

burden for clinical budgets. The regional data analysis indicates that patient access to EGFR-mutation testing is significantly related to the density of clinics and of specialized physicians in respective federal states. **CONCLUSIONS:** Decentralized organization and funding of health care and diagnostics have led to significant regional disparities. Therefore, a detailed analysis of regional health care structures in oncology is necessary.

#### PMD89

##### DIAGNOSTIC ACCURACY OF EARLY BIOMARKERS FOR ACUTE CORONARY SYNDROME (ACS)

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**OBJECTIVES:** Current practice for suspected acute coronary syndrome (ACS) involves troponin testing 10–12 hours after symptom onset to diagnose myocardial infarction (MI). We aimed to estimate the diagnostic accuracy of early biomarkers for MI to determine if an earlier, accurate decision was possible. **METHODS:** A systematic review of all diagnostic cohort studies of patients presenting with suspected ACS comparing the following biomarkers at presentation with a reference standard based on the Universal definition of MI (troponin at 10–12 hours): early troponin I and T; Heart-type Fatty Acid Binding Protein (HFABP); ischaemia modified albumen (IMA) and myoglobin. A systematic search was undertaken of 10 electronic databases, citation lists and expert contacts, to identify relevant studies. The study selection, data extraction and quality assessment decisions were all verified by more than one reviewer. Citations retrieved were divided between two reviewers (CC, SG) and screened for relevance to the review. Any discrepancies were resolved by discussion and reference to the full paper. Risk of bias was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. Meta-analysis was conducted using Bayesian Markov chain Monte Carlo simulation. **RESULTS:** Compared with the Universal definition of MI, sensitivity and specificity (95% predictive interval) were 77% (29–96%) and 93% (46–100%) for troponin I; 80% (33–97%) and 91% (53–99%) for troponin T (99th percentile threshold); 81% (50–95%) and 80% (26–98%) for quantitative HFABP, 68% (11–97%) and 92% (20–100%) for qualitative HFABP; 77% (19–98%) and 39% (2–95%) for IMA and 62% (35–83%) and 83% (35–98%) for myoglobin. **CONCLUSIONS:** Early troponin I and T and H-FABP have modest sensitivity and specificity for MI at presentation, when compared with the gold standard, but estimates are subject to substantial uncertainty and primary data are subject to substantial heterogeneity. More research on high sensitivity troponin assays at presentation is required.

#### PMD90

##### RENAL DENERVATION FOR RESISTANT HYPERTENSION: HTA REPORT OF THE VENETO REGION

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**OBJECTIVES:** The regional Committee for Medical Devices Evaluation drafted the HTA report for decision making on denervation of renal artery by catheter-based radioablation in the treatment of resistant hypertension. **METHODS:** The report was implemented in the respect of the INAHTA checklist form and its next versions (WP4-EUnetHTA Project). Major literature and institutional databases were searched (November 2011). A budget impact analysis (3-year horizon) in the regional perspective was implemented on patients (aged 35–75) affected by resistant hypertension (diastolic blood pressure >140mm/Hg) on politherapy treatment (four antihypertensive drugs, including a diuretic). The target population excluded secondary hypertension and included subjects actually hypertensive, treated, and resistant to therapies, affected by comorbidities. The model was populated by literature data as to epidemiology, resources consumption of denervation procedure and cost/patient/year of antihypertensive therapy (visits, drugs, comorbidities management). Units costs were derived from a hospital accounting office (2010 values). **RESULTS:** No guidelines mentioned radiofrequency energy device as alternative to antihypertensives. Published clinical data, even limited, reveal an encouraging security profile. Two trials assessed blood pressure reduction in treated patients, at 2 years and 6 months. Seven clinical trial were found as on going. No report of HTA or cost evaluation are published. The model target population consisted of 8.559 subjects. Procedure costs, including overheads costs, was estimated to be about €7,000; usual antihypertensive treatment about €600/patient/year. The introduction of the device in clinical practice (hypothesis: 2% at 3rd year) would increase regional expenditure in the range of 5%–22%, respectively at 1st and 3rd year from implementation. The model was sensitive to antihypertensives cost and number of eligible patients. On the basis of clinical evidences, a one-year controlled introduction of procedure was decided. **CONCLUSIONS:** Renal denervation is a potential alternative in the treatment of patients affected by resistant hypertension.

#### PMD91

##### SCENARIO ANALYSIS AND REAL OPTIONS MODELING OF HOME BRAIN MONITORING IN EPILEPSY PATIENTS

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**OBJECTIVES:** A lot of uncertainties exist when introducing new technologies to the health care market. The objective of this study is to construct different implementation scenarios of Home Brain Monitoring (HBM) in epilepsy patients and to value these scenarios by making use of real options modeling to address uncertainty. This model tries to show the (financial) consequences of different uncertainties on the total value of the HBM project to facilitate investment decisions in the future. **METHODS:** Individual semi-structured interviews were used to present (imple-

mentation) uncertainties to 19 epilepsy experts. Expert elicitation was used to collect beliefs regarding uncertainties of HBM and to estimate probabilities of 'success' of uncertainties. Scenarios were constructed, each of which describe a set of uncertainties. These uncertainties were resolved in order to obtain a production process with a certain expected value. Finally, a real options model was developed that shows the influence of uncertainties on the total value of the HBM project. Sensitivity analysis was used to demonstrate the impact of different uncertainties. **RESULTS:** Elicited judgments show that a promising implementation scenario of HBM in the diagnostic track of epilepsy could be the implementation of HBM after a negative routine EEG, as a substitution of subsequent recordings and with the support of a detection algorithm to detect events automatically. The probability of success was lowest for implementing HBM without making use of a detection algorithm. However, implementing HBM before the first EEG recording yields the highest value, but it is not likely to happen. **CONCLUSIONS:** The implementation of HBM after routine EEG seems to be preferred. The real options model provides an innovative way to represent and value uncertainty in R&D projects. This model is used for the first time in health care technology and provides a comprehensive, but not-too-detailed view of challenges and key criteria for success.

#### PMD92

##### INHALER USE IN FIVE EUROPEAN COUNTRIES: ANALYSIS OF SALES DATA FROM Q4 2005 TO Q4 2011

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**OBJECTIVES:** A range of inhaler devices is available for the delivery of treatments for respiratory diseases (pressurized metered-dose inhalers [pMDIs], non-refillable and refillable dry-powder inhalers [DPIs], and breath-actuated metered-dose inhalers [BA-MDIs]). Sales data from retail pharmacies in the five largest European countries for the period from Q4 2005 to Q4 2011 were analysed as a measure of inhaler use in respiratory disease therapy. **METHODS:** Sales data were obtained from the MIDAS database (IMS Health, London, UK) for CFC-free pMDIs, DPIs (non-refillable and refillable) and BA-MDIs. Retail unit (RU) sales were analysed on a quarterly basis, with one RU equating to one pack of inhalers. **RESULTS:** pMDIs accounted for more than 50% of the total inhalers used across the four device types in every quarter analysed. At the beginning of the study period, pMDIs accounted for 58.0% of inhalers used, with non-refillable DPIs, refillable DPIs and BA-MDIs accounting for 25.2%, 12.5% and 4.3%, respectively. At the end of the study period, the corresponding percentages were 55.6% for pMDIs, 25.8% for non-refillable DPIs, 15.3% for refillable DPIs and 3.3% for BA-MDIs. For each quarter, the number of pMDI RUs sold was approximately twice that of non-refillable DPIs and three times that of refillable DPIs. The highest total number of RUs (45.7 million) was recorded in the most recent quarter analysed; pMDIs accounted for 25.4 million RUs, compared with 11.8 million for non-refillable DPIs, 7.0 million for refillable DPIs and 1.48 million BA-MDIs. **CONCLUSIONS:** These retail pharmacy data suggest that pMDIs are the most commonly used inhaler for the treatment of respiratory disease in the five largest EU countries. The trends observed in this analysis may reflect physician consideration of factors such as the real-world effectiveness of, and the overall health care costs associated with, the different inhaler types.

#### PMD93

##### PRACTICE VARIATION IN DIAGNOSTIC IMAGING WORKUP AND TREATMENT CRITERIA FOLLOWING A RECENT TIA OR MINOR ISCHEMIC STROKE: CONSEQUENCES FOR EARLY ECONOMIC EVALUATIONS

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**OBJECTIVES:** Early evaluations of new technologies require knowledge about current care. Guidelines are sometimes used as a proxy. We examined the degree of compliance to guidelines for the care of patients with a recent TIA or minor ischemic stroke. We specifically focussed on the guidelines for carotid stenosis imaging and treatment criteria. **METHODS:** Semi-structured interviews are being conducted with neurologists and radiologists in 13 hospitals in different regions in the Netherlands. Questions were asked about the use of initial and confirmatory non-invasive imaging tests to assess carotid stenosis (emergency and outpatient clinic), criteria used to perform confirmatory tests and treatment criteria. We also examined the causes of variation and reasons for deviating from the guidelines. **RESULTS:** To date, we have conducted interviews with specialists at nine hospitals. The Dutch guidelines recommend duplex ultrasonography (DUS) as initial test. If carotid stenosis is >70% for females or 50–69% for males, a confirmatory computed tomography angiography (CTA) or magnetic resonance angiography is advised. We observed that only four of nine hospitals actually follow these guidelines in current practice; the other hospitals use differing test combinations (e.g. CTA only with no confirmatory test; or two DUS tests, followed by confirmatory CTA if DUS results differ). According to clinicians, these differences are caused by varying expertise in performing tests, capacity problems and preferences of vascular surgeons. We observed little variation in treatment criteria, with good correspondence to the guidelines. **CONCLUSIONS:** If guidelines are not followed, then early economic evaluations using guidelines as the basis to describe current care may lead to incorrect conclusions about the cost-effectiveness of a new technology. Moreover, important practice variation means that the use of just one comparator is unjustified. Assessments of health and economic impact of new imaging technology will therefore be hospital-dependent and require multiple comparisons and scenarios.