developed from the perspective of a Belgian hospital. Costs are discounted at 3%, in line with Belgian guidelines for pharmacoeconomic evaluation. The model takes into account device acquisition costs and other direct and indirect costs associated with NSIs occurring from infusion, injection, blood collection and insulin administration for diabetes care. Model input data were derived from the Institut National d’Assurance Maladie-Invalidité (INAMI), published studies, clinical guidelines, and market research. For a 420-bed hospital, an estimated 384,720 sharps procedures occur annually. Over five years, the total cost of conducting these procedures using conventional devices was estimated to be €580,700, of which €26,700 or 5% was spent managing 510 NSIs. If all procedures were instead conducted using SEDs, the model estimates that the number of NSIs would be reduced to 75. Total costs with SEDs are estimated to be €528,500, representing an overall cost saving of €52,200 or 9%. Greater acquisition costs for SEDs are offset by a decline in NSI management costs. CONCLUSIONS: Costs associated with NSIs are a significant, avoidable cost of conducting sharps procedures. SEDs may reduce the economic burden of managing NSIs, which may partially or completely offset any increase in device acquisition costs.

PMD13 PROJECTED ECONOMIC IMPACT OF UTILIZING FRACTURAL FLOW RESERVE (FFR)-GUIDED VERSUS CORONARY ANGIOGRAPHY-GUIDED PERCUTANEOUS CORONARY INTERVENTIONS (PCI) IN PATIENTS WITH MULTIVESSEL CORONARY DISEASE: A BUDGET IMPACT MODEL
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OBJECTIVES: Coronary angiography is the current gold standard in diagnosing coronary lesions. However, coronary angiography does not definitively determine whether a lesion is ischemic or not. Compared to angiography alone, Fractional Flow Reserve (FFR) has demonstrated clinical superiority in diagnosing ischemic coronary lesion functional severity, while concurrently providing cost savings. The goal of this model is to demonstrate the hospital budgetary implications of utilizing FFR to guide clinical decision making in PCIs compared to angiography alone. METHODS: A customizable Excel®-based hospital budget impact model was developed for a hypothetical cohort of 500 patients with multivessel coronary disease. Cost components included procedural, device, hospital stay and cardiovascular complication costs during the one-year period after PCI. A decision tree model was utilized to convert the expected probabilities of cardiovascular complications into incremental cost savings. Probabilities and costs were derived from The Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) clinical trial data. Costs were converted to 2011 US dollars. Sensitivity analysis was carried out over reported ranges of values of model inputs. RESULTS: Using Fractional Flow Reserve in 20% of the multivessel cases resulted in estimated cost savings of £297,247 per year compared to using angiography alone in all of the multivessel cases. Fractional Flow Reserve usage resulted in reduced costs of the procedure, hospital stay and complications. Potential cost savings were most sensitive to variations in the cost of hospitalization and the probabilities of cardiovascular complications. CONCLUSIONS: Analysis shows that compared to angiography alone, FFR-guided coronary intervention for patients with multivessel disease both (1) reduces rates of adverse events and (2) reduces total costs including procedural, hospital and complication costs. As such, FFR provides hospitals a cost saving technology with clinical outcomes as compared to angiography alone.

PMD14 POTENTIAL IMPACT OF REGIONAL CEREBRAL OXYGEN SATURATION MONITORING DURING CORONARY ARTERY BYPASS SURGERY ON THE PATIENT REIMBURSEMENT BUDGET IN TURKEY
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OBJECTIVES: Care for cardiovascular diseases is an important issue for health care systems. Coronary artery bypass grafting surgery (CABG) is utilized to treat coronary artery disease. Intensive care stay (ICS) and acute stroke (AS) are important drivers of post-operative costs. In Turkey, ICS and AS receive add-on payments to the packaged payment for CABG from the Social Security Agency (SSA). Effective use of regional cerebral oxygen saturation monitoring (rSO2) during CABG reduces intensive care stay (ICS) from 1.87 to 1.25 days and acute stroke (AS) incidence from 2.21% to 0.61%. We modelled the potential impact of rSO2 add-on payment for rSO2 on SSA add-on payments for ICS and AS after CABG. METHODS: Turkish volume of CABG was estimated as 47,973 procedures for 2012 (Cediven ICD-10 study of Turkey), increasing at 7.2% per year (National Cardiology Policy Report). SGK was assumed to cover 75% of procedures. ICS cost was taken from SGK. AS cost was taken from published cost of rebleeding (taken as €100,000 per patient. Cost of rSO2 InvosTM disposable sensor). Utilization of rSO2 in CABG with add-on payment was estimated as 15% in 2013, 30% in 2014, and 50% in 2015. Discount rate was 5%. RESULTS: Under current care paradigms, estimated SGK cost for ICS and AS following CABG would be €945,785 and 86,540 in 2013, 2014 and 2015, respectively. However, if add-on payment facilitates utilization and benefits of rSO2 in CABG, potential SGK cost for ICS and AS following CABG would decrease to 78,5, 75,3 and 70,6 million TL in those years. CONCLUSIONS: The cost of ICS and AS after CABG is substantial in Turkey. Add-on payment for rSO2 during CABG may decrease cumulative ICS cost by nearly 28% and AS cost by nearly 70% between 2013 and 2015.

PMD15 BUDGET IMPACT ANALYSIS OF VASCULAR CLOSURE DEVICES (VCDs) IN ITALY AND SPAIN
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OBJECTIVES: Recent literature suggests complication rates associated with current Vascular Closure Devices (VCDs) are comparable or reduced when compared to manual compression. However, well-documented differences exist among VCDs regarding the type and frequency of complications. A recent global budget impact model based on a naive indirect treatment comparison (ITC) estimated the cost-saving associated with use of the VCD EXOSEAL™ vs. EXOSEAL™, Perclose™ and Mynx™ from the US hospital perspective. Based on this ITC, the analysis was adapted to Italy and Spain from the National Health System (NHS) perspective over a one year time horizon. METHODS: The ITC was used to calculate the cost of reintervention requiring manual compression (AMC), endovascular procedure (EP), transfusion (TR) and ultrasound guided interventions (UGI) following complications associated with each VCD. The annual number of VCDs used and costs of reinterventions were obtained from local databases. The means and 95% confidence intervals (95%-CI) for the budget impact were estimated using bootstrap methods (1,000 simulations) assuming 100% use of EXOSEAL™. RESULTS: Compared to 100% use of another VCD, and 100% use of EXOSEAL™ 2010 VCD market-share for percutaneous coronary interventions (PCI) procedures. Device acquisition costs were assumed identical. RESULTS: Savings per procedure with EXOSEAL™ (Italy/Spain) would be approximately (22,891,1.96) vs. Angioseal™, (15,5613,94) vs. Starclose™, (83,1672,66) vs. Perclose™ and (11,2616,46) vs. Mynx™. CONCLUSIONS: Using EXOSEAL™ would have annual VCD costs of 2.680.876 (95%-CI: 2.538.334 – 2.823.406) for the Italian NHS and 797.070 (95%-CI: 734.236 – 859.906) for the Spanish NHS.

PMD16 THE BUDGETARY IMPACT OF USING THE SIMTOMAX® TESTING KIT FOR THE DIAGNOSIS OF COELIAC DISEASE IN THE UK
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OBJECTIVES: There has been growing interest in the potential benefits arising from the use of medical diagnostic technologies, primarily due to possible reductions in resource use and time to diagnosis. The objective of this study was to provide an estimate of the potential financial implications resulting from using SimtomaX®, a rapid point of care test, for the diagnosis of coeliac disease and IgA deficiency. The study, performed from the perspective of the UK NHS, aimed to demonstrate that the additional test acquisition costs would be offset by resource savings. METHODS: A 1 year budget impact model was developed looking at the key financial drivers of diagnosing coeliac disease, based on the NICE pathway. This included the cost of blood tests and other contributing costs, including GP visits, nurse visits, paediatric outpatient visits for testing children and carriage. RESULTS: Using ExSymtomax® in the current diagnosis pathway which comprises of serological testing for IgA tissue transglutaminase (tTGA) and a possible IgA deficiency test, using ELISA laboratory testing. Costs were taken from national sources with the exception of carriage costs which were estimated by a clinician as a national figure was not available. RESULTS: The additional test acquisition costs would be offset by resource savings. CONCLUSIONS: The additional test acquisition costs would be offset by resource savings. This analysis suggests that the use of SimtomaX® for the diagnosis of coeliac disease would be financially beneficial because it may result in decreased resource use and cost savings. Additionally, the time required for health care professionals to diagnose coeliac disease could be reduced meaning patients receive treatment faster.

PMD17 USE OF STERRAD® STERILIZERS RESULTS IN COST-SAVINGS COMPARED TO STEAM STERILIZATION IN AN ITALIAN HOSPITAL SETTING
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OBJECTIVES: The STERRAD® Sterilizers are a versatile group of systems that use low-temperature, hydrogen peroxide gas plasma technology to sterilize medical devices safely and effectively. Literature data suggest significant reductions in the number of damaged rigid endoscopes with STERRAD® compared to steam sterilization. The aim of this study was to assess the potential savings associated with the STERRAD®100NX® system compared to steam for endoscope sterilization. METHODS: A dynamic budget-impact model was developed to estimate the costs with and without a system company namely STERRAD® in the hospital decision-maker perspective and with a one-year time horizon. Data were collected from two Italian hospitals running approximately 800 sterilization cycles per year, and costs of sterilization per cycle, endoscope repair costs, testing and maintenance were considered. Costs were estimated using a Monte Carlo simulation with a repair cost reduction of 33% was used in the base case analysis. Gamma distributions for cost parameters and Bootstrap methods were used to generate 1000 simulations. The acquisition costs of STERRAD®100NX® and steam systems were not considered. RESULTS: In the base case analysis, the annual costs with STERRAD® were €55,540, and the mean costs (SD) from the simulations were €51,471 (€25,186). For steam sterilization, the corresponding figures were annual costs of €59,736 for
the base case, resulting in a cost-saving with STERRAD® of €4,196, and a mean cost of €58,078 (SD €33,785) from the simulations, giving mean probabilistic cost-savings with STERRAD® of €6,608. With a reduction in endoscope repair costs of 41.6%, as calculated from published studies, savings with STERRAD® increased to €8,803.

**CONCLUSIONS:** This analysis suggests that the use of STERRAD® for the sterilization of endoscopes may result in important cost-savings compared to reprocessing with steam. Costs for the sterilization of other heat-sensitive devices were not considered; therefore these cost-savings may have been underestimated.

**PMD18**

**INTRODUCTION OF NOVEL BIOMARKER TESTING FOR OVARIAN CANCER:**

**BUDGET IMPACT ANALYSIS FOR AN ITALIAN REGIONAL HEALTH CARE SERVICE**

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**OBJECTIVES:** A major goal in the work-up of women with pelvic mass is to assess the risk of ovarian malignancy. Ovarian cancer has high mortality rates with 3000 deaths annually in Veneto Region of Italy. The utility of novel biomarkers, such as HE4 (Human Epididymis Protein 4), in diagnosis of ovarian cancer was investigated by a number of groups. These studies showed a high negative predictive value (NPV) of 97-99% indicating that almost all patients who tested negative were correctly diagnosed as having benign ovarian pathology. The objective of our study was to perform a budget impact analysis (BIA) and estimate the annual cost of the introduction of HE4 testing for differential diagnosis of women with pelvic mass for Regional Health Service in Veneto.

**METHODS:** The study compares the cost of surgical intervention for pelvic mass versus the preoperative laboratory testing of HE4 biomarker for pelvic mass diagnosis. The incidence of pelvic malignancy and interventions and costs for both procedures (surgery and HE4 test) were based on available statistics and reimbursement rates.

**RESULTS:** The cost of additional diagnostic work-ups (such as office visits and diagnostic procedures), index in- or outpatient hospitalization and surgical intervention was estimated at €1,130.75. The false negative rate for HE4 test, it can be hypothesised that cost from unnecessary procedures would be reduced. The BIA showed that if HE4 testing was performed in all potentially eligible women for preoperative pelvic mass evaluation (50% test) and as an additional 2nd follow up test in women who tested negative and avoided surgery, a conservative estimate of 10% reduction of surgical interventions would have a cost-neutral or even slightly positive impact on annual budget in Veneto, Italy.

**PMD19**

**BUDGET IMPACT ANALYSIS OF BALLOON SINUSPLASTY VERSUS CLASSIC FUNCTIONAL ENDOSCOPIC SINUS SURGERY. USING A BUDGET IMPACT MODEL TO IDENTIFY COUNTRY SPECIFIC MARKET ACCESS STRATEGY**

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**OBJECTIVES:** Balloon sinusplasty (BSP) is a novel technology to treat patients with chronic rhinosinusitis (CRS) refractory to conventional care. The BSP technology is an alternative tool used during functional endoscopic sinus surgery (FESS). Recent clinical trials have identified favorable clinical outcomes of BSP compared to classic FESS. Specifically, the non-invasiveness of the procedure may result in fewer post-operative complications. These findings point to potential cost-efficiency of the BSP procedure compared to classic FESS. In this study, the cost of treatment for patients undergoing either classic FESS or BSP was compared using a budget impact model. The model was designed to be versatile and allow for country-specific analyses using regional cost and care assumptions.

**METHODS:** The budget impact model was designed to identify costs by therapeutic treatment (FESS specific analyses using regional cost and care assumptions).

**RESULTS:** At 1 and 2-year post-operative time points and using assumptions specific to different European countries, the cost of BSP was lower in specific target groups than that of FESS.

**CONCLUSIONS:** The model suggests savings in target groups, based on clinical outcomes data from BSP and classic FESS, at 2 years post-baseline. These findings could support BSP as a less-invasive alternative for patients with CRS who are refractory to conventional care.

**PMD20**

**BUDGET IMPACT ANALYSIS OF DRUG ELUTING BALLOONS FOR INTERMITTENT CLAUDICATION FROM SUPERFICIAL FEMORAL ARTERY DISEASE IN THE UNITED STATES HEALTH CARE SYSTEM**

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**OBJECTIVES:** To estimate the costs of drug-eluting balloons (DEB) as treatment for intermittent claudication due to superficial femoral artery atherosclerosis by payors and providers in the U.S., compared to percutaneous transluminal angioplasty (PTA), bare metal stents (BMS) and drug-eluting stents (DES). **METHODS:** We estimated the costs of the index procedure (DEB, PTA, BMS, or DES) and clinically-driven target lesion revascularization (TLRs). TLR proportions were pooled from randomized controlled trials. Other follow-up durations were converted via ratios to six-month proportional. The patient friendly technology offers manufacturers the opportunity to seek efficient resource utilization whilst diminishing costs.

**CONCLUSIONS:** Treatment of secondary revascularization techniques (given index procedure) were derived from expert opinion. U.S. Medicare Ambulatory Payment Classification (APC) and Current Procedural Terminology (CPT) payments constituted payors’ budget impact. AFC revenue minus device costs constituted the overhead revenue for providers. The utilization of Reveal® was estimated at 1,960 per patient. Total treatment cost for spinal fusion with Grafton and LB mix was €180,221 compared with €110,221. Procedure Grafton and LB mix was thus estimated to have lower costs of €200. Grafton and LB was still cost saving when no costs for complications were included in a one-way sensitivity analysis, and when other studies were used to inform additional surgery time and hospital stay with ICBG. Of nine scenarios ICBG was cost saving in one. **CONCLUSIONS:** In this study spinal fusion surgery with BSY and ILR was found to generate similar or lower costs than comparable procedures with ICBG. Given that previous studies have shown that the clinical outcomes are comparable between the two interventions Grafton mixed with LB can be considered a viable alternative to ICBG in spinal fusion procedures.

**PMD21**

**FINANCIAL IMPACT OF ADOPTING IMPLANTABLE LOOP RECORDER (ILR) DIAGNOSTICS (REVEAL®) FOR UNEXPLAINED SYCONE IN PORTUGAL: COMPARISON WITH CONVENTIONAL DIAGNOSTIC PATHWAYS**

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**OBJECTIVES:** Estimate the short- and long-term financial impact of early referral for ILR (REVEAL®) of Unexplained Syncope patients under the perspective of the Portuguese National Health Service. **METHODS:** Markov Model to estimate the expected number of Hospital Admissions due to Unexplained Syncope and their financial impact, comparing ILR vs. patients following conventional diagnostic pathways, in a 3 year and lifetime time horizons. A hypothetical cohort of patients with unexplained recurrent syncope, age ≤61 years old with similar characteristics to the patient population from the PICTURE trial was modeled. These patients face annually the probability of death, receiving a diagnosis and suffering a recurrent event. **RESULTS:** Model parameters and transition matrix were estimated using the cost-effectiveness of the PICTURE trial. The average cost of an event was estimated at €958 per patient. Total treatment cost for spinal fusion surgery with Grafton and ICBG was estimated at €180,221 compared with €110,221. Procedure Grafton and LB mix was thus estimated to have lower costs of €200. Grafton and LB was still cost saving when no costs for complications were included in a one-way sensitivity analysis, and when other studies were used to inform additional surgery time and hospital stay with ICBG. Of nine scenarios ICBG was cost saving in one. **CONCLUSIONS:** In this study spinal fusion surgery with Grafton and ILR was found to generate similar or lower costs than comparable procedures with ICBG. Given that previous studies have shown that the clinical outcomes are comparable between the two interventions Grafton mixed with LB can be considered a viable alternative to ICBG in spinal fusion procedures.

**PMD22**

**FINANCIAL IMPACT OF ADOPTING IMPLANTABLE LOOP RECORDER (ILR) DIAGNOSTICS (REVEAL®) FOR UNEXPLAINED SYCONE IN PORTUGAL: COMPARISON WITH CONVENTIONAL DIAGNOSTIC PATHWAYS**

Providência R1, Morais C2, Elvas L1, Candeeiros R3, Sandina V4, Farinha S5, Furtado D6

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