



# Value IN HEALTH

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**RESULTS:** A substantial share of the variance (around 20%) was related to the hospital level. Preliminary results suggest that supplementary fees had a borderline significant positive impact on DES use. Further hospital characteristics also had a significant impact on the use of DES ( $p < 0.05$ ), as well as area characteristics. **CONCLUSIONS:** Although there seems to be a small influence of supplementary fees on the use of DES, further hospitals' and area characteristics might be of higher importance than reimbursement incentives. Attributing the diffusion of technologies to financial incentives only would fall too short.

## PMD65

## SYSTEMATIC REVIEW OF STUDIES OF THE EFFICIENCY OF NEGATIVE PRESSURE THERAPY FOR COMPLEX FOOT WOUNDS IN DIABETIC PATIENTS

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**OBJECTIVES:** Systematic analysis of the available studies of the clinical effectiveness and safety of negative pressure therapy, as compared with traditional courses of treatment, in complex foot wounds in diabetic patients. **METHODS:** A bibliographical search was performed in the following databases: Embase.com, Medline and Cochrane Library, covering from 2000 until the present. The following descriptors and key words were used: diabetic foot, negative-pressure wound, vacuum-assisted closure and diabetic ulcers. The Jaddad criteria were used to determine the quality of the clinical trials. The studies selected were randomized clinical trials that featured patients older than 18 years, with complex ulcers, postoperative wounds, or wounds resulting from the amputation of the foot, with a control group comparing negative pressure therapy with conventional therapies (saline solution, alginates or hydrophilic substances). The treatments were applied every 48 hours. A total of 12 studies, of which only 7 were pertinent, were selected. Two independent reviewers extracted the information and determined the methodological quality of the selected studies. **RESULTS:** Of the 7 studies selected (539 patients), 5 involved patients with postoperative wounds and 2 used the same group of patients. One of the two studies involving ulcers of the foot was limited by its simple size ( $N = 10$ ). The methodological quality of the studies is moderate-low. **CONCLUSIONS:** The evidence supports the effectiveness and security of negative pressure wound therapy in complex foot ulcers in diabetic patients. Given that it is unlikely that further research will change this positive appraisal (despite the moderate-low quality of the studies analyzed, its cost profile and the absence of adverse effects) it is possible to make a strong recommendation in favor of the therapy.

## PMD66

## DEMAND FOR ROUTINE IN OFFICE FOLLOW-UP VISITS FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED) IN GERMANY AND THE UNITED KINGDOM

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**OBJECTIVES:** Based on clinical trial evidence, remote follow-up (FU) has been recommended for replacing in office visits routinely scheduled to monitor device functionality and health status of patients with CIED. No data exist on the actual demand for such visits. To estimate the total number of calendar based in-office FU visits in Germany and the UK (UK) by 2015. **METHODS:** Official national sales data for implantable pacemakers (PM), cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT) devices were combined with published replacement rates and estimates for patient mortality and device longevity. Following HRS/EHRA guidelines on FU frequency, demand for FU consultations until 2015 was modelled. **RESULTS:** For 2010, the model estimates about 677'800 prevalent patients with a CIED in Germany and 225,000 in the UK. The growth in CIED patients recently seen in the UK is expected to slow down but to continue to be higher than in Germany (+8.3% per annum until 2015 versus 4.8%). Assuming two annual visits for PM patients and four visits for ICD and CRT patients, the total number of routine FU visits is estimated to increase from 1.66 mio in Germany (2010) to 2.23 mio (2015). For the UK, service numbers will increase from 538,000 (2010) to 836,000 (2015). These estimates do not include unscheduled FU visits. **CONCLUSIONS:** Regular FU services for CIEDs are mandatory to ensure device functionality and monitor disease status. Increasing patient volumes will push demand for these services, placing a potentially unmanageable burden on cardiology service providers, payers and patients, unless infrastructure investments occur. High demand for services and low actionability of routine visits may result in inappropriate guideline adherence with potentially negative impact on patient safety and device longevity. Clinics need to become aware of this situation and adopt strategies for handling the expected workload in the future.

## PMD67

## THE COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION IN ELDERLY PATIENTS WITH SEVERE AORTIC STENOSIS WHO ARE CONTRAINDICATED FOR CONVENTIONAL SURGICAL AORTIC VALVE REPLACEMENT IN THE UNITED KINGDOM

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**OBJECTIVES:** To assess the cost-effectiveness of transcatheter aortic valve implantation (TAVI) versus medical management (MM) for severe aortic stenosis (AS) in elderly patients with excessive surgical risk. **METHODS:** A Markov model was developed of survival, quality-adjusted life-years (QALYs) and medical costs, in elderly patients in the UK with severe AS and excessive risk for conventional aortic valve replacement (cAVR). Incremental cost-effectiveness ratios (ICERs) were esti-

mated as cost per QALY-gained, from the National Health Service (NHS) perspective, over 3 years. Clinical and utility outcomes over the first year were derived from published results of a head-to-head randomized controlled trial comparing [transfemoral] TAVI and MM. Base-case analyses assumed no additional procedure-related adverse events after the first year—not including re-hospitalizations due to cardiovascular events—and constant treatment-specific mortality after the first month. Costs of procedures, adverse events, re-hospitalizations and long-term health care utilization were estimated using NHS tariff and reference cost schedules, National Institute of Health and Clinical Excellence reports, peer-reviewed literature and clinical experts. Outcomes and costs (2010€) were discounted at 3.5% per annum. **RESULTS:** Under conservative assumptions, treatment with transfemoral TAVI is estimated to result in better survival (35% vs. 13% at three years) and more QALYs (1.17 vs. 0.76) than MM. TAVI is also associated with higher costs of initial treatment and procedure-related adverse events, partially offset by lower costs of re-hospitalizations (net costs of £34,500 vs. £23,700). The base-case ICER of £26,100 is sensitive to variation in assumptions about long-term mortality for MM and long-term cardiovascular events for TAVI but remains below £30,000; the model is also sensitive to assumptions on long-term care use. **CONCLUSIONS:** In elderly patients who are contraindicated for cAVR, TAVI is estimated to result in better survival and fewer re-hospitalizations over a three-year period compared with MM, and can be considered cost-effective at 3 years with a base-case ICER of ~£26,000.

## PMD68

## PURCHASING AND ADOPTING CARDIOVASCULAR DEVICES: A GLOBAL SURVEY

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**OBJECTIVES:** The objectives of this study were to: 1) evaluate, from a global perspective, the decision-making processes, roles of individuals involved, and physicians' and administrators' beliefs about future decision making for the adoption of cardiovascular devices and medical technologies; and 2) determine which clinical and health economic factors decision makers consider the most influential and what types of data they use when making decisions. **METHODS:** We surveyed cardiovascular physicians and hospital administrators in the US, UK, Australia, France, Germany, and Japan using a web-based questionnaire. Respondents were asked about their involvement in and opinions on the decision-making process in their institutions, and the role that clinical and economic data play in influencing decisions. Chi-squared tests were used to test for statistical differences between physicians and hospital administrators (all countries combined) and across countries. **RESULTS:** The questionnaire was completed by 151 physicians and 154 administrators across the six countries with roughly 25 physicians and 25 hospital administrators responding from each. Physicians, followed by hospital committees, were most frequently responsible for making decisions, but respondents believed influence would shift towards committees in the future. Physicians (78%) and administrators (81%) believed costs would more heavily influence decisions in the next 5 years. Approximately half of hospital administrators consulted economic data often when making device adoption decisions. Use varied somewhat by country with most frequent use by both physicians and hospital administrators in the U.S., U.K., and Australia. **CONCLUSIONS:** Physicians' and hospital administrators' roles in decision making for cardiovascular devices appear to be changing in many countries, with committees and administrators assuming more important roles. While clinical data is most influential to the decision process, the impact of health economic data seems to be growing.

## PMD69

## TREATMENT OF URINARY TRACT INFECTIONS IS COMMON AMONGST SWEDISH PATIENTS IN NEED OF CHRONIC CATHETERISATION

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**OBJECTIVES:** To collect real-life data from a Swedish setting on treatment patterns and frequency of urinary tract infection (UTI), amongst patients in presumed need of chronic, intermittent catheterisation. **METHODS:** We used the CEBRxA database, which combines data from a public claims database for the South-West region of Sweden, comprising around 1.5 million individuals, with national Swedish registers on drug utilisation and mortality. We identified two sets of patients; Population I: spinal injury, in addition to neurogenic bladder, and Population II: self-catheterisation training (GB005). A list of antibiotics, known for their frequent use in treating UTIs was used to evaluate treatment patterns. In addition, a prophylactic treatment for UTI was evaluated (J01AXX05). An antibiotic regime was defined through considering all dispatches that occurred within 14 days from each other, simultaneously (data available from 2005-07-01 until 2009-12-31). **RESULTS:** We identified 295 and 989 patients for Population I and II, respectively. Both populations consisted primarily of males, while Population I was on average much younger (44 vs. 65 years). For Population I, we observed an average frequency of 2.5 UTI-related antibiotic regimes per year. For Population II, an average rate of 1.9 UTIs per year was observed, while females showed an elevated rate of 2.5. Interestingly, prophylactic use of antibiotics was widespread in Population I, with usage in 25% of patients, while for Population II, only 3% of patients had dispatched J01AXX05. An evaluation of the prescribed dose for Population I prophylaxis users, pointed to an almost continuous use, at an average 235 DDD per patient and year. **CONCLUSIONS:** Through studying UTI-related antibiotic treatment patterns we demonstrated a high disease burden for UTIs in two, primarily male, populations, in presumed catheterisation need. The frequent use of prophylactic treatment in the spinal injury population pointed to an even larger disease burden for these patients.

external data using Bayesian MCMC methods. Economic analysis was undertaken using 1) standard cost-utility decision rules within each topic, and 2) constrained optimisation across all modelled topics. **RESULTS:** The guideline included fifteen individual economic evaluation topics. Under usual processes, piecewise economic modelling would have been used to evaluate between one and three guideline topics. The Whole Disease Model provided a consistent platform for the economic evaluation of eleven of the fifteen guideline topics, ranging from alternative diagnostic technologies through to cytotoxic treatments for metastatic disease. The constrained optimisation analysis identified a configuration of colorectal services which was expected to maximise QALY gains without exceeding current expenditure levels. **CONCLUSIONS:** This study demonstrates that Whole Disease Modelling is feasible and can allow for the economic analysis of virtually any intervention across a disease service within a consistent conceptual and mathematical infrastructure. The approach may be especially valuable in instances whereby a substantial proportion of a disease service has not previously been subjected to economic evaluation.

## PCN194

#### THE USE OF LARGE GPS LONGITUDINAL DATABASE IN THE RESEARCH OF CAUSAL ASSOCIATIONS AMONG PATHOLOGIES: THE CASE OF DIABETES AND CANCER INCIDENCE

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**OBJECTIVES:** To study the association between Diabetes Mellitus (DM) and the incidence of Cancer, focusing on type-specific and sex-specific cancers. **METHODS:** Study's data were obtained from CSD LPD, an Italian General Practitioner's longitudinal database. We have evaluated the risk of Cancer incidence among people with DM compared with those without this pathology, in patients who had no reported history of Cancer at the start of the follow-up on January 2006. For the DM group, patients with at least one diagnosis of DM and a GP contact from January - December 2005 have been selected, while for the DM free group, patients without a diagnosis of DM and a contact with the GPs in the same period have been selected. Both groups have been followed-up for 5 years. In order to evaluate an association between the presence of DM and the incidence of Cancer multivariate logistic models adjusted by age and sex have been implemented. **RESULTS:** A total of 73.144 (6%) patients with a diagnosis of DM and 1.119.652 (94%) patients without DM diagnosis were selected. During follow-up 8.824 and 82.477 incident cases of Cancer were documented from the DM and DM free groups respectively. Statistical analysis showed an Adjusted (age and sex) Odds Ratio of 1,06 (95% CI 1,06-1,20) suggesting that patients with DM have a 6% increased risk of cancer incidence (all types). Regarding type-specific cancer analysis the OR for Liver cancer (2,44 [95% CI 2,11-2,82]) and Pancreas cancer (2,27 [95% CI 1,95-2,66]) were higher for DM patients. Regarding sex-specific cancers, the risk of Uterine body cancer was higher for diabetic women (1,52 [95% CI 1,17-1,99]), while in men DM seems to have a protective effect, for example in Prostate cancer (0,86 [95% CI 0,79-0,95]). **CONCLUSIONS:** Patients with DM may be at increased risk of total, site-specific and sex-specific cancer.

## PCN195

#### BAYESIAN CALIBRATION OF A CERVICAL CANCER MODEL USING MARKOV CHAIN MONTE CARLO

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**OBJECTIVES:** Simulation models are an essential tool in estimating the impact of vaccination, screening and treatment on cancer rates. Model calibration is the process of identifying reasonable values for model parameters, such that the outputs of the model are close to values observed in a real population. The purpose of this work was to calibrate an existing model for cervical cancer using Irish data and Markov Chain Monte Carlo (MCMC) in a Bayesian framework. This is compared and contrasted with a previous random search calibration. **METHODS:** An existing microsimulation model for cervical disease which was coded in C was embedded in a loop running in R. MCMC, which is an iterative algorithm was implemented in parallel on multiple desktop machines and the results were collated for analysis. The calibration method used differs from pure optimisation strategies and identifies a probability distribution on the parameter space, which is of benefit for models requiring probabilistic sensitivity analysis. **RESULTS:** Estimates of the model parameters were obtained from both MCMC and from the fitting of existing reference parameter sets resulting from a random search of the parameter space. These are compared on the basis of goodness of fit statistics (the sum of squared errors between targets and fitted values). Of 20 MCMC chains that were run, 5 of them gave better fits than the best fit sets for the random search method. However, 8 of the 20 chains had not reached parameter sets that gave good fits when compared with the best 135 fitted sets from the random search method. **CONCLUSIONS:** MCMC is a useful technique which provides probabilistic estimates of the parameters of interest in a calibration exercise. Care is needed with starting values and proposal distributions to ensure that the chains have converged and that the parameter space is properly explored.

## PCN196

#### REVIEW OF COST EFFECTIVENESS OF TRASTUZUMAB IN EARLY BREAST CANCER

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**OBJECTIVES:** The treatment of breast cancer is associated with high costs, influenced by the introduction of more effective but expensive drugs, such as trastuzumab. This study aims to review cost-effectiveness studies of trastuzumab in the adjuvant setting of early breast cancer and to explore the relation between (methodological) differences in study design and cost-effectiveness outcomes. **METHODS:** A systematic review was performed to identify cost-effectiveness studies of trastuzumab published between January 1998 and March 2011. All costs were converted to 2009 Euros. Sources of variation in study design were identified and divided into three categories: 1) methodological factors prescribed by national guidelines; and 2) intrinsic factors, such as methodological or practical choices made by the principal researchers; 3) extrinsic factors, such as the price of trastuzumab. **RESULTS:** Fourteen cost-effectiveness studies were identified of which one was a meta-analysis integrating data of multiple clinical trials. All were modelling studies. ICERs of chemotherapy + trastuzumab vs. chemotherapy alone ranged from being the dominant strategy to € 87.889/QALY gained. The level of detail presented regarding study design and outcomes differed strongly, hampering the identification of factors influencing this wide range of outcomes. However, of the mutually presented aspects, especially the treatment regimen of the underlying clinical trial seemed to influence outcomes. Variation among studies using the same clinical trial appeared related to methodological factors prescribed by national guidelines, such as perspective and time horizon, intrinsic factors, such as assumed duration of benefit and extrinsic factors, e.g. country specific practice variation. **CONCLUSIONS:** Cost-effectiveness levels of trastuzumab differed strongly, even between modelling studies based on the same clinical trial. Outcomes were influenced by methodological aspects such as time horizon chosen and assumed duration of benefit. A higher level of detail presented in the articles is needed to increase insight in causes of variation in cost-effectiveness outcomes.

## PCN197

#### HEALTH RELATED QUALITY OF LIFE IN LONG TERM SURVIVORS OF LYMPHOMA: A POPULATION BASED STUDY

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**OBJECTIVES:** To assess the health related quality of life (HRQoL) in the growing group of long term lymphoma survivors with preference based instruments. **METHODS:** Population based cross-sectional data was collected in patients diagnosed with Hodgkin lymphoma (HL) or non-Hodgkin lymphoma (NHL) (N=778). HRQoL was measured using both a generic and a disease specific preference-based instrument, the EQ-5D 5-level and a time-trade-off valued version of the EORTC QLQ-C30. **RESULTS:** On average patients with HL or NHL were diagnosed 4.35[±SD 2.56] years prior to the study. Mean QoL was 0.83 using EQ-5D [±SD .16, Range -.11 - 1.0] and 0.88 using QLQ-C30 [±SD .10 Range .38 - 1.0]. Mean EQ-5D score for lymphoma survivors is significantly lower than the average HRQoL found in the Dutch population (p<0.001). However, mean QLQ-C30 score for lymphoma survivors did not differ from the Dutch population. Regression analysis identified a significant lower HRQoL with having active disease (measured by treatment activity) and comorbidities depression, high blood pressure, respiratory diseases, osteoarthritis, and back-pain. Age, type of lymphoma, and time passed since diagnosis did not affect HRQoL. The discrepancy between EQ-5D and QLQ-C30 in deviation from the Dutch population is likely to be caused by better discrimination of worse health states in the EQ-5D. **CONCLUSIONS:** The average HRQoL in long-term lymphoma survivors seems relatively high, especially when measured by the QLQ-C30. However, subgroup analyses revealed HRQoL was affected by active disease and comorbidities, other than, but perhaps related to, cancer. This has two important implications. Firstly, population-based studies need to incorporate comorbidities to adequately assess and forecast HRQoL in lymphoma survivors. Secondly, in economic evaluations the modelling of cancer free survival needs to be reconsidered since HRQoL in life years gained is affected by comorbidities. Future economic evaluations should incorporate these two implications to obtain more accurate HRQoL estimates.

## PCN198

#### REVIEW OF ECONOMIC ASSESSMENTS OF EMERGING GENOMIC TECHNOLOGIES IN ONCOLOGY

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**OBJECTIVES:** A systematic review of the economical assessment studies on genomics and proteomics in the field of oncology. Our aim is to analyze those emerging diagnostic and therapeutic technologies whose cost effectiveness ratio make them suitable for its adoption in the different health systems from a social point of view. **METHODS:** We locate the most relevant studies in the last 10 years in Medline, Embase, Cancerlit, Cochrane Library databases and we analyze the results. The following keywords were used: genetic screening, gene, pharmacogenomics, proteomics, microarrays, biochips, cost analysis, cost effectiveness, cost benefit, cost minimization, neoplasm, tumour and cancer. **RESULTS:** We analyze 13 studies from which 5 assess aspects about breast cancer, 7 about colorectal neoplasm, and 1 about urologic pathology. From these analyzed studies, 4 were cost utility studies, 8 were cost effectiveness studies, and one was a cost minimization study. **CONCLUSIONS:** We highlight the increase of economical assessment studies on genomics and proteomics, constituting an invaluable help for the sanitary and medical decision makers over the suitability and relevance of incorporating the contributions of genomics and proteomics in the field of oncology, introducing the specific ethical and social aspects of this specialty.