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 antidiabetic 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 12,941subjects 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.

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. Desk research was carried out to further investigate hospital IC 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 protocols are generally not reported. **CONCLUSIONS:** Primary and secondary research findings suggest that compliance with IC protocols is critical to improving HAI outcomes. Expanding hospital quality reporting metrics to include factors impacted by MDx could support value-based contracting efforts by associating testing with improved IC practices, and will ultimately support improved HAI outcomes.

PMD134

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

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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 lateralization. This study estimated the incremental budgetary 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 payor/self-insured employer. The model was created to be dynamic and adaptable to different countries. Estimates of the prevalence of CRS; rates of ESS; and effectiveness outcomes; along with direct and indirect costs from CRS were obtained from a best-evidence systematic review of the published literature. A total population of 1.5 million members was used for the analysis. All cost data obtained from the published literature were adjusted to April 2015 US dollars using the medical care component of the Consumer Price Index. The comparator groups were ESS with BDESI compared to the current clinical peri-/ post-operative care. Primary outcome was the incremental budget impact reported using per-member-per-month (PMPM) costs. Scenario-based, probabilistic, and one-way sensitivity analyses were performed. **RESULTS:** For a US payor/self-insured employer health plan of 1.5 million members, the incremental PMPM impact of BDESI was estimated to range from -$0.009 to $0.09. The results varied based on the parameters included in the individual scenario. Sensitivity analyses revealed these findings to be robust to specified parameter value ranges. **CONCLUSIONS:** Previously published studies have documented the clinical benefits of BDESI. This study has demonstrated the use of BDESI during ESS procedures has negligible impact on the healthcare budget. Additional research is necessary to determine the budget impact for different countries based on the same factors described within this analysis.

PMD135

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

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OBJECTIVES: To investigate the situation of disposable insulin syringe needles re-use in the 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 30.52% 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 safety problems of insulin syringe needles re-use was 458.74 RMB per patient per year. **CONCLUSIONS:** At first health education should be enhanced on how to use the insulin syringe needles correctly and take it into consideration of bring the insulin syringe needles into insurance reimbursement list at appropriate time to alleviate the economic burden of the diabetics.

PMD136

COST-EFFECTIVENESS OF LOCAL INSUFFLATION OF WARM HUMIDIFIED CO2 DURING OPEN AND LAPAROSCOPIC COLORECTAL SURGERY

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OBJECTIVES: To determine the cost-effectiveness of local insufflation (via a humidifier) of warm humidified CO2 (WH-CO2) compared with standard care in patients undergoing open or laparoscopic colorectal surgery. **METHODS:** A decision-analytic model was developed to estimate the costs and quality-adjusted life-years (QALYs) associated with open and laparoscopic colorectal surgery from a UK NHS perspective. WH-CO2 was compared with no insufflation in open surgery patients and with unheated CO2 (U-CO2) in laparoscopic patients. Efficacy data were derived from a published randomised controlled trial reporting on the proportion of patients with hypothermia, a US database analysis of hypothermia patients for open surgery, and from an unpublished UK NHS before and after study of laparoscopic surgery patients. Other parameter inputs were obtained from published literature. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of results. Scenario analyses were undertaken to explore structural uncertainty within the model. **RESULTS:** The use of WH-CO2 dominated standard care, as it was both cost saving and generated greater QALYs, for both open and laparoscopic surgery patients over a one year time horizon. Results varied by the number of patients undergoing surgery per humidifier per year. Based on 250 patients using the humidifier each year over a five year lifetime of the humidifier, WH-CO2 dominated no insufflation in open surgery patients in 71% of model iterations and dominated U-CO2 in laparoscopic surgery in 98% of model iterations. WH-CO2 remained the cost-effective treatment option at a willingness-to-pay threshold of £20,000 per QALY throughout all scenario and sensitivity analyses considered, provided 10 or more patients used each humidifier over its life span. **CONCLUSIONS:** The analyses conducted suggest that based upon 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.

PMD137

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

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OBJECTIVES: Although several hemostats are available, drawbacks include limitations with efficacy and ease-of-use. Despite their use, uncontrolled bleeding still remains common and is associated with important clinical and economic burden. A study was conducted to estimate the economic impact of a novel fibrin sealant matrix (EVARREST®) versus standard of care (SoC) in problematic severe soft tissue surgical bleeding in the United Kingdom (UK). **METHODS:** An economic model quantified 30-day cost impact of EVARREST® from a UK hospital perspective. Severe soft tissue bleeding trial resources included quantity of initial treatment, re-treatment, surgery time, transfusion risk, amount transfused, and hospitalization (ICU and ward stay). SoC was composed of Surgicel® (88%) and conventional methods (e.g., manual compression). The surgical analysis included resources clinically related to the significant hemostasis benefit of EVARREST®(i.e., initial and re-treatment, operating time, transfusion). A hospital analysis included all resources collected. Published data on UK costs were applied to resource use. A subgroup analysis was conducted for patients meeting coagulopathic criteria based on abnormal values for at least one of the trial coagulation parameters collected. **RESULTS:** The surgical base-case analysis predicted that EVARREST® cost was offset by averted resource use with 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.

PMD138

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

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OBJECTIVES: The aim of this benchmarking study is to provide a detailed analysis of medical devices (MD) price and to identity 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 (5 elastic bandages, 2 implants, 8 common MD and 3 captive MD). In terms of pricing, results between hospitals being close for similar quantifies and none can be defined as the benchmark leader. Rebates are a common mechanism and the level of discount depends on the MD considered and type of funding (activity based or additional payments). Open public tenders are the most commonly procurement procedure used, whereas negotiated procedures are more efficient for captive MD. There is practically no relationship between volume purchased and purchased prices. MD price can change over time and the relevance of the contract start date is confirmed: older the contract is, cheaper is the price for some MD, or on the contrary for others. **CONCLUSIONS:** There is no connection between catalogue prices and purchased prices especially for MD paid by activity based payment (discount rates can reach 50% to 90%). As the volume effect has no evident impact on MD discounts, the advantage of joining a centralized purchasing group has not been confirmed. The crucial factors are mainly the MD considered, the contract start date and the procurement procedure.