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 electronic infrastructure for the full benefit of those 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
Hill D, Stewart D, Balman E
MAP Healthcare Ltd., Cambridge, UK
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 relevant product safety directives in the EU. 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. This means that the product can be marketed anywhere in the EU.

RESULTS: 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 is not conformity. 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"?
Scott RA, Jones J, Steen RG
Biomimetics Durango, USA
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 (fracture healed / not healed / failed). We present data from patients who began 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 from 0 to 90 days post-fracture in 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% (246 healed / 250 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 CLAIMS OF HEALTHCARE SYSTEM BENEFITS
Murray Cγ, Crowe Lγ, Howells Rγ
1Abacus International, Manchester, UK; 2Abacus International, Biscester, UK

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 decision-making processes. 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 associated with 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 conclusion was then compared to 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 limited cost considerations. CONCLUSIONS: The MTEP is the most commonly used process to assess routed technologies and the majorities 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 "balance of available evidence". 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
Grimes RT, Bennett K, Henman M
Pharmaceuticals, Dublin, Dublin, Ireland

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 anti-diabetic and cardiovascular disease prescription costs. METHODS: A total of 12,941 subjects were included in the study. Of these, 45% used 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 was associated with an overall reduction of 14% in prescription costs. 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 derived 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
Sad Mγ, Krisz Cγ, Kolominsky-Rabas Pγ, DiPaolo A, Marcarelli AD, Girardi M
1Centre for Health Technology Assessment (HTA) and Public Health (ZEPH), Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany, 2Centre for Health Technology Assessment (HTA) and Public Health (ZEPH), Friedrich-Alexander University of Erlangen-Nürnberg, National Leading Edge Cluster Medical Technologies ‘Medical Valley EMN’, Erlangen, Germany
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 will focus on the role of regulatory authorities, regulations, processes and documentation required to enter the market of the national medical devices policy agenda of Egypt and Saudi Arabia respectively. METHODS: A systematic search of the literature for medical device regulatory policy and procedures for Egypt and Saudi Arabia was carried out, drawing on a broad range of Arabic and English sources. Literature was identified through a systematic search of the following databases: PubMed, Embase, Web of Science, 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 interrim 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
DiPaolo A, Marcarelli AD, Girardi M
1OR, WAYLAND, MA, USA

OBJECTIVES: Given the increasing number of hospital acquired infections (HAI) 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 explore the adoption of this technology, both MDx manufacturers and hospital quality stakeholders have expressed interest in value-based contracting for HAIs.
To further understand this opportunity, this research sought to identify key IC practices that would be impacted by MDX testing and could support improved HAI outcomes. METHODS: Telephone-based primary research was conducted with 34 hospital quality and IC stakeholders across the US and UK to understand the impact of HAIs, current IC practices, quality metrics, outcomes and opportunities for MDX-related policies. RESULTS: Primary research findings suggest that compliance with IC protocols is critical to improving HAI outcomes. Expanding hospital quality reporting metrics to include factors such as MDX testing would support wider implementation of HAI prevention strategies and reporting metrics. RESULTS: Hospitals have implemented a variety of strategies aimed at reducing and preventing the incidence of HAIs. Hospitals assess the success of their IC strategies by benchmarking their infection rates against national or regional reports and measuring compliance with certain IC protocols. There are various IC practices that could be impacted by MDX testing such as patient isolation and timely administration of targeted antibiotic therapy, however, metrics associated with these practices are generally not reported. CONCLUSIONS: Primary and secondary research findings suggest that compliance with IC protocols is critical to improving HAI outcomes.

PMD134
BUDGET IMPACT ANALYSIS OF BIOABSORBABLE DRUG-ELUTING SINUS IMPLANTS FOR ENDOCRINE SINUS SURGERY

Rudmik L, Mallow PJ, Puliti S, Rizzo JA

1University of Calgary, Calgary, AB, Canada, 2CTI Clinical Trial and Consulting Services, Cincinnati, OH, USA, 3Stony Brook University, Stony Brook, NY, USA

OBJECTIVES: Bioabsorbable drug-eluting sinus implants (BDESI) inserted during endoscopic sinus surgery (ESS) have been shown to improve post-operative outcomes in the management of refractory chronic rhinosinusitis (CRS) through reduced post-operative scarring, inflammation, polyposis and middle turbinate laterization. This analysis estimated the incremental budget impact of incorporating BDESI in CRS patients undergoing ESS.

METHODS: A budget impact model (following ISPOR’s Good Practice Report) was developed from the perspective of the United States of America (USA). Costs were obtained from a published randomised controlled trial reporting on the proportion of patients using different care strategies.

RESULTS: When compared to conventional sinus surgery, BDESI showed a cost per patient of USD 2,506 ($2,506), with a cost per patient/year of USD 221 ($221). The incremental budget impact of incorporating BDESI into conventional sinus surgery was USD 2,727 ($2,727) per patient. The incremental budget impact of incorporating BDESI into conventional sinus surgery over a patient’s lifetime (5 years) was USD 13,635 ($13,635).

CONCLUSIONS: BDESI significantly reduced post-operative scarring, inflammation, polyposis and middle turbinate laterization in patients undergoing endoscopic sinus surgery compared to conventional sinus surgery.

PMD135
RE-USE OF INSULIN SYRINGE NEEDLES AND ITS EXTRA DISEASE BURDEN FOR DIABETIC PATIENTS IN BEIJING

Cui Z, Deng F, Liu RB, Zhang P, Wei L, Li T

1Peking University, Beijing, China, 2Beijing Tiantan Hospital, Beijing, China, 3Beijing Medical Economics Research Association, Beijing, China

OBJECTIVES: To investigate the situation of disposable insulin syringe needles re-used by diabetic patients in Beijing and the safety problems due to re-use as well as the extra disease burden. METHODS: Use the semi-constructed questionnaire to investigate how the insulin injection needles were re-used and its disease burden on diabetic patients who had been treated by insulin injection for at least half a year in 21 hospitals in Beijing. RESULTS: 45.25% of the insulin syringe needles were obtained from the pharmacies outside hospitals and the average price was 2.76 RMB per piece. Only less than 2% of the diabetics use new disposable needle per injection and 30.35% of them only changed their needles once per week. The main cause of 84.53% of the diabetics was cost saving. More than half of the surveyed diabetics got needle-injection-related hurts such as lipohypertrophy and skin infection. 61.98% got hypoglycemia symptoms in the last 3 months. It was estimated that the extra disease burden resulted from the insulin syringe needles into insurance reimbursement list at appropriate time to bring the diabetes under control.

CONCLUSIONS: The analyses conducted suggest that based on the currently available clinical evidence, WH-CO2 is a cost-effective use of resources for patients undergoing either open or laparoscopic colorectal surgery within the UK NHS.

PMD136
ECONOMIC ANALYSIS OF EVARREST® SEALANT MATRIX COMPARED WITH STANDARD OF CARE IN SEVERE SOFT TISSUE SURGICAL BLEEDING: A UNITED KINGDOM HOSPITAL PERSPECTIVE

Jamous N, Carter S, Perks M, Hogan A, Corral M

1Ethicon Endo-Surgery, Burkeville, TX, USA, 2Pulmonary and Critical Care Medicine, Leeds Teaching Hospitals, Leeds, UK, 3Cornerstone Research Group Inc., Burlington, ON, Canada, 4Ethicon Bissurgery, USA, Somerville, NJ, USA

OBJECTIVES: Although several hemostats are available, drawbacks include limitations in ease of use and cost. EVARREST® (SoC) was demonstrated to be cost-effective for surgical bleeding in the United Kingdom (UK).

METHODS: An economic model quantified 30-day cost impact of EVARREST® from a UK hospital perspective. The model was based on a published model that identified outcomes in patients undergoing colorectal surgery. Sensitivity analyses were conducted.

RESULTS: The use of EVARREST® cost offset was avowed resource use per patient cost impact of £464 (sensitivity range: -£422 to £1,351) vs. SoC. The hospital analysis predicts further resource reduction with EVARREST® leading to cost-savings of £1,006 per patient (sensitivity range: -£2,546 to £534). In coagulopathic patients, the results dramatically improved, with the surgical and hospital analysis both showing cost savings of £2,526 and £5,720 per patient with EVARREST® vs SoC respectively.

CONCLUSIONS: In problematic bleeding situations, EVARREST® may result in important cost savings for hospitals, in addition to meeting an important unmet need. This analysis suggests results may depend on bleeding type, with increased benefit in challenging (i.e., coagulopathic) bleeding patients. Further study is needed to confirm findings.

PMD137
MEDICAL DEVICES: WHY DO SOME PAY MORE THAN OTHERS? ANALYSIS OF PRICE VARIATION IN FRENCH PUBLIC HOSPITAL IN 2013

Grande M, Le Loutre AC, Haba M, Bertrand L, Paulot P

1Assistance Publique-Hôpitaux de Paris (AP-HP), PARIS, France, 2Centre Hospitalier de Saint Denis, SAINT DENIS, France, 3Faculté de pharmacie, Paris Descartes University, Sorbonne Paris Cité, Paris, France, 4Health Law Institute, Inserm, UMR S 1145, Paris Descartes University, Sorbonne Paris Cité, Paris, France, PARIS, France

OBJECTIVES: The aim of this benchmarking study is to provide a detailed analysis of medical devices (MD) price and to identify what drove price dispersion. METHODS: A large panel of MD level price data was collected in 3 French public healthcare institutions and 10 centralized purchasing groups (representing 37% of French public hospitals). MD were selected according to the Pareto law (20% of the MD represent 80% of the expenditure) and expert opinion to ensure that each MD had sufficiently large demand. Several factors were considered such as volume purchased, affiliation to a purchasing group, procurement procedure and contract start date. RESULTS: Finally, 18 MD were retained following up on the provided answers (6 elastic bandages, 2 implants, 8 common MD and 3 captive MD). In terms of pricing, results between hospitals were close for similar quantities and none can be defined as the benchmark lender. Rebates are a common mechanism and the level of discount was found to be practical and ranged between 10% and 50% of the purchase price depending on the level of discount community and type of funding (activity based payment vs. global budget). Rebates were calculated from the perspective of the hospital and the contract start date. The hospital analysis predicts further resource reduction with EVARREST® leading to cost-savings of £1,006 per patient (sensitivity range: -£2,546 to £534). In coagulopathic patients, the results dramatically improved, with the surgical and hospital analysis both showing cost savings of £2,526 and £5,720 per patient with EVARREST® vs SoC respectively.

CONCLUSIONS: In problematic bleeding situations, EVARREST® may result in important cost savings for hospitals, in addition to meeting an important unmet need. This analysis suggests results may depend on bleeding type, with increased benefit in challenging (i.e., coagulopathic) bleeding patients. Further study is needed to confirm findings.