

eligibility, order, delivery and invoicing) in an integrated manner in order to easily activate new market opportunities from the perspective of Companies, Payers and Patients. By defining appropriate minimum datasets, it is possible to involve all stakeholders obtaining systematic, homogeneous and high-quality real-world data on the use and appropriateness of such devices. **CONCLUSIONS:** The introduction of online integrated and shared infrastructures allows to activate common processes among Payers and Companies in the challenge of introducing innovative therapies and devices in a strained macroeconomic scenario, with the aim to simplify market access, facilitate transparency, monitor related costs, while enabling the collection of Healthcare Big Data for scientific purposes.

#### PMD128

##### WHAT IS CE MARKING? HOW TECHNOLOGIES ARE CLASSIFIED, AND HOW TO NAVIGATE THE SYSTEM

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**OBJECTIVES:** Affixing a CE mark to a product means that the manufacturer is declaring that the product meets all legal requirements as well as conforming to relevant product safety directives in the EU. CE marking is mandatory, but only applies to products that are covered by the subject matter of one or more of the New Approach Directives. We aim to clarify the process for obtaining a CE mark. **METHODS:** Published reviews, our experience and government and industry records were used to outline the complexities of this process, including how to determine the relevant type of classification and the steps that need to be taken to gain a CE Mark. **RESULTS:** Medical devices fall into three categories, each of which are governed by a different EU directive: Directive of Active Implantable Medical Devices (90/385/EEC), Medical Devices Directive (93/42/EEC), and Directive of In Vitro Diagnostic Medical Devices (98/79/EC). Each one will encompass guidelines relating to an individual product and whether it is required to bear a CE mark. Once a CE Mark has been obtained a 'declaration of conformity' must be signed before you can place the CE mark on your product. This states that the manufacturer takes sole responsibility for the conformity within all the legal requirements to achieve a CE mark. CE marking means that the product can be marketed anywhere in the EU. **CONCLUSIONS:** A CE mark states that a product has been assessed before being placed on the market and satisfies legislative requirements of the applicable EC directives. It ensures that a product has 'free-movement' within the EU as well as permitting the 'withdrawal of products', which do not conform. More and more products are required to have a CE mark if they want to gain access to EU market.

#### PMD129

##### WHEN IS A BONE FRACTURE NO LONGER "FRESH"?

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**OBJECTIVES:** Robust literature demonstrates the clinical value of low-intensity pulsed ultrasound (LIPUS) in the treatment of fresh bone fractures. However, each published study used an arbitrary time post-fracture to define a "fresh fracture" for study inclusion. In the absence of an accepted clinical definition of fresh fracture, many third-party payers have adopted study inclusion criteria as de facto definitions of fresh fracture. Yet exclusion of older fractures may deny access to patients who could benefit from LIPUS. We pooled data from patients in a post-market LIPUS registry required by the Food & Drug Administration to analyze the inflection point at which fracture heal rates begin to decline. **METHODS:** Patients are evaluated if the following data are known: days to LIPUS treatment; days on LIPUS treatment; and outcome of treatment (Heal / Fail). We present data from 7,117 patients treated with LIPUS within 365 days of fracture. We plot (Heal rate) vs. (Days to LIPUS treatment), to determine the inflection point at which Heal rate begins to decline. **RESULTS:** Heal rate (Number of patients healed / Number of patients treated) did not differ significantly or clinically for at least 10 weeks following fracture. In 284 fracture patients who began LIPUS within 1 week of fracture, the heal rate was 97.2% (276 healed / 284 treated). In 246 patients who began LIPUS treatment 10 weeks after fracture, the heal rate was 97.6% (240 healed / 246 treated). There may be a decrease in heal rate after 10 weeks, but the heal rate for patients at week 12 was 95.6% (195 healed / 204 treated). **CONCLUSIONS:** Heal rate with LIPUS was ~97% for ≤10 weeks following fracture. Many patients who could benefit may be unnecessarily excluded from treatment by payer guidelines. We will evaluate heal rate bone-by-bone (tibia, femur, humerus, radius, metatarsal) using this method.

#### PMD130

##### THE MEDICAL TECHNOLOGIES EVALUATION PROGRAMME (MTEP): AN ANALYSIS OF NOTIFICATIONS, DECISION-MAKING AND THE INTERPRETATION OF CLAIMED HEALTHCARE SYSTEM BENEFITS

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**OBJECTIVES:** Firstly, to identify what proportion of medical technologies notified to the National Institute for Health and Care Excellence's (NICE) Medical Technologies Appraisal Committee (MTAC) are selected for evaluation by the MTEP. Secondly, to analyse the MTEP Committee's interpretation of claimed healthcare system benefits and identify the influence of these benefits on decision-making. **METHODS:** The NICE website was used to identify technologies considered by the MTAC up to May 2015; the routing information for each technology; the healthcare system benefit claims and decision data for all technologies routed to the MTEP. The healthcare system benefit claims were categorised according to criteria listed in the NICE MTEP methods guide to facilitate identification of any association between the type of benefit claimed and the decision outcome. The decision-making committee's conclusions on the claimed healthcare system benefits were interpreted. **RESULTS:** By May 2015, the MTAC at NICE had considered 157 products, of which 99 were not selected for evaluation. Of the 58 products selected for evaluation, 35 were routed to the MTEP. Seventy-one per cent of MTEP decisions endorsed technology adoption. There have been instances of claimed health system benefits being accepted by

the Committee for technologies that ultimately did not receive positive endorsement due to clinical benefit or cost considerations. **CONCLUSIONS:** The MTEP is the most commonly used process to assess routed technologies and the majority of MTEP evaluations have resulted in positive endorsement. The MTEP process assigns equal prominence to healthcare system and patient benefits, with decisions being based on the full body evidence available for a technology. However, where evidence of clinical effectiveness was associated with uncertainty, the influence of demonstrated healthcare system benefits appeared to have limited effect on final decision-making.

#### PMD131

##### THE IMPACT OF SELF-MONITORING OF BLOOD GLUCOSE (SMBG) ON PRESCRIPTION COSTS IN NEWLY TREATED TYPE 2 DIABETES MELITUS (T2DM): A RETROSPECTIVE COHORT ANALYSIS

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**OBJECTIVES:** To describe the use of self-monitoring of blood glucose (SMBG) in a cohort of newly treated T2DM subjects and to assess the contribution of SMBG on overall antidiabetic and cardiovascular disease prescription costs. **METHODS:** A population based retrospective cohort study was conducted using the Irish national pharmacy claims database. Newly treated T2DM patients were identified for 2012 as being initiated on oral antidiabetic monotherapy and having received no anti-diabetic therapy in the previous year. Subjects were followed for one year post treatment initiation. The association between prescription costs and SMBG was assessed using generalised linear model with gamma family and log link functions to handle the right skew of the data adjusting for various demographic and treatment factors. Cost ratios and 95% CIs were obtained from this analysis and were used to determine the contribution of SMBG to prescription costs. **RESULTS:** A total of 12,941 subjects were eligible for the study with 64% of subjects using SMBG. SMBG use was highest in subjects aged 40-49 years (71%) and decreased with age, with 48% of subjects aged 80-89 years using SMBG. Most subjects used SMBG greater than once a week but less than daily (41%) or daily and more frequently (51%). Use of SMBG resulted in dispensing costs that were overall 81% higher than those without SMBG use (95% CI 1.76, 1.92). **CONCLUSIONS:** Use of SMBG in newly treated T2DM was high including the frequency of use and resulted in high associated costs. SMBG represents a significant financial component in diabetes care, yet previous work has shown no clear benefit in newly treated type 2 diabetes patients on oral therapy. There is the potential for cost savings by introducing a review or limit on the amount of SMBG tests available to newly treated T2DM patients.

#### PMD132

##### ACCESSING THE MEDICAL DEVICES MARKET IN EGYPT AND SAUDI ARABIA: A SYSTEMATIC REVIEW OF POLICIES AND REGULATIONS

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**OBJECTIVES:** The objective of this research is to provide an overview of the regulatory process of medical devices market access in Egypt and Saudi Arabia. The research paper identifies regulatory institutions, processes, and policy framework of the national medical devices policy agenda of Egypt and Saudi Arabia respectively. **METHODS:** A systematic search of the literature for medical device regulatory information was performed, in academic journals and in relevant regulatory authorities' data sources (Egyptian Drug Authority and Saudi FDA web portals). The following databases were searched: PubMed (Medline), Science Direct (EMBASE), Scopus and the Arabic database Al Manhal. The search methodology employed was in line with PRISMA guidelines. The search language was limited to English and Arabic. **RESULTS:** In total, 41 records were included in the qualitative synthesis of this review. The governance, process and implementation of medical devices market access have been analyzed in detail. The policy framework of both countries is adopted from the International Medical Device Regulatory forum and certain reference countries. Concerning products' technical requirements, direct testing of medical devices is not required. However, documentary evidence of a medical device's authorization to be sold in a reference country is mandatory. Challenges are related to the interim nature of medical devices legislation in both countries, presence of a considerable degree of corruption. In addition there is a lack of transparency and electronic databases, especially in Egypt. **CONCLUSIONS:** In both Saudi Arabia and Egypt, medical devices market access is straightforward if there is proof of authorization to sell a product in a reference country. However, this system has disadvantages in terms of safeguarding patient safety and enabling fast access of innovations. Lack of transparency, incomplete regulations, corruption, and a lack of comprehensive policy for medical devices are challenges faced by both countries.

#### PMD133

##### IDENTIFYING OPPORTUNITIES FOR VALUE-BASED CONTRACTING FOR MOLECULAR DIAGNOSTICS AS A MEANS TO IMPROVE OUTCOMES OF HOSPITAL ACQUIRED INFECTIONS

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**OBJECTIVES:** Hospital acquired infections (HAIs) can have a serious impact on both clinical and economic outcomes. As a result, hospitals implement infection control (IC) policies to prevent and reduce the transmission of HAIs including various approaches to screening and testing incoming or admitted patients. Early identification of HAIs is key to limiting their clinical and economic impact. Molecular diagnostics (MDx) have the potential to improve IC strategies by quickly and accurately identifying patients with suspected or confirmed infections. To increase adoption of this technology, both MDx manufacturers and hospital quality stakeholders have expressed interest in value-based contracting for HAI tests.