

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 reusable 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

Romagnolo C<sup>1</sup>, Maggino T<sup>2</sup>, Gion M<sup>3</sup>, Berto F<sup>4</sup>

<sup>1</sup>Obstet. Gynecol. Dept., G. Fracastoro Hospital, San Bonifacio (Verona), Verona, Veneto, Italy,

<sup>2</sup>Obstet. Gynecol. Dept, Mestre, Venezia, Veneto, Italy, <sup>3</sup>Regional Center Biological Markers,

Mestre, Venezia, Veneto, Italy, <sup>4</sup>University of Padova and Analytica Laser, Verona, Italy

**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 masses, surgical interventions and costs for both procedures (surgery and HE4 test) were based on available statistics and reimbursement rates. **RESULTS: AND CONCLUSIONS:** If HE4 testing was performed in all potentially eligible women who present for preoperative pelvic mass evaluation in Veneto Region at a proposed cost of €35/patient, the total cost for Regional Health Service would be €1.130.075. Given the low false-positive rate for HE4 test, it can be hypothesized 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 (1st 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 SINUPLASTY VERSUS CLASSIC FUNCTIONAL ENDOSCOPIC SINUS SURGERY. USING A BUDGET IMPACT MODEL TO IDENTIFY COUNTRY SPECIFIC MARKET ACCESS STRATEGY

Sorgelese T<sup>1</sup>, Demaire C<sup>2</sup>, Stueve M<sup>3</sup>

<sup>1</sup>Johnson & Johnson Medical, Acclarent, Diegem, Belgium, <sup>2</sup>Johnson & Johnson Medical, Acclarent,

Issy Les Moulineaux, France, <sup>3</sup>Johnson & Johnson Medical, Norderstedt, Germany

**OBJECTIVES:** Balloon sinuplasty (BSP) is a novel technology to treat patients with chronic rhinosinusitis (CRS) refractory to conservative 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 treatments and complications. These findings point to potential cost effectiveness of the BSP procedure versus 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 vs. BSP vs. conservative care). Inputs included frequency and unit costs of preoperative work-ups (such as office visits and diagnostic procedures), index in- or out-patient surgery, frequency and unit cost of treatment for post-operative complications, post-operative procedures and relapse/reoperation rates. Secondary analyses included productivity calculations using a human capital approach. The follow-up period was limited to 2 years post-index. Supplementary analyses were conducted to determine the cost impact of early intervention on total budget. **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-operative. The patient friendly technology offers to payers the opportunity to seek efficient resource utilization whilst diminishing costs.

## PMD20

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

Pietzsch JB<sup>1</sup>, Geisler BP<sup>1</sup>, Jaff MR<sup>2</sup>

<sup>1</sup>Wing Tech Inc., Menlo Park, CA, USA, <sup>2</sup>Mass General Hospital, Boston, MA, USA

**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 rates to six-month proportions. The distribution 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. APC revenue minus device costs constituted the overhead revenue for providers. The time horizon was two years for both scenarios. Second-order Monte Carlo-simulation varied clinical parameters in 5,000 random draws. **RESULTS:** Pooled TLR rates were comparable between DEB, BMS, and DES (5.1%, 5.9%, and 4.8%, respectively) but not to POBA (16.1%). Initial DEB was the least expensive strategy from a payor perspective (\$6,715). From the provider perspective, BMS provided the most overhead revenue after device costs (\$8,250 vs. \$4,614 for DEB). Probabilistic sensitivity analyses revealed that 90–94% of simulations were cost-saving when comparing DEB with POBA. **CONCLUSIONS:** While the clinical performance of DEB is comparable to BMS and DES, DEB is a cost-saving strategy from a U.S. payor perspective. Clinical preferences, which may vary from lesion to lesion, must be considered.

## PMD21

## COST COMPARISON OF SPINAL FUSION PROCEDURES WITH GRAFTON MIXED WITH LOCAL BONE COMPARED TO ILIAC CREST BONE

Borgman B

Medtronic Trading Sàrl., Tolochenaz, Switzerland

**OBJECTIVES:** Clinical evidence suggest that Grafton, a demineralized bone matrix, mixed with local bone (LB) can achieve similar fusion rates in lumbar fusion spinal surgery as iliac crest bone graft (ICBG). It would thus be possible to avoid harvest site morbidity. However, as of yet the cost difference between these alternatives have not been investigated. The objective is to study the cost for spinal fusion surgery with Grafton and LB mix compared with ICBG. **METHODS:** A modeling approach was taken. Additional resource use for second harvest site required for ICBG procedures were taken from published literature. U.K. costs were used and collected from publicly available price lists and published HTA reports. One way sensitivity analysis was performed. **RESULTS:** ICBG and a second surgery site due to bone harvesting was found in the literature to be associated with pain, difficulty walking and working, infections, hematomas, prolonged wound drainage, reoperations, additional surgery time and hospital stay. Health care costs for these resources were estimated to be £958 per patient. Total treatment cost for spinal fusion with Grafton and LB compared with ICBG was £10821 compared with £11021. Procedures using Grafton and LB mix were 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 LB 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 SYNCOPE IN PORTUGAL: COMPARISON WITH CONVENTIONAL DIAGNOSTIC PATHWAYS

Provincia R<sup>1</sup>, Morais C<sup>2</sup>, Reis H<sup>3</sup>, Elvas L<sup>1</sup>, Candeias R<sup>4</sup>, Sanfins V<sup>5</sup>, Farinha S<sup>6</sup>, Tsintzos S<sup>7</sup>

<sup>1</sup>Centro Hospitalar e Universitário de Coimbra, S.Martinho do Bispo, Coimbra, Portugal, <sup>2</sup>Hospital Prof. Dr. Fernando de Fonseca, Amadora, Portugal, <sup>3</sup>Hospital de Santo Antonio, Oporto, Porto, Portugal, <sup>4</sup>Hospital Distrital de Faro, Faro, Portugal, <sup>5</sup>Centro Hospitalar do Alto Ave, Fafe, Fafe, Portugal, <sup>6</sup>Medtronic Portugal, Lisbon, Portugal, <sup>7</sup>Medtronic, Mounds View, MN, USA

**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 syncope event. Model parameters and transition probabilities were derived from landmark publications. The average cost of a syncope admission was estimated from the latest official Portuguese cost tables and the PICTURE trial. Costs were discounted at 5% p.a. The cost of implanting ILRs was estimated for a total of 215 patients with unexplained syncope, based on the total number of hospitalised syncope patients during one year in Portugal according to the latest National DRG report. PSA was performed to explore the impact of the uncertainty in the input parameters (HR of Death; number of syncope events per year and yield of diagnose) in three year and lifetime time horizons. **RESULTS:** The average cost of an event was estimated at 1.960€. The total cost of syncope admissions over three years was 66% lower with ILR (501.338€) vs. SoC (1.486.503€). ILR clearly lead to earlier diagnosis and consequently to a lower number of syncope admissions allowing important savings, that in this case were estimated between 985.165€ over three years and 2.177.254€ over patient lifetime. **CONCLUSIONS:** The utilization of Reveal® leads to less hospital admissions and investigations, proving its potential for significant cost savings in the Portuguese population.