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in the remuneration for services with a high proportion of technical services, it is feared that products will be withdrawn from the market for economic reasons or that they will not be marketed.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

https://doi.org/10.1017/S0266462319001971 Published online by Cambridge University Press