processing of relevant data. A stronger involvement in the evaluation process is needed as well as more transparency in the Joint Federal Committee (G-BA) and faster evaluation processes.

Conclusions. The MDR increases the burden especially for small businesses, and it is doubtable that the ultimate goal – improving patient safety – will be achieved. The increased demands and rising costs of the new EU MDR and bottlenecks at Notified Bodies can be a risk for the MD industry. Due to the general reduction in the remuneration for services with a high proportion of technical services, it is feared that products will be withdrawn from the market for economic reasons or that they will not be marketed.

PP32 Joint Early Dialogs Between Medical Device Regulation and Health Technology Assessment

Petra Schnell-Inderst (petra.schnell-inderst@umit.at) and Claudia Wild

Introduction. In Europe, the new Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) that entered into force 2017 will have to be applied until 2020 and 2022, respectively. Under the old regulation, there was a large gap between evidence requirements for market approval and market access for high risk (class IIb and III) medical devices (MD). The MDR/IVDR will require appropriate clinical investigations for these MD classes. Despite the different purpose of market approval and surveillance and reimbursement decisions, there are possible synergies with regard to evidence generation, for example, design of pivotal trials and post-launch evidence generation with observational data. In the MDR, early scientific advice can be provided by expert panels of the European Commission if requested by MD developers. For medicinal products, the European network for Health Technology Assessment (EUnetHTA) has established joint early dialogs (JED) of HTA agencies with the European Medicines Agency and manufacturers. A similar approach might be possible with the Medical Device Coordination Group (MDCG). The objective was to explore possible synergies for JED with the MDCG and EUnetHTA.

Methods. In 2018, EUnetHTA established a task force for HTA and MDR/IVDR. A workshop, which will explore possible synergies and activities on JED as well as the viewpoints of stakeholders will be held in May 2019. Participants will be Directorate-Generals GROW (Internal Market, Industry, Entrepreneurship and SME) and SANTE (Health and Food Safety), EUnetHTA members assessing MD, representatives of national competent authorities, Team Notified Bodies, MedTech Europe, patient representatives and academia.

Results. A report on the presentations, the results of the discussion, and next steps in a possible collaboration will be presented.

Conclusions. Joint early scientific advice to manufacturers on the European level for evidence generation by HTA agencies and the MDCG has the potential to streamline evidence generation in the life cycle of high risk MD.

PP34 Costs Of Healthcare-Associated Infections In Latin America

Ângela Bagattini (angelabagattini@gmail.com), Martha Martinez-Silveira, Ana Zara, Valeska Stempliuk and Cristiana Toscano

Introduction. Healthcare-associated infections (HAI) are among the most common preventable health adverse event, associated with significant burden globally. Limited data on HAI costs in lower and middle-income countries is available. The aim of this study is to assess the cost, additional length-of-stay (LOS) and extra-mortality of HAI in the Latin American and Caribbean (LAC) Region.

Methods. We searched Medline/PubMed, Embase, Web of Science, Lilacs, Cochrane, National Health Service Economic Evaluation Database, Centre for Reviews and Dissemination, EconLit, and gray literature published in any language without restriction of date till July 2017. We included observational studies addressing the outcomes of interest, in which hospitalized patients with HAI are compared to those without HAI. The following study designs were included: quasi-experimental, controlled before-after, prospective and retrospective comparative cohort, case-control, and cross-sectional studies. We considered the following HAI-sites: surgical site infections (SSI), catheter-associated urinary-tract infections (CA-UTI), ventilator-associated pneumonia (VAP), and central line-associated bloodstream infection (CLA-BSI), as well as cross-infection (CI). Screening of citations, data extraction, and risk of bias assessment were conducted in duplicate by independent reviewers, according to the study protocol registered on PROSPERO. Reported costs were converted to USD considering official exchange rates.

Results. We identified 4,339 citations. After removing duplicates, a total of 3,029 citations were screened for eligibility. A total of 87 studies from 17 countries were included. The majority (27.4 percent) reported on VAP, followed by CLA-BSI (21.2 percent), SSI (16.4 percent), and CA-UTI (14.4 percent). Most studies (46.7 percent) reported on incremental LOS, with an average of 14.8 days (range 0.9-49 days). Costs were reported by 25 percent of studies, with average incremental costs of USD 3,460 (range 49-12,155). Average extra-mortality of 15.6 percent (range -2.8-45.2 percent) was reported by 12.6 percent of studies.

Conclusions. Available evidence from the LAC Region reports significant economic burden of HAI. This information will be useful for cost-effectiveness analysis of interventions aimed at reducing HAI economic and health burden.

PP35 Valuing Intersectoral Costs And Benefits Of Interventions

Ruben Drost (r.drost@maastrichtuniversity.nl), Aggie Paulus, Dirk Ruwaard and Silvia Evers

Introduction. There is a lack of knowledge about methods for valuing health intervention-related costs and monetary benefits in the education and criminal justice sectors, also known as 'intersectoral costs and benefits' (ICBs). The objective of this study was

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to develop methods for obtaining unit prices for the valuation of ICBs.

Methods. By conducting an exploratory literature study and expert interviews, several generic methods were developed. The methods' feasibility was assessed through application in the Netherlands. Results were validated in an expert meeting, which was attended by policy makers, public health experts, health economists and Health Technology Assessment (HTA) experts, and discussed at several international conferences and symposia.

Results. The study resulted in four methods, including the opportunity cost method and valuation using available unit prices, self-constructed unit prices or hourly labor costs.

Conclusions. The methods developed can be used internationally and are valuable for the broad international field of HTA.

PP36 Inflammatory Bowel Disease: The Disability Costs Among Italian Workers

Claudia Nardone (claudia.nardone@uniroma2.it), Simone Russo, Simone Gazzillo, Raffaele Migliorini, Marco Trabucco Aurilio and Francesco Saverio Mennini

Introduction. The aim of the study is to estimate the disability insurance costs (social security system in Italy is financed by public expenditure) induced by patients with Inflammatory Bowel Disease (IBD) and specifically for Crohn's disease (CD) and Ulcerative Colitis (UC) between 2009 and 2015.

Methods. We analyzed the database about the disability insurance awards and the mean cost per benefit of the National Institute of Social Security (INPS) for two types of social security benefits: incapacity pensions (IP - for people without workability) and disability benefits (DB - for people with reduced work ability). From this data, we have estimated the total benefit provided and the total costs for each disease. A probabilistic model with a Monte Carlo simulation was developed in order to estimate the total benefits provided and costs.

Results. For CD, an average of 820 beneficiaries of social security benefits were detected per year (2009-2015): the total expenditure was EUR 50 million, EUR 7 million per year (about EUR 7,900 per patient); for UC, about 1,550 beneficiaries per year were detected and the total expenditure was EUR 93 million, EUR 13 million per year (about EUR 8,600 per patient).

Conclusions. The disability insurance costs related with the management of CD and UC showed a significant impact on the expenditure for the Italian system: the most important costs for disability for CD and UC in Italy in the analyzed period were DB (92 percent for CD and 95 percent for UC). Rapid access to innovative treatments could reduce the costs incurred by the social security system.

PP38 Productivity Loss In Patients With Chronic Diseases: A Pooled Analysis

Omar Rashdan (ph.rashdan@gmail.com) and Valentin Brodszky

Introduction. Due to the unprecedented increase in medicine prices in recent years, the socio-economic perspective started gaining importance in health economic evaluations. Productivity loss evaluations provide a long-term economic impact visualization for a more informed reimbursed medicine decisions.

Methods. A pooled analysis of patient-level data from 11 cross-sectional, retrospective, cost-of-illness studies was performed. SPSS software was used for our statistical analysis. Analysis of variance (ANOVA) and correlation analysis were utilized to measure the effect of different variables on lost productivity hours. All costs were recalculated to account for the cumulative inflation till 2018.

Results. The sample size of included studies ranged between 68 (Multiple Sclerosis) and 480 (Diabetes), and the total number of patients enrolled in the analysis was 1,881 of which 956 were female. A total of 6,795 hours were reported as missed working hours per year. Overall, the female population reported a mean of 689.5 lost productive hours compared to 324.7 in males ($p < 0.001$). This translated into higher indirect costs at EUR 2,748 and EUR 1,530 for females and males, respectively. Patients with a college degree or higher reported lower yearly lost productive hours and indirect costs (358.4 hours and EUR 1,749) ($p < 0.001$) compared to patients with lower education level (845.6 hours and EUR 3,534) ($p < 0.001$). The average indirect cost as a percentage of gross domestic product per capita was highest in Schizophrenia patients at 97.5 percent and lowest in Benign Prostatic Hyperplasia at 1.9 percent. In patients below 65 years of age, a weak positive correlation was observed between age and lost productive hours with a Pearson value of 0.1 ($p < 0.001$).

Conclusions. Female gender and older age resulted in higher productivity loss, and Schizophrenia was the disease with the highest indirect costs per patient per year.

PP39 Budget Projections And Health Impact Of PD-1/PD-L1 Inhibitors

Alexander Roediger, Julie van Bavel, James Pellissier, Stefano Lucherini, Neil Davies, Paul Okhuoya and Boris Rachev (boris.rachev@merck.com)

Introduction. The rapid expansion of immuno-oncology treatment options has led to concerns around their long-term affordability. Evidence on the potential budget and health impact of these new treatment options is required to inform public health policy and ensure adequate allocation of budget for the future.

Methods. The Health Impact Projection model was developed to compare the economic impact and health outcomes observed with and without PD-1/PD-L1 inhibitors using traditional budget impact analysis. Seven types of high-incidence cancers were included: melanoma, first- and second-level non-small cell lung, bladder, head and neck, renal cell carcinoma, and triple negative breast. Inputs were based on publicly available data and literature, and over 10 key experts (oncologists, health economists) were involved in the model development. The model draws on five-year budget impact analysis.

Results. Using the experience of Belgium, Slovenia, Switzerland, and Italy, the model estimates budget and health impact of the PD-1/PD-L1 inhibitor class. It shows that for 2018-2022, the

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