS:** Disparities concerning modalities of reimbursement in Europe have been highlighted. These disparities can be in part explained by the fact that each country has its own policy. Regarding the results, France seems to have the “most generous” system of care, since NOAs are reimbursed without any condition.

**PSY135: NO PRICE NEGOTIATION – THE STRATEGY OF AOK BAVARIA TESTED – FOR INPATIENT HEMOPHILIA CARE**

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**OBJECTIVES:** In Germany the reimbursement of inpatient factor products is negotiated between hospitals and statutory sick funds on region or on hospitals level. The payment for groups of factors or each individual product brand is determined. Exception is Bavaria, where the local AOK sick fund skipped negotiating and allows free pricing. The hospitals are appealed to bill within federal average. This project should test this concept for established products and new market entries. Additionally the results are compared with published Swiss inpatient factor products reimbursement levels. **METHODS:** All published reimbursement schemes for factor products of German hospitals had been researched from 2012-2017. The SwissDRG 6.0 scheme had been researched for funding of factor products. Results were compared for established products and new entrants. **RESULTS:** The reimbursement for inpatient factors varies per product type up to 5% from average. Negotiation of single brands leads to higher prices.
In established products the prices in Bavaria are above average and always in the highest quartile. In all single factors the more expensive product-classes have in Bavaria higher shares. New entrants are firstly reimbursed in Bavaria and set the level for Germany. Example: recombinant porcine factor VIII for gross €3.45 per unit, which is more than 50% above EU-average. Reimbursement in Bavaria is in average 24% higher than in Switzerland. The potential savings with negotiation are 1.24 m€ for inpatient factor use in Bavaria and estimated 20 m€ in outpatient setting CONCLUSIONS: Free riding on the negotiation in other German states leads to minor financial losses in established markets in Bavaria. But new products enter firstly the Bavarian market and are setting prices far above the EU-level which are successively accepted all over Germany. This explains partly the extremely high price level for factor products in Germany. The AOK Bavaria should consider to rethink its non-negotiation strategy.

PSY136: ACCESS TO PSORIASIS DRUG TREATMENT AMONG BRAZILIAN PATIENTS

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OBJECTIVES: To evaluate the access to the prescribed treatment for Brazilian moderate-to-severe plaque psoriasis patients. METHODS: This was a cross-sectional, observational and multicenter study enrolling Brazilian patients with moderate-to-severe plaque psoriasis. Disease severity was defined according to physician evaluation. Data were collected between December/2015 and November/2016 in 10 specialized centers. Access to the treatment was evaluated in two dimensions: (1) ways of drug acquisition and (2) level of difficulty in acquiring the drug. The first dimension comprised two questions: the first one addressed if the patient acquired the drug from public system (SUS), private insurance and/or out-of-pocket; the second one assessed if legal injunctions were used. In the second dimension, the difficulty in drug acquisition was assessed through a dichotomous response (yes/no) and respective reasons. RESULTS: The study enrolled 188 patients, mean age at study visit and at disease onset were 48 (±13.1) and 33 (±16) years respectively. Most of them were female (52.1%), Caucasian/white (68.6%) and marriage/stable union (61.7%). 45/145 (31%) patients reported psoriatic arthritis (PsA) concomitantly. The ways of drug acquisition were: through SUS and out-of-pocket (72/187; 38.5%); totally out-of-pocket (67/187; 35.8%); totally through SUS (37/187; 19.8%); totally through private insurance (2/187; 1.1%). Among those patients with PsA concomitantly, 20/41 (48.8%) reported acquiring their drugs totally through SUS and 9 (22.0%) through SUS and out-of-pocket. 12.8% (24/187) of patients reported having used legal injunction to obtain the prescribed treatment. 65/187 (34.8%) patients reported difficulty in obtaining these drugs regardless the ways of access. Among those who reported any difficulties (n=65), the drug unavailability (43.1%) and financial problems (38.5%) were the most frequent issues. CONCLUSIONS: These study pointed out several aspects of access in Brazil: poor drug coverage for moderate-to-severe plaque psoriasis patients; use of legal injunctions to drug access; drug shortage and financial difficulties faced by these patients.

PSY137: HOW DOES THE SCOTTISH MEDICINES CONSORTIUM ASSESS THE VALUE OF ORPHAN AND ULTRA-ORPHAN DRUGS?

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OBJECTIVES: Orphan drugs rarely achieve standard cost-effectiveness thresholds due to high acquisition costs and a paucity of clinical data. The Scottish Medicines Consortium (SMC) has no stated threshold for such treatments. The National Institute for Health and Care Excellence (NICE) recently proposed guidelines for highly specialised technology (HST) appraisal for very rare conditions in which a threshold of £300,000 per quality-adjusted life-year (QALY) would be employed. This study investigates whether the SMC use an implicit cost-effectiveness threshold and any alternative aspects of value considered when assessing orphan drugs. METHODS: The SMC database was searched from January 2015 to May 2017 for submissions made under the Orphan or Ultra-Orphan submission processes. Data were extracted regarding the submission process, SMC recommendations, use of patient access scheme (PAS), and incremental cost-effectiveness ratio (ICER). If a with-PAS ICER was unavailable, the without-PAS ICER was extracted. Patient and Clinician Engagement (PACE) criteria were reviewed to assess additional aspects of value taken into account by the SMC. RESULTS: A total of 49 submissions were identified. The SMC accept technologies for orphan drugs with ICER values around £50,000 per QALY gained. There were 15 submissions accepted with ICERs above £30,000 per QALY, the highest acceptance being £56,000 per QALY gained. The SMC reject submissions lacking satisfactory rigour even when the ICER is substantially below £50,000 per QALY. In cases with high ICER values, other frequently cited aspects of value include age of the population, whether treatment may facilitate return to work, carer burden, delay in disease progression, and unmet need. CONCLUSIONS: NICE’s proposed threshold for orphan diseases may lead to disparities in access to treatments across the United Kingdom. Though the SMC does incorporate PACE criteria considering additional aspects of value, transparency of SMC requirements for reimbursement of orphan drugs would be welcomed by Scottish patient groups and submitting companies.
**PSY138: REVIEW OF REIMBURSEMENT DECISION DRIVERS FOR RARE CANCER THERAPIES ACROSS EU5 MARKETS**

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OBJECTIVES: To review health technology assessment (HTA) decisions for rare cancer therapies and rationale for these decisions across EU5 countries. METHODS: We used the Global Market Access Solutions (GMAS) database to assess HTA decisions for seven rare cancers across EU5 countries. Additional information was extracted from individual HTA reports. Decisions were categorised as recommended, restricted, or rejected. Clinical and economic factors influencing decisions were analysed. RESULTS: In total, 24 HTA reports were identified, which assessed 12 interventions across seven rare cancers. Across HTA agencies, 50% of submissions resulted in an intervention being recommended. No relevant reports were published by the Spanish HTA agencies. The French HTA agency (Haute Autorité de Santé [HAS]) was most likely to recommend an intervention (100% recommended; 7 submissions) based on demonstration of clinical effectiveness (overall survival and response rates) and generic substitution of branded drugs. Demonstration of clinical effectiveness was the key criterion for a 'recommended' status (in 66% submissions). All interventions for hairy cell leukaemia and malignant pleural mesothelioma were recommended. The Scottish Medicines Consortium (SMC) was most likely to reject an intervention (88% rejected; 8 submissions) due to lack of robust economic analysis data resulting in high incremental cost-effectiveness ratios (ICERs) versus comparator therapies. In other countries, interventions were rejected mainly due to no additional benefit being demonstrated, absence of submission, and inappropriate choice of comparator/patient population. CONCLUSIONS: Manufacturers developing new therapies in rare cancers should consider providing robust clinical data in HTA submissions. Provisions are made by HTA agencies for early access and managed entry programmes, which allow for some uncertainty when unmet need is high and few or no alternative therapies are available. However, robust economic analysis that adjusts for uncertainty and incorporates appropriate cost and utility values could facilitate reimbursement, particularly in markets driven by cost-effectiveness.

**PSY139: DETERMINANTS OF THE OPTIMAL ROUTE TO REIMBURSEMENT FOR ORPHAN MEDICINAL PRODUCTS (OMPs) IN ENGLAND**

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OBJECTIVES: NICE appraise approximately half of new medicines and there is uncertainty regarding the alternative options for obtaining reimbursement in England. We identify possible routes to market for OMPs in England and conduct a critical appraisal of which route is most suited to appropriately evaluate OMPs. METHODS: The route to reimbursement for OMPs launched between January 2012 and June 2017 was evaluated via online searches of NICE and NHS England (NHSE) websites. The assessments were reviewed to ascertain key elements of the analysis and their outcomes to help identify successful strategies. RESULTS: OMPs may undergo a NICE Highly Specialised Technology (HST) appraisal, however these are specifically reserved for ultra-orphan (not “just” orphan) treatments and NICE only have scope to evaluate 3 HSTs per year. When a product does not meet HST criteria, it can only undergo a standard NICE appraisal that limits cost-effectiveness to an ICER of £30,000. If a product is not appraised by NICE, OMPs may be reimbursed through an NHSE Commissioning Policy but the process for determining commissioning policies relies on published evidence and prioritises treatments by net cost per patient per year, thereby penalising orphan treatments which tend to be costlier due to limited population size. Alternatively, reimbursement may be gained via individual funding requests made by clinicians on a per-patient basis for 5 patients per region, up to a maximum of 20 patients across England. CONCLUSIONS: Despite increasing research and development of orphan treatments, current reimbursement assessment processes are not well suited to OMPs as they are typically assessed against the same criteria as non-orphan products. The gap between non-orphan and HSTs is commonly referred to as the “doughnut hole”. Non-HST products with an ICER above £30,000 currently have no chance of success in a NICE appraisal and the only chance of success is via a NHSE Commissioning Policy.

**PSY140: STATISTICAL TREND ANALYSIS OF GERMAN BENEFIT RATINGS AND THEIR CORRELATION WITH NEGOTIATED REBATES FOCUSING ON ORPHAN ONCOLOGICS**

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OBJECTIVES: We evaluated the development of the Early Benefit Assessments (benefit rating) of the German Federal Joint Committee (G-BA) and their influence on the outcome of the later net price negotiations across all therapeutic areas and for orphan and oncology drugs in particular. METHODS: We collected and analyzed the outcome of all 230+ G-BA resolutions until June 2017. We evaluated them by therapeutic area and by orphan status over 2 year time bins and tested their relation with linked rebate levels of 100+ marketed pharmaceuticals (pPU, Lauer-Taxe) with Pearson correlation coefficient. RESULTS: The share of quantifiable positive benefit ratings, e.g.
minor, considerable or mayor benefit, for orphan drugs (42%) is similar to that of non-orphan drugs (44%) across all therapeutic areas. Over time, the distribution of benefit ratings of orphan drugs shows a trend towards non-quantifiable benefit. Oncology therapies represent the major share of submissions to the G-BA (~34%, non-orphan and orphan). Comparing different therapeutic areas, we find that therapies in oncology achieve more positive ratings (59%) than therapies in any other therapeutic areas (13%-42%), but the share of positive benefit ratings in oncology decreased from ~65% to ~50% in the past 2 years. The number of orphan oncology assessments increased from 4 in the first two years to more than 10 in the past two years with the share of non-quantifiable benefits. The adaptation benefit ratings of orphan oncology therapies worsened over time but are not correlated to the negotiated rebate. This trend may have contributed to the worsened perception of orphan drugs.

**PSY141: RELATIONSHIP BETWEEN THE PRICE DIFFERENCES IN ORPHAN DRUGS WITH MORE THAN ONE BENEFIT ASSESSMENT IN AMNOG AND THE POTENTIAL INFLUENCING FACTORS**

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**OBJECTIVES:** Since the Act on the Reform of the Market for Medicinal Products (German: Arzneimittelmarktverordnungsgesetz, AMNOG) has been implemented in 2011, medicinal products including orphan drugs with active ingredients or indication extension after 2011 have been undergone a benefit assessment (Rules of procedure (VerfO) of the Federal Joint Committee (FJC), chapter 5, §8). Whilst for non-orphan drugs the price is based on the comparator, the pricing of orphan drugs is unclear. Since no comparative assessment is required (VerfO, chapter 5, §12). The objective of this analysis is to identify any pattern in the pricing of orphan drugs by analyzing the relationship between the price differences and potentially influencing factors from two benefit assessments of the same active ingredient. **METHODS:** Therefore, all orphan drugs with at least two benefit assessments have been identified by the IMS HTA Datenbank. For orphan drugs with re-submission, a descriptive analysis regarding the change in the extent of the additional benefit has been conducted. For orphan drugs with indication extension, the relationship between the price differences in several benefit assessments and the change in possible influencing parameters has been analyzed. **RESULTS:** Using a correlation method, the weighted European costs of an orphan drug was identified as the factor with the biggest influence on the percentage price change, followed by the percentage change in the size of the target population and in the annual therapy costs. The change in the extent of the additional benefit seems to have no verifiable effect. **CONCLUSIONS:** For orphan drugs the relationship between the price differences from two benefit assessments and the potential influencing factors, except the weighted European costs, is difficult to identify. The pricing mechanism for orphan drugs remains non-transparent but seems to be dependent on a variety of factors and is not based on the additional benefit alone.

**PSY142: ADAPTATION OF INTERNATIONAL COST-EFFECTIVENESS ANALYSES TO A SINGLE COUNTRY - THE CASE OF BARIATRIC SURGERY VERSUS CONVENTIONAL TREATMENT FOR OBESITY AND OVERWEIGHT**

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**OBJECTIVES:** The aims of this study were to a) identify published cost-effectiveness studies regarding bariatric surgery versus conventional treatment for obesity and overweight, b) assess their reporting quality, c) assess their transferability to Switzerland, and d) to adapt transferable cost-effectiveness results to Switzerland. **METHODS:** A systematic literature search was performed in MEDLINE, Embase and other databases. Two reviewers independently undertook the screening, extraction of studies, assessment of reporting quality utilising the Consolidated Health Economic Evaluation Reporting Standards, assessment of transferability, and adaptation of cost-effectiveness results. Adaptation of cost data was performed in three steps: correction for different levels of resource utilisation, for different prices of healthcare services, and for changes in level of resource utilisation and prices over time. **RESULTS:** Fifteen studies (Europe, the United States and Australia) fulfilled criteria for numerical adaptation of incremental cost effectiveness ratio (ICER) results to Switzerland. Adapted ICERs for patients with body mass index (BMI) >35 kg/m² indicated a cost-saving (dominant) situation or showed ICERs of CHF 8,000-44,000 per quality adjusted life years (QALYs) gained for bariatric surgery versus conventional treatment. Adapted results for patients with BMI <35 kg/m² showed ICERs of CHF 3,000-50,000 per QALY gained for bariatric surgery versus conventional treatment. Procedure-specific differences showed that gastric bypass appeared better than gastric banding in terms of benefits, but was more expensive. **CONCLUSIONS:** Nearly all studies found bariatric surgery to be cost saving or cost-effective, compared to conventional treatment. Differences were due to approaches to the modelling of effectiveness (in terms of duration of BMI changes and dependent effects on morbidity, mortality) costs, time horizon, population studied, exact type of intervention studied, and possibly other unidentified reasons. The adaptation
strategy described may be useful for individual countries in which financing or capacity for economic analyses is scarce.

**PSY143: A COMPARISON OF THE NICE HIGHLY SPECIALISED TECHNOLOGY (HST) PROGRAMME WITH ASSESSMENT BY THE NATIONAL AUTHORITY FOR HEALTH (HAS; FRANCE), AND THE FEDERAL JOINT COMMITTEE (G-BA; GERMANY)**


**OBJECTIVES:** NICE defines ultra-orphan drugs as those treating life-threatening or seriously debilitating conditions affecting ≤1:50,000 people and developed the HST programme to assess these drugs, which are unlikely to meet standard HTA criteria. We compare outcomes of HST evaluations with assessment by HAS and the G-BA. **METHODS:** HST final evaluations published by June 2017 were identified (n=7). HAS and G-BA evaluations of the same drugs were then identified. **RESULTS:** The HST programme assessed unmet need, cost to NHS/personal social services, and value for money. NICE recommended six of the seven drugs, three outright, two with managed access agreements (MAAs) requiring additional data collection to account for uncertainty, and one for a subpopulation with an MAA. Despite acknowledgement of clinical need and likely benefit, sebelipase-α was not recommended because of high costs. HAS consider additional benefit (ASMR) of orphan drugs with expected budget impact (BI) <€30 million/year to be proven at marketing authorisation. However, the drugs reviewed here were assessed through normal processes. HAS considered six drugs to provide additional benefit (two ASMR II, one ASMR III, three ASMR IV) but requested additional data for each, due to uncertainty. Eliglustat received ASMR V. Sebilipase-α (ASMR IV) was withdrawn by the manufacturer, suggesting that price agreement was not reached. The G-BA assume additional benefit for orphan drugs based on marketing authorisation. The remaining criterion was assessment of expected BI, with a threshold of €50 million/year in the first three years. All seven drugs were recommended, three with validation periods. **CONCLUSIONS:** While HTAs of ultra-orphan technologies were largely based on clinical benefit and BI, and all three bodies requested follow-up data to manage uncertainty, their recommendations varied. As further high-cost ultra-orphan drugs are introduced, additional criteria, such as the HST QALY threshold, may be considered to manage combined BI.

**PSY144: DETERMINING THE VALUE OF SELEXIPAG FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) IN SPAIN BY MULTI-CRITERIA DECISION ANALYSIS (MCDA)**

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**OBJECTIVES:** Ascertain the value of the orphan drug selexipag (Uptravi®) in PAH compared to the main therapeutic alternative in Spain through MCDA. **METHODS:** Literature review (PICOTS methodology, indexed, grey literature, primary and secondary search) completed with reference documents (regional and hospital evaluations, clinical guidelines). EVIDEM framework (v. 4.0) weighted by 45 Spanish national and regional evaluators was used. A panel of 32 multidisciplinary experts (cardiologists, pulmonologists, rheumatologists, internists, hospital pharmacists, decision-makers and patient representatives) assessed and validated the adapted framework. The relative value contribution of selexipag vs. iloprost was obtained considering criteria scoring and weighting assigned by the panel. **RESULTS:** Comparative value analysis was supported by real clinical practice experience with iloprost reported by clinicians given that data for selexipag (oral) and iloprost (inhaled) come from non-comparative (design, population and variables) clinical trials. When compared with iloprost, selexipag was considered a new oral drug for PAH which adds value in the following MCDA quantitative criteria (scale -5 to -5): relative efficacy (2.3±1.8), patient reported outcomes (2.5±1.9), preventive benefit (2.8±1.0), therapeutic benefit (3.0±0.7), other medical costs (2.3±1.6) and other non-medical costs (2.1±1.5). Based on clinical trial outcomes, selexipag was considered to have a potentially slightly worse safety profile (-0.3±1.8) although it was acknowledged that adverse events were transient, dose dependent and easily managed with symptomatic treatment. **CONCLUSIONS:** PAH is an orphan indication considered a serious disease with high mortality and important unmet needs. MCDA methodology allowed detailed analysis and discussion of overall value of selexipag in PAH treatment in a systematic, objective, pragmatic and transparent way from the key stakeholders’ point of view and relative to alternative treatment with iloprost in Spain. The use of reflective MCDA methodology favoured discussion between panel members about what constitutes value in PAH which may be useful in drug evaluation and decision-making processes.

**PSY145: COMPARISON OF RECENT HTA APPRAISALS OF ORPHAN DRUGS BY NICE, SMC AND HAS IN 2015-2017**
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OBJECTIVES: Orphan Drugs (OD) treat a variety of aetio logically different disorders, which are characterised by low prevalence. Therefore, ODs are an interesting case study from a health technology assessment (HTA) perspective. This research aims to explore recently appraised ODs by HTA bodies (HTABs) in England, Scotland and France, to identify key drivers behind their recommendations. METHODS: All ODs granted with a European marketing authorisation (MA) between 1st January 2015 and 30th April 2017 were identified. Corresponding appraisals from the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Agency (SMC) and the Haute Autorité de Santé (HAS) were identified, reviewed and final decisions were extracted. RESULTS: A total of 39 MAs for ODs were identified. Consequently, 41 appraisals encompassing 24 ODs were extracted across NICE, SMC and HAS. NICE recommended 5 (86%) out of 7 ODs appraised, SMC recommended 9 (69%) out of 13 ODs appraised and HAS recommended 19 (90%; SMR important or moderate) out of 21 ODs appraised. The main drivers behind OD recommendations by all three HTABs were clinical effectiveness and high unmet need. Furthermore, NICE and SMC considered patient access scheme (PAS) for all the recommended drugs. Additionally, a post-marketing study for 7 of the recommended ODs was requested by HAS. While the main drivers behind lack of recommendations by NICE and SMC were lack of cost-effectiveness and sufficiently robust economic analysis, HAS indicated lack of acceptable methodology to demonstrate efficacy and relevant endpoints, absence of comparator and safety issues. CONCLUSIONS: Overall, all three HTABs tend to evaluate ODs favourably and have mechanisms to facilitate access, namely PASs (NICE, SMC) and early access through temporary authorisation of use (HAS). NICE and SMC recommended less ODs than HAS due to emphasis on cost-effectiveness. Nonetheless, recommended ODs need to undergo economic negotiation to access French market.

PSY146: DOES ACCESS TO HIGHLY SPECIALISED MEDICINES DECLINE IN A NORTHERLY DIRECTION?

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OBJECTIVES: To compare the outcome of technology appraisals of highly specialised medicines in England, Scotland, France and Germany. METHODS: An analysis of medicines undergoing the Highly Specialised Technology (HST) appraisal process in England and decisions for the same technologies in Scotland, France and Germany as reported on agency websites. RESULTS: Variations in outcomes and timings of health technology appraisals in different European countries have been reported previously. For orphan medicines the level of variation may be even more marked than for non specialised medicines. In 2015 the National Institute for Health and Care Excellence (NICE) introduced an appraisal process for highly specialised medicines, the HST process; to date four HST appraisals have been published and ten are in development. The fourteen orphan drugs with published technology appraisals or appraisals in development via the NICE HST process were assessed for availability in Scotland, France and Germany. Of the four HST appraisals published by NICE all were positive recommendations with some restrictions. However outcomes were delayed by over a year for three out of four medicines when compared with recommendations by the Haute Autorité de Santé (HAS) in France. For two medicines where an HST is in development, the HAS issued positive guidance over a year previously. The Scottish Medicines Consortium (SMC) has issued restrictive guidance for one out of the four drugs approved by NICE and a “not recommended” for the remaining three. In Germany the added medical benefit of orphan drugs is deemed as proven by the fact that they have been approved. These drugs are therefore approved for use in Germany at marketing authorisation. CONCLUSIONS: Despite the introduction of the HST process by NICE, access to some orphan drugs is delayed in England and restricted in Scotland when compared with France and Germany.

PSY147: DOES THE PRESENCE OF AN ORPHAN DRUG POLICY AFFECT HTA RECOMMENDATIONS FOR ONCOLOGIC ORPHAN DRUGS?

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OBJECTIVES: To improve patient access, the EU has implemented orphan drug policies. Canada, however, has yet to adopt a formal policy. This study aimed to compare health technology assessment (HTA) recommendations between Canada, Germany, and the United Kingdom (UK) for orphan products in oncology. METHODS: Oncology drugs with an orphan designation approved by the Food and Drug Administration (FDA) between 2012 and 2017 were included. Associated HTA recommendations were retrieved from publicly available sources (Canada: pan-Canadian Oncology Drug Review [pCODR]; UK: National Institute for Health and Care Excellence [NICE] and Scottish Medicines Consortium [SMC]; Germany: Institute for Quality and Efficiency in Healthcare [IQWIG]). Decisions were categorized as either recommended or not recommended. RESULTS: Of the 73 identified indications for orphan drugs, SMC received the most submissions (74%), followed by IQWIG (60%), pCODR (SB%) and NICE (36%). For the submissions assessed by pCODR, 69% (n=29) were recommended and 31% (n=13) were not recommended. NICE and SMC had similar recommendation rates (73%, n=19; 63%, n=34 respectively), while IQWIG
had the lowest rate of positive recommendations (25%, n=11). Of the positive recommendations at pCODR, 34% (n=10) were conditional on improving cost-effectiveness. **CONCLUSIONS:** The proportion of positive HTA decisions for oncology therapies with an orphan designation are consistent between Canada and the UK, with these countries providing more positive recommendations than Germany. The absence of a Canadian orphan drug policy does not appear to negatively influence the HTA recommendation of therapies for oncologic rare diseases. IQWIG places a high priority on products supported by head-to-head trials, and this possibly affects their decisions on orphan drugs. This study is limited to publicly available data and not representative of all recommendations within the EU. Future studies will include additional EU countries, assess the impact of incremental cost-effectiveness ratios on HTA decisions and formulary access.

**PSY148: WHY DO ‘TRUE’ ORPHAN MEDICINES HAVE SUCH A LOW ACCEPTANCE RATE WHEN ASSESSED BY THE SMC?**


**OBJECTIVES:** The 2016 Montgomery report raised concerns about the low acceptance rate for ‘true’ ultra-orphan (TUO) medicines compared to all UO medicines when appraised by the Scottish Medicines Consortium (SMC). We examined possible reasons for ‘not recommended’ SMC advice for TUO medicines and compared appraisals to those conducted by the National Institute for Health and Care Excellence (NICE). **METHODS:** The SMC website was searched in April 2017 for detailed advice on all TUO medicines using the search term “ultra orphan”. TUO medicines were defined as per the definition used in the 2016 Montgomery report. The NICE website was also searched to identify equivalent appraisals for each intervention/indication pair. **RESULTS:** Nine TUO medicines were identified, of which only two were accepted and one was restricted by the SMC (33% acceptance rate), despite the use of Patient and Clinician Engagement meetings and SMC decision modifiers in all appraisals. Of the six ‘not recommended’ medicines, incremental costs in pharmacoeconomic evaluations were typically in excess of £1 million, resulting in incremental cost-effectiveness ratios well above SMC thresholds, and clinical evidence from multi-arm randomised controlled trials was used in only two appraisals. Of the nine TUO medicines assessed by the SMC, four were approved by NICE for the same indication. Three of these medicines received positive NICE guidance but were not recommended by the SMC; each of these three ‘NICE-recommended’ medicines were assessed via the Highly Specialised Technology process and included restrictions of use/a formal managed access agreement. **CONCLUSIONS:** Compared to NICE, the existing appraisal process used in Scotland for UO medicines does not appear to substantially improve access to TUO medicines; as such, changes to the SMC UO appraisal process may be warranted. ‘Not recommended’ SMC advice is likely related to the high cost and limited evidence base for these medicines, as noted in the 2016 Montgomery report.

**PSY149: FAIR PRICING OF ORPHAN DRUGS IN RELATION TO ADDITIONAL HEALTH GAINS AND DISEASE PREVALENCE**

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**OBJECTIVES:** In case of orphan drugs (ODs) a high incremental cost-effectiveness ratio (ICER) is more acceptable if the indication disease is rarer and significant health gain is provided. A recent NICE proposal declares that treatments deemed to provide significant quality adjusted life year (QALY) benefits could benefit from being assessed against a maximum threshold of £300,000 per QALY. The objective of this research was to explore whether manufacturers priced their product higher if the additional health gain was more significant and/or the indication disease was rarer. **METHODS:** Publicly available results of cost-utility analyses of ODs were searched in the United Kingdom from the appraisal reports of relevant public institutes. ICER values, incremental QALY gains and prevalence of the indication diseases were systematically collected for all ODs that received marketing authorization until 2016. The relationship between these three parameters was investigated. **RESULTS:** From the 85 ODs with marketing authorization both ICER and incremental QALY gain were available for 13 drugs. With an approach that jointly assessed ICER, QALY gain and prevalence, three groups were separated: 1) overpriced; 2) fairly priced; and 3) underpriced drugs. 6 ODs were considered overpriced; these drugs provided small additional health gains and targeted relatively large populations. Four drugs were considered fairly priced. Three drugs were considered underpriced; two provided large health gains with low ICERs; one had high ICER, but due to the very low prevalence of the disease this was still justifiable. **CONCLUSIONS:** Based on our findings the anticipated relationship between the three parameters cannot be established yet. Despite of several limitations, our study sample showed that manufacturers tend to overprice their drugs and their pricing decisions in the past did not rely on the additional health gains and/or prevalence of the disease. The three examined parameters should be incorporated simultaneously into technology appraisal of ODs in the future.
PSY150: THE ROLE OF PATIENT GROUPS IN NICE TECHNOLOGY APPRAISALS FOR DRUGS FOR RARE DISEASES

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OBJECTIVES: NICE involves patient organisations in its technology appraisals, enabling them to inform decisions on which technologies will be available in the NHS. In NICE’s appraisal process, systematic reviews of scientific research are combined with submissions of evidence from industry, clinical experts and patient organisations. This multi-stakeholder approach may be especially useful when new drugs for rare conditions are assessed, due to limited clinical data and expertise available. The objective of this research is to analyse previous NICE technology appraisals and highlight the criteria supported by patient groups in the evaluation of new drugs for rare diseases. METHODS: We analysed NICE technology appraisals between July 2016 and June 2017. From the 58 appraisals, 11 were related to rare diseases. We identified criteria used by patient groups in the appraisals as follows: 1. Description of the disease, complications and impact on patient QoL; 2. Social costs, loss of productivity for patients and family; 3. Treatment benefits; 4. Economic aspects of drug use. RESULTS: In 40% of the documents analysed, patient groups supported evidence related to the disease, societal costs, improvement in QoL and life expectancy for patients that can access new treatments. In 50% of the HTA reports, patient experts highlighted the psychological distress for patients affected by rare disorders, the need to improve disease management and the adherence to treatment, as well as the patient pathway in primary and secondary care settings. In 10% of the reports, patient groups supported the economic aspects and the potential cost-savings of the new drugs. CONCLUSIONS: Patient groups’ role in NICE technology appraisals is highly important. Their contribution is not limited to informing HTA decision makers on the features of the disease, patient QoL and potential benefits associated to new treatments, but can also provide support to evidence on the economic burden to the wider society.

PSY151: MARKET ACCESS AND ITS IMPACT ON DECISION MAKING IN SPAIN. AN EXAMPLE IN ACUTE MYELOID LEUKEMIA

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OBJECTIVES: To implement a database that summarizes drug assessments information from Spain and includes recommendations on the use of these drugs in a specific therapeutic area. METHODS: This database reviews the national therapeutic positioning reports and the drug assessments from primary healthcare centres and hospitals for different diseases. Efficacy, safety and economic information of these drugs were included and analyzed in order to position a new medicine within a specific therapeutic area. Current treatment algorithms were also evaluated according to clinical guidelines. As an example, a drug review was conducted to determine the current point of the management of acute myeloid leukemia (AML) and the benefit of new therapeutic interventions in elderly patients. RESULTS: Azacitidine and decitabine are two hypomethylating agents that demonstrated to extend survival, control disease progression and improve quality of life of elderly patients or in a poor health state. Recommendations on patient characteristics and treatment options were also provided, as well as criteria for treatment interruption. Future assessments should be based on direct comparison of both drugs and more compelling evidence is being required to determine the optimal duration of the treatment with decitabine. CONCLUSIONS: This database on drug reviews has demonstrated to be a robust tool to assess the efficacy and safety measures of new drugs, including recommendations on crucial aspects for future drug assessments that can optimize the market access of a new drug.

PSY152: REVIEW OF RARE DISEASE REGISTRIES ACROSS EU5 COUNTRIES

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OBJECTIVES: Due to the widely-dispersed small number of patients with a given rare disease (RD), there is generally a lack of validated biomarkers and endpoints in RDs. This poses a major challenge for generating clinical data for healthcare decision-making in RD. Registries can provide a rich source of real-world evidence to aid healthcare providers, payers, and regulators in decision making. This review aimed to identify and assess key characteristics of the RD registries reporting data from EU5 countries. METHODS: Registries were identified through a systematic search of MEDLINE® and EMBASE® databases for the last 15 years. Any data on RD patients from EU5 countries were included. Registry publications (English language only) and websites were assessed for information on patient demographics and disease characteristics, epidemiology, disease management, resource use, patient-reported outcomes (PROs) and funding agency. RESULTS: The review identified 52 registries reporting data for RDs. Six were multinational, while 46 were national. Twenty registries collected data from the UK, 15 from France, 12 from Germany, 10 from Italy, and nine from Spain; 31 registries collected data for a specific RD, while 21 registries
collected data for various RDs. The number of included patients varied from 61 to 12,500. Of these registries, 41% were initiated during the last 10 years and 14% were industry-funded, 55% were non-industry-funded, while funding information was unclear for 31% registries. Data were available for baseline demographics (in 96% of registries), patient and disease-related characteristics (96%), incidence/prevalence (77%), mortality (69%), treatment-related information (42%), PROs (6%), and cost/resource use (4%). A dedicated website was available for 62% of registries; however, information on data accessibility was not clearly available for most of these registries. CONCLUSIONS: Our review demonstrates that registries can provide valuable real-world information on patients with RD, supplementing the limited findings from clinical trials, to inform health-care decision-making.

**PSY153: EUROPEAN REAL WORLD DATA SOURCES TO CHARACTERISE FLARES IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A REVIEW**

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**OBJECTIVES:** Systemic lupus erythematosus (SLE) is a chronic autoimmune disease that is characterised by periods of mild disease activity alternating with flares of increased disease activity causing significant morbidity. There are limited data on the characteristics of and impact of flares on clinical and economic outcomes in patients with SLE in Europe. We carried out a review of registries and databases that could potentially be used to investigate flares in patients with SLE in the UK, Germany, Italy, Spain and France. **METHODS:** A comprehensive literature review to identify observational studies describing characteristics (clinical, demographic, interventions, costs and outcomes) of patients with SLE (with or without flares) in EMBASE and Medline (2000 to 2017). A list of registries and databases were identified from included studies and assessed for suitability. **RESULTS:** Of 2387 titles and abstracts screened, nine registries and databases were identified that met the inclusion criteria. None of the publications pertaining to these registries to date have been used to investigate flares, however several were identified as being potentially suitable for future research. These included general databases (e.g. Clinical Practice Research Datalink), disease-specific registries (e.g. Spanish Society of Rheumatology Registry of Patients with SLE) or treatment-specific registries (e.g. The German Registry for AutoImmune Disease). Suitability assessment identified potential challenges to the use of some of these data sources, including accessibility and the ability to define flares and assess periods of remission. **CONCLUSIONS:** This review identified nine registries and databases that have published data on patients with SLE. No publications identified reported flare or remission activity longitudinally. Our findings represent a potentially valuable source of real world evidence for use in research on characterising flares and describing their predictors, management, outcomes, and economic impact. Such information would help guide resourcing decisions and management of patients with this chronic autoimmune disease.

**PSY154: DIVERGENCE OF EVALUATION OF ORPHAN DRUGS BETWEEN REGULATORS AND PAYERS: IMPLICATIONS FOR PATIENT ACCESS IN US AND EU**

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**OBJECTIVES:** Recent years have witnessed a plethora of regulatory reviews of orphan disease drugs with sub-optimal evidence package submitted to FDA and EMA. In disease of highly unmet need, it is not unusual for orphan disease drug manufacturers to request expedited approval from regulatory agencies to bring the newest innovation to the patients. This research aimed to analyse diverging decisions amongst regulators about orphan disease treatments within the same therapy area, and its impact on subsequent patient access by health authorities. **METHODS:** A pragmatic review of literature was undertaken for this research to evaluate the regulatory decisions for Duchenne muscular dystrophy (DMD) therapies, and their subsequent impact on patient access, across the USA and Europe. Approval decisions from FDA and EMA websites for these orphan drugs were analysed and supplemental secondary research was conducted to extract patient access information from European health authorities and USA commercial plans’ websites. **RESULTS:** The FDA has taken a liberal approach to the review and approval of EXONDYS51TM, a targeted therapy for DMD, by allowing the manufacturer to submit data on a rolling basis. Similarly, TRANSLARNATM was awarded a conditional approval by the EMA, even though primary endpoints in clinical trials were not met. However, both products faced payer backlash post-approval in their respective geographies. Private insurers in the USA severely restricted (based on time-bound clinical improvement parameters) or outright denied reimbursement for EXONDYS51TM, while TRANSLARNATM was made available in England only through a managed access agreement, involving outcomes-based incentives. In France, the product received “moderate” SMR and ASMR IV ratings from the HAS. **CONCLUSIONS:** Clear regulatory guidance, evidence needs and pathways should be developed and harmonised for evaluation of orphan disease drugs across regulatory agencies. Otherwise, health authorities will restrict them severely despite high unmet patient need.

**PSY155: REGIONAL POLICIES IMPACT ON BIOSIMILAR ADOPTION FOR AUTOIMMUNE DISEASES IN ITALY**
OBJECTIVES: Deflazacort (EMFLAZA™) is the first Food and Drug Administration (FDA)-approved corticosteroid treatment for DMD in patients >=5yrs of age. Deflazacort is available both as tablet (6/18/30/36mg) and oral suspension. Objective of this analysis is to evaluate real-world dosing patterns associated with deflazacort in EAP in the U.S.

METHODS: Deflazacort EAP was an open label study implemented between Sept 2015 and May 2017, per following inclusion criteria: patients >=5yrs of age with DMD who were ineligible/unable/otherwise unwilling to enroll in a clinical study while marketing application (for deflazacort) was under preparation/review; child or adolescent patients (<18yrs) weighed >=13kg, with body mass index (BMI) <40kg/m2, and were up-to-date on childhood vaccinations; adult patients (>18yrs) had 18.5kg/m2<BMI<40 kg/m2. Patients with history of hypersensitivity or allergic reaction to steroids or their formulations and those who, in physician judgment, had a history/current medical condition that could pose safety/risk to patient were excluded. Protocol-recommended dose of deflazacort was 0.9 mg/kg/day and physicians adjusted dose per clinical judgment. RESULTS: In total, 860 eligible DMD patient records were included in the analysis. Patient characteristics included: mean age:12.8yrs, % prescribed tablet/oral suspension:86.1%/13.9%, % prescribed once-daily dosing:89.9%. Weight varied from 14.8-136kg. Mean daily protocol-recommended dose vs. actual-prescribed dose was 40.4mg (STD:18.8mg) vs. 27.0mg (STD:10.9mg); the corresponding mean difference in daily protocol-recommended vs. actual-prescribed dosing was 13.3mg (STD:16.8mg) across the cohort; this mean daily dose difference increased as the patient weight increased. Corresponding mean % variance of actual-prescribed dose from protocol-recommended dose was: 10-19kg:+0.5%, 20-29kg: -5.2%, 30-39kg: -17.7%, 40-49kg: -27.6%, 50-59kg: -37.5%, 60-69kg: -43.0%, 70-79kg: -54.0%, 80-89kg: -51.9%, 90-99kg: -57.1%, 100-109kg: -57.7%, 110-119kg: -66.4%, >=120kg: -63.4%. CONCLUSIONS: In this cohort of EAP patients on deflazacort, the actual prescribed dose was lower than the protocol-recommended dose and the variance increased with patient weight.