procedure specified for implant registries in general. Therefore, the aim of this work is to identify quality criteria for the design and development of implant registries and to develop a minimal data set. **METHODS:** The systematic literature search was performed in different databases (Pubmed, Medline, the Cochrane Library, Scopus, Embase as well as the CRD York database) and different journals. **RESULTS:** Ten articles were identified that describe a general implant registry design and structure as well as 45 articles about the creation of specific registries. Most recommendations for the organization of implant registries could be found in the field of arthroplasty. To generalize the results, it can be said, that all registries have to deliver a minimal data set including prostheses, patient and surgical procedure details. The geographical area, length and periodicity of data collection, number of patients enrolled, the composition of the team as well as information about security and confidentiality of data should be reported. **CONCLUSIONS:** Well-structured registries are a cornerstone of the regulatory process of medical devices and a major tool for decison makers and managers. However, only a small number of papers that describe specific requirements for the construction of an implant registry could be identified. With the establishment of clear guidelines, the outcomes of the implant registries can be fundamentally improved. This project is supported by the German Federal Ministry of Education and Research (BMBF) as part of the National Cluster of Excellence, Medical Technologies – Medical Valley EMN' (Project grant No. 13EX1013B).

PRICING STUDIES

PR1

PRICE DIFFERENCES TRIGGERED BY THE AVAILABILITY OF BIOSIMILARS IN DEVELOPED COUNTRIES

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OBJECTIVES: The goal of this study is to analyse price differences triggered by the availability of biosimilars in developed pharmaceutical markets. **METHODS:** 1) Market availability of biosimilars in the following markets was studied: Australia, Canada, France, Germany, Italy, Spain, UK, Japan and the United States. Biosimilars were selected based on their availability in these markets, and 2) Ex-factory price differences at launch between biosimilars and their originator counterparts were analysed. **RESULTS:** Price differences between biosimilars and their originator counterpart were on average 25%. One exception aside, biosimilars always trigger double digit price differences. Given the limited availability of biosimilars, it is too soon to say if results will be consistent over time. Nevertheless, the general trend shows that large price differences are observed in Canada and the US (at least 35%) and lower trends in Australia (around 16%). In the top 5 European pharmaceutical markets, price differences range between 17% and 30%. In Japan, price differences are also high, 29% on average. It should also be highlighted that the market entry of biosimilars does not always trigger the price of their originator to drop; in rare occasions only are their prices brought into line. **CONCLUSIONS:** Owing to the fact that biologic drugs are commonly expensive and with double digit price differences between biosimilars and their originator counterpart, the market entry of biosimilars should enable governments to generate significant savings. Nevertheless, a limited number of biosimilars are at the moment approved and in addition to the fact that no legislation is in place in the US, there is no sign of improvement in the other countries studied. As a consequence, savings will only be achieved if governments incentivise the development of biosimilars as well as their use.

PR2

PHARMACEUTICAL POLICIES, REGULATION AND EFFICIENCY

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OBJECTIVES: In the context of ever increasing demand and expenditure for health services it is important to identify policies which may maximise efficiency. Often, pharmaceuticals (approximately 20% of total health care expenditure) are a primary target for achieving efficiencies. This study aims to study the efficiency of pharmaceutical control policies. **METHODS:** Data on pharmaceutical policies and markets across 65 countries were collected from the published literature, with emphasis on the following domains: pricing, reimbursement, dispensing, expenditure and demand control. In each domain, policies were classified and through a multiple-country expert survey were graded for the degree of regulation. Countries were clustered according to their policy mix. Principal component analysis (PCA) served to group policies into three components: pricing policies, reimbursement policies and demand and cost control policies. Regression analysis with pharmaceutical expenditure as % of GDP as dependent variable was used to analyse the efficiency of policies. Independent variables were life expectancy, dependency ratios, mortality rates, GDP per capita and health system type. **RESULTS:** Spearman correlation coefficients indicated that there was no statistically significant association between total pharmaceutical expenditure as % of GDP and regulation in the coverage, pricing, reimbursement, dispensing policy and system type. A statistically significant positive correlation between regulation and indirect price and cost controls (0.334, p=0.028) and demand controls (0.333, p=0.019) implies that more regulation in these domains is associated with higher expenditure. Following the PCA, regulation in demand control policies was associated with higher expenditure (0.342, p=0.025) and the same applies for the aggregate of the components (0.314, p=0.040). In regression analysis the coefficients (p-value) were pricing:-0.003(0.950), demand control:0.062(p=0.067), reimbursement: -0.057(0.439), mortality: 0.001(0.414), Life Expectancy: 0.062(0.474), elderly ratio: 0.689(0.774), GDP-per-capita: -1.788(0.017). **CONCLUSIONS:** A variety of policies were developed recently to control pharmaceuticals. More regulation does not appear to increase efficiency or decrease expenditure.

PR3

VARIABILITY IN HYBRID DRUG AVAILABILITY AND PRICING IN EUROPE

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OBJECTIVES: Medicinal products where active substance, strength, form, or administration route have been modified differ from generic drugs as bioequivalence cannot be demonstrated. In Europe, these 'hybrid' products have a clear registration pathway (Directive 2001/83/EC) requiring investment in pre-clinical and clinical trials. However; beyond the regulatory pathway, pricing and market access remains a national matter and few countries have specific methods to evaluate hybrids; both innovative- and generic-like prices may result. This study evaluated hybrid price differences and consequences for availability of hybrids across Europe. **METHODS:** Using IMS MIDAS data and the HMA database of registered drugs, we screened 5,000 products to identify 40 hybrid products which were significantly differentiated from the reference product, launched between 2008-2012 and analysed their prices and availability based on sales achieved, versus the reference product within and across 10 European markets. **RESULTS:** Hybrid prices vary widely, but most frequently, generic rules are applied, limiting the interest of companies to make hybrids available across European markets. There is wide variation in availability of hybrids across markets, suggesting a decision not to launch in markets where prices are particularly unfavourable. Countries applying fixed generic pricing rules appear to have fewer hybrids. Yet where they are launched, hybrids are not classified as generics, so uptake is inhibited by non-substitution rules and prescribing quotas. **CONCLUSIONS:** The lack of clear evaluation criteria and pricing variability within and across countries are barriers to the availability of hybrid products to patients in Europe. To the degree that such products better meet patient needs versus generic medicines, these barriers reduce patient welfare and prescriber choice. In a context where patient-oriented outcomes are increasingly seen as important, hybrid drugs have a role to play given their ability to improve administration, compliance, convenience and in some cases improve safety and efficacy. Consequently, clear rules for hybrid evaluation, pricing and access are desirable as they would improve patient care and reduce uncertainty for hybrid manufacturers.

PR4

OVERVIEW OF COVERAGE WITH EVIDENCE DEVELOPMENT IN SWEDEN

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OBJECTIVES: Coverage with evidence development (CED) in Sweden has become common over the last decade. It is considered as a tool to address uncertainty. The objective of this research is to assess from 2005 to 2012 CED in Sweden. **METHODS:** We downloaded available CED from pricing authority (TLV) database, and extracted detailed information in an ad hoc grid developed for that purpose. The following information was extracted: date of product approval, name, indication, date of CED installation, end of CED, type of evidence to be generated, limitation of initial file supporting the need of additional evidences. **RESULTS:** A total of 28 cases were retrieved covering 9 main disease areas. Eleven were for orphan drugs and 10 for Central nervous system (CNS) disorders including depression anxiety, epilepsy, pain, ADHD, schizophrenia, restless syndrome and Parkinson disease. Other were classified as follow, 5 for cardiovascular disorders, 3 oncology, 2 diabetes, 2 respiratory disorders and 5 others. The main drivers to request CED were weak cost-effectiveness model (14 cases) driven by uncertainty about utility, patients benefit, transition probabilities, model structure etc. The second reason was low relevance of clinical evidence for clinical practice (8 cases), followed by long term efficacy extrapolation (5 cases) and others mainly related to comparative effectiveness, daily dosage, safety, target population, etc. (11 cases). For each CED more than one driver could be identified. Requirements were mostly real world evidence generation. **CONCLUSIONS:** CED in Sweden is likely to be driven more by uncertainty than drug prices due to low involvement of oncology, inflammation and other disease area where biologics are prescribed. Orphan drugs represent a leading target for CED as often little information is available at time of launch. Most CED are not finalised to assess the actual CED impact on long term coverage.

RESEARCH ON METHODS – PRO/QOL STUDIES

QL1

MAPPING THE CCQ ONTO EQ-5D SCORES (IM)POSSIBLE?

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OBJECTIVES: Studies assessing the effectiveness of new Chronic Obstructive Pulmonary Disease (COPD) treatments commonly use disease-specific health-related quality-of-life (HR-QoL) instruments such as the Clinical COPD Questionnaire (CCQ). However, for the economic evaluations, utility data is necessary. This study aims to develop a model to predict mean utility values for a group of COPD patients using CCQ data. **METHODS:** We combined the data from two trials (RECODE and GO-AHEAD) including over 5000 observations with a broad range of disease severity. Data was randomly split into an estimation and validation sample. The overlap between the CCQ and EQ-5D was assessed using principal component and correlation matrix analysis. Different types of models were created with increasing complexity. We analysed the effect of using different observations of the same patients as unique observations and performed a sensitivity analysis using different EQ-5D value sets to estimate EQ-5D utilities. The external validity was tested with the dataset of the MARCH trial. **RESULTS:** The principal component analyses showed a poor correlation of the dimension pain/discomfort with any of the CCQ items and the CCQ items cough and produce phlegm did not load onto any EQ-5D dimension. The model using ordinary least square with the individual CCQ items as dummy variables, controlled for sex, resulted in the best predicted performance. The mean