PMD70
A REVIEW OF THE GEOGRAPHIC VARIATIONS IN THE IMPLANT RATE OF TRANSCATHETER AORTIC VALVES IN 14 EUROPEAN COUNTRIES
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OBJECTIVES: Multiple medical reimbursement systems exist in Europe, which may create unequal dissemination and coverage of innovative medical devices. Even in the setting of regularly revised systems, uptake of new technology may be delayed leading to unequal reimbursement. **METHODS:** This study analyzed the 2010 geographical trends of transcatheter aortic valve implantation (TAVI) rates in 14 countries (Medtronic CoreValve System and Edwards Sapien). Implant data were gathered from BIBA Medical Ltd, a UK-based provider of consulting and market analysis services for the medical device industry. In addition demographic and economic data were gathered from Eurostat, a statistical office of the European Union. Regression techniques were used to explore the relationship between implant rate and a number of key variables. **RESULTS:** In 2010, a total of 14,400 TAVI procedures were documented providing an average country-based implant rate of 36.2 per million/Inhabitants. A seven-fold difference in implantation rate existed between the highest and lowest implanting countries (Germany, 77 per million/inhabitants vs. Norway 12 per million/inhabitants). Implant rates were correlated with per-capita GDP (r^2=0,015), health expenditure (r^2=0.15) and number of implanting centers in the country (r^2=0.18). At this time, only two European countries have a dedicated tariff for TAVI that is applicable nationwide and covers both the device and the procedure (Germany – €34,900, France - €28,477). Differences between country-specific tariffs depend on the method of DRG calculation. In Austria, the TAVI tariff was made to equal that of surgical aortic valve replacement. Countries such the UK and Italy have adopted case-by-case funding. In countries such as Belgium and the The Netherlands TAVI is funded by the hospital-based budget. **CONCLUSIONS:** Significant differences in TAVI rates exist among European countries. These observations may help us to better understand unequal patterns of dissemination and coverage of innovative medical devices such as TAVI.

PMD71
RESOURCE USE CAUSED BY IN-OFFICE FOLLOW-UP VISITS FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED) IN GERMANY AND THE UNITED KINGDOM
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OBJECTIVES: Expert consensus recommends follow-up (FU) for patients with pacemakers to be performed twice annually, with implantable cardioverter defibrillators or cardiac resynchronization therapy devices four times annually. Most of the routinely scheduled calendar based FU in-office visits do not require further action but contribute to the consumption of limited health care resources. This model estimates the resource use associated with in-office FU visits in Germany and the UK (UK). **METHODS:** Own estimates on the number of FU visits were combined with previously published data on frequency and distance of private and public transport. Recently published data on healthcare personnel resource use were considered to model hospital resource use. Data were modeled until 2015. **RESULTS:** If service providers continue the current service model of routine calendar based in-office visits for CIED patients, about 2.23 mio visits will be needed in Germany, and 836'000 in the UK in 2015. These visits would consume approximately 1.11 mio hours of time in consulting rooms in Germany, and 418,000 hours in the UK. More than 87,000 ambulance transports in Germany and 33,000 in the UK will be required for patients attending FU visits. Patients able to use their own transport will drive about 287 mio kilometers in Germany and 28 mio kilometers in the UK. Workload for physicians, nurses and technicians will reach 1.1 mio hours in Germany, and 406,000 hours in the UK, most of them being provided by physicians. These estimates do not yet include unscheduled and emergency services for CIED patients. **CONCLUSIONS:** The increasing number of in-office FU visits will continue to place a heavy burden on primarily cardiology service providers but also on patients. Technologies such as BIOTRONIK's Home Monitoring can assist hospitals in handling the increasing service demand, free patients from unnecessary travel burden, and ensure adherence to FU.

PMD72
MAMMA CARCINOMA – DATA ANALYSES AND CLASSIFICATION OF TREATMENT IN AUSTRIA
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OBJECTIVES: Cost of illness analysis of breast cancer in Austria using mainly Austrian billing data from intramural and extramural medical treatment based on data from 2006/07 for treatment and degree of severity evaluation. Regarding this project a detailed treatment course classification has to be realized to evaluate the costs and patient ways in Austrian health system. **METHODS:** Main strategy of the project is the combination of data samples detected by Austrian cancer registry and billing data of intramural and extramural single person datasets in combination with intake data of medication for each patient. By combining the recorded data from national statistics, including TNM-classification of each new breast cancer case, and the ICD10-diagnoses, as well as medical individual services, results in classification of breast carcinoma on single person level are achieved. For separation of drug treatment concerning chronical diseases versus cancer indicated drug administration, the half year time span before the first mamma carcinoma detection and the year afterwards is analyzed separately. Special medication groups are assessed in detail and inclusion/exclusion – criteria for costs and treatment are defined. **RESULTS:** Based on this identification an alternative subsumption of new detected carcinoma in six groups (hormone receptor positive, Her 2 positive, hormone receptor positive and Her 2 positive, triple negative, metastasizing mamma carcinoma, early stage mamma carcinoma without chemo therapy in course of treatment) is defined. **CONCLUSIONS:** This classification leads to better insights for cost evaluation representing the state of the art in Austria. This strategy also leads to better overall reliability because the margin of uncertainty of the parameters can be reduced significantly.

PMD73
COMPARISONS OF ANAPHYLACTOID REACTIONS ASSOCIATED WITH DIFFERENT GADOLINIUM PRODUCTS AND IODINATED CONTAST MEDIA USING THE FDA'S ADVERSE EVENT REPORTING SYSTEM
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OBJECTIVES: To review reports of anaphylactoid reactions from gadolinium products (GPs) and iodinated contrast media (ICMs) and to compare events, outcomes, and signals associated with different GPs. **METHODS:** We reviewed ARs in the FDA Adverse Event Reporting System (AERS) and compared reports for GPs and ICMs. We searched FDA-AERS using all reaction terms for ARs linked with GPs and, separately, ICMs. We compared demographics, outcomes, and types of reactions between GPs and ICMs. We compared signal detection results for each GP using proportional reporting ratios (PRRs) and 95% confidence intervals (CI). **RESULTS:** Through March 2010, there were 494 and 2,533 reports for GPs and ICMs, respectively. The data are not confluent since ICM usage preceded GP usage (first ICM event date: 1943, received by FDA: 1969; first GP event date: 1969, received by FDA 1998). Mean ages (± standard deviation) were 49.1±18.0, and 57±18.5, and % male/female were 38%/59% and 40%/43% for GPs and ICMs, respectively. The ARs for GPs and ICMs were serious in 91.7%/97.5% and fatal in 7.5%/13.9%, respectively. Proportions of reports and PRRs (CI) for linear GPs were: gadopentetate dimeglumine = 45.3%, 5.03 (4.34-5.71), gadobenate dimeglumine = 25.9%, 11.41 (9.67-13.46). For the other linear GPs, gadodiamide was reported in 7.9% and gadoversetamide in 0.1%, but the number of cases of use of the agents alone were too small to determine PRR. Gadoteridol, a cyclic GP, was reported in 18.2% of cases with a PRR of 5.27 (4.30-6.45). Overall, PRRs were indicative of safety signals for both GPs and ICMs, 5.9, (5.4-6.4), 7.4 (CI: 7.1-7.7), respectively. **CONCLUSIONS:** FDA-AERS data indicate that GP-associated ARs generate a safety signal comparable to ICMs. Although over 80% of GP-associated ARs were with linear GPs, there was a significant safety signal for one macrocyclic structure GP as well as two linear structure GPs.

PMD74
HOME DIALYSIS MODALITIES: THE DEVELOPMENT OF A FRAMEWORK TO IDENTIFY AND QUANTIFY FAVOURABLE RENAL POLICY AND REIMBURSEMENT FACTORS
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OBJECTIVES: The use of home dialysis modalities such as peritoneal dialysis and home haemodialysis varies across Europe and North America from today <5% in Germany to 28% in Denmark. These differences have often been attributed to reimbursement and renal care organization factors. This analysis was undertaken to quantify the strength of association of potential factors influencing usage of home dialysis modalities with the intent to later facilitate evidence based policy choices. **METHODS:** A 4-pillar framework including 8 different factors (home target, reimbursement level, payment flow, pre-dialysis education, assisted dialysis, home guideline/policy, incentives for home, monitoring/planning tool) was postulated to explain the variation in home dialysis usage across countries. A semi-quantitative scoring algorithm was developed and used to rate the renal care organization of 12 European countries, Canada, and the USA based on publicly available information. A regression analysis was used to explore the relationship between the score and the use of home dialysis modalities as retrieved from the latest available renal registry reports. The most significant factors were identified by analysis of variance. **RESULTS:** A significant (r^2=0.694; p<0.001) correlation was found between the total score and home dialysis usage. Countries like Denmark and Sweden achieving a score of 5 have a 26-28% usage of home modalities. In comparison, Germany had a score of −2 and <5% of dialysis patients are on home modalities. Three factors were especially significant: well funded and independent pre-dialysis education (p<0.001), clinical guideline/policy favouring home modalities (p=0.002), and (absence of) provider-driven demand (p=0.035). **CONCLUSIONS:** The 4-pillar framework appears to be useful to identify gaps in a country renal care policy and decide on further actions to be taken when intending to increase usage of home dialysis modalities. Actions to implement/correct pre-dialysis education, clinical guideline/policy favouring home modalities and (absence of) provider-driven demand should probably be prioritized.

PMD75
PATIENT SELF-TESTING OF ORAL ANTICOAGULATION THERAPY BY COAGUCHEK® XS SYSTEM. RAPID HEALTH TECHNOLOGY ASSESSMENT IN SLOVAK HEALTH CARE ENVIRONMENT
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OBJECTIVES: to explore the effects of patient self-testing (PST) of oral anticoagulation therapy (OAT) by CoaguChek® XS System compared to standard available care (laboratory testing) for selected group of patients. **METHODS:** Health Economy Model (HECON), using Cost-Effectiveness Analysis (CEA), complemented by Budget-Impact Analysis (BIA) on public health insurance coverage in Slovakia. We searched MEDLINE, Cochrane and available grey literature (Industrial Sources and Expert Opinions) for meta analyses, systematic reviews, economic evaluation studies and health technology reports on PST of OAT. Outcomes analyzed were feasibility and accuracy of PST, thromboembolic events, hemorrhagic complications and mortality. Real-world data from General Health Insurance, Inc. were used for costs associated with corresponding diagnoses, complications and management of patients on OAT, including full cohort of patients (n=100, average age of 63 years) on PST. Markov Model (life time horizon) for OAT patient management was developed, comparing PST with standard care. Outcomes observed were major thromboembolic events, major hemorrhagic complications and mortality. Payer perspective and direct healthcare costs only, associated with OAT management were considered in CEA and BIA for diagnosis subgroups. Discount rate of 5% was used for costs as well as outcomes. Sensitivity analysis for major complications was performed. **RESULTS:** CEA for PST vs. standard care associated with OAT shows that intervention is cost-effective (dominant) for all diagnosis subgroups. Net costs (BIA) associated with PST for expanding the existing cohort of patients 10 times (n=1000) are 1.596 mil. € in Year 1 (up to 3.579 € in Year 5). **CONCLUSIONS:** PST of OAT is considered cost-effective in terms of International Normalized Ratio (INR) regulation and safer in terms of complications. Moreover, analysis of selected subpopulations (mitral and/or aortic mechanical heart valve implantation, aortic and/or other aneurysm and congenital cardiovascular malformations) shows that PST brings the most significant cost-savings especially for those OAT patient segments.

PMD76

ARE HEALTH TECHNOLOGY ASSESSMENTS OF MEDICAL DEVICES CATCHING UP WITH PHARMACEUTICALS?

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OBJECTIVES: To evaluate how HTA is applied to medical devices (MD) and to assess whether established HTA agencies have similar influences over MD coverage and reimbursement decisions compared to pharmaceuticals. **METHODS:** Manual search of 69 HTA agencies' websites was conducted to determine whether they undertake MD HTAs. Of the agencies that reported MD assessments, we evaluated the HTA process in respect to methodological approaches and influence on market access decisions. **RESULTS:** The majority (49 out of 69) of HTA agencies conduct MD assessments and make these appraisals publically available. Thirty-five of these agencies provide reimbursement advice in their reports. In most cases recommendations serve as non-mandatory guidance, aimed at helping local and national stakeholders make informed decisions about the use of the device within their health care system. Despite widespread use of MD evaluations, the number of completed reviews is relatively low. Sixty percent of the agencies that performed MD HTAs (29 out of 49) applied similar methodologies to both MD and drug assessments. **CONCLUSIONS:** While the majority of HTA agencies are adding MD assessments to their work plans, procedural pathways are not as transparent and robust as those for pharmaceuticals. Combined with the low output of publications this currently leads to limited application of MD HTAs to market access decisions. However, a new system is emerging which recognizes the unique features of MD and the distinctive level of evidence needed for regulatory approval. In future we anticipate that market access of medical devices will be centralized under the umbrella of existing HTA agencies. Thus, following the example of NICE, HAS and CVZ which have established one national HTA process, with independent pathways within their agencies for both drug and MDs.

PMD77

COMPONENTS OF HEALTH TECHNOLOGY ASSESSMENT FOR RADIOLOGY IN CHILE

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OBJECTIVES: The objectives of this paper are to present the current status of HTA in the field of radiology and describe the role played by Chilean Health System governmental institutions and private agents in the decision-making process in order to allocate resources for the incorporation of new technology. **METHODS:** A bibliographical review was made based on the opinions of local experts, and a review of the available local literature. **RESULTS:** The decision-making process of acquiring a new technology in radiology is different depending on whether the provider is public or private. For public providers, first, the hospital solicits to include the purchase of the equipment in the budget for the year immediately following. Then, the decision is taken by the Ministry of Health (MINSAL). It is a centralized decision, but not subdue to a formal economic assessment. For private providers, the decision usually comes from the clinical need. An economic assessment for viability is carried out, expected demand and budgeted costs of examination are calculated in order to calculate the payback time on investment and finally decision to purchase is made. **CONCLUSIONS:** Data on health economics are increasingly important to the Chilean health authorities, even though, they are not considered essential to make decisions. At present, there is more awareness of the importance of implementing methods of analysis. Therefore, it is advisable to continue providing such information. On the whole, the decision to purchase a new technology in radiology depends on whether the provider is public or private. It does not involve variables derived from complex economic or structured studies, but depends on the need of the equipment and market availability.

PMD78

BENEFIT-RISK ANALYSIS IN ABSENCE OF CLINICAL EVIDENCE: DECIDING FOR TREATMENT OF SKULL DEFORMITY IN BABIES AGED 5 MONTHS

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OBJECTIVES: Skull Deformaty (SD) is a flattening of the head as a result of pressure on the malleable skull in infants in the first months of life. Presently, a RCT is conducted to compare the effect of an orthotic helmet to the natural recovery of skull shape in the first three years of life. Burden of treatment is considerable; the helmet has to be worn 23 hours a day for at least 6 months. Possible harms include acceptation problems, pressure wounds and severe skin rash or eczema. The harms of treatment are perceived as an important reason for low adherence to and parental refusal of helmet treatment. The objective of this study is to estimate the risk-benefit trade-off in SD management in pediatric physiotherapists. **METHODS:** A discrete choice experiment was performed with the most important attributes of SD management. A total of 267 pediatric physiotherapists stated their preference for treatment of a 5 month old child with SD. A three scenario design was chosen Each scenario was characterized by its effect, its burden and the harms of treatment. Logistical regression analysis was performed to analyze the results of the discrete choice experiment. **RESULTS:** Not surprisingly, child physiotherapists' ideal treatment has a high probability of timely success with low burden and minimal harms. At present, most attributes indicate a strong preference for awaiting natural recovery. Risk benefit assessment favoring the helmet will only be attained if the helmet can show highly significant clinical benefit. **CONCLUSIONS:** This study shows that risk benefit analysis can give early indications on the potential of a treatment, by estimating the effectiveness at which the treatment becomes more favorable than its comparator. Whether the risk-benefit analysis will be in favor of helmet treatment in the case of SD, is questionable, as earlier studies have not demonstrated superiority of the helmet.

PMD79

AN EVALUATION OF THE NON-INVASIVE IMAGING TESTS USED IN CURRENT CARE OF TIA AND MINOR ISCHEMIC STROKE IN THE NETHERLANDS: HOW MUCH PRACTICE VARIATION IS THERE?

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OBJECTIVES: There is increasing interest in estimating the health and economic impact of a new technology in the early phases of its development. However, this requires knowledge about current care. We examined how non-invasive imaging is currently used to assess carotid stenosis in patients with a recent TIA or minor ischemic stroke, as a first step in an early economic evaluation of new imaging technologies which will be used for the prediction of the risk of plaque rupture. **METHODS:** We first examined the current guidelines in the The Netherlands, Europe and US regarding the use of non-invasive imaging tests (i.e. CT angiography (CTA), duplex ultrasonography (DUS), MR angiography (MRA)) in the assessment of carotid stenosis in patients with a TIA or minor ischemic stroke. In addition, semi-structured interviews were conducted with neurologists in several Dutch hospitals to determine how patients are actually diagnosed in daily clinical practice. **RESULTS:** Current guidelines differ in the use of non-invasive imaging tests in assessing carotid stenosis in patients with a recent TIA or minor ischemic stroke. In addition, practice variation is high, since hospitals use different (combinations of) tests. According to the neurologists, these differences are probably caused by capacity problems, degree of expertise in performing certain tests and lack of evidence regarding effectiveness and cost-effectiveness of the imaging tests in assessing carotid stenosis. **CONCLUSIONS:** The observed practice variation is high, and has implications for assessing the health and economic impact of the new technology, since estimating impact requires comparison with current care. The choice of just one comparator representing current care is therefore meaningless, since choice of comparator may strongly affect the estimated health and economic impact of the new technology. The final impact of a new technology will be hospital-dependent, and therefore multiple comparisons and scenario analyses are needed.

Medical Device/Diagnostics – Research On Methods

PMD80

PATIENT DEMOGRAPHICS AND SURGICAL EXPENDITURE IN HERNIA REPAIR SURGICAL COHORTS USING A RETROSPECTIVE NATIONWIDE PATIENT DATABASE

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OBJECTIVES: Several observational studies have examined the epidemiological and social characteristics of patients undergoing hernia surgery, but conclusions drawn from these studies are generally limited due to the small sample population. Here we describe patient demographics of hernia repair patients and surgical expenditure using a population-based approach with a retrospective nationwide database. **METHODS:** Premier Inc has established one of the largest hospital databases worldwide. It collects patient data from around 500 hospitals in the US. Hernia surgery was stratified by inpatient or outpatient treatment, hernia repair surgery type (inguinal, incisional or umbilical), surgical procedure (laparoscopic or open), and the type of mesh used (flat, tissue-separating or device). Patient demographics were recorded and are presented for every cohort of patients. Surgical