

($p=0.596$). **CONCLUSIONS:** Time preference rates were aligned with those in the published literature but the association between time preference and adherence was non-significant in both primary and secondary analyses at an individual country level.

CV3

PATTERNS OF GENERIC AND PROPRIETARY PRESCRIBING OF STATINS OVER TIME IN ENGLAND

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OBJECTIVES: Given economic pressure on UK National Health Service resources, it has been recommended that general practitioners prescribe more low-cost, generic drugs as opposed to high-cost, proprietary drugs when a substitution can be made without compromising patient care. One of the Better Care Better Value (BCBV) indicators of good prescribing practice proposed by the NHS Institute for Innovation and Improvement is an increase in the prescription of low-cost drugs for lipid modification. The objective of this analysis was to evaluate patterns of generic and proprietary prescribing of statins from 2007–2012 inclusive. **METHODS:** Prescription Cost Analysis databases from data.gov.uk were reviewed between 2007–2012. Data on the number of prescription items dispensed each year in the community in England for simvastatin and atorvastatin (as commonly-prescribed examples) were extracted, along with each drug's preparation class: drugs prescribed and available generically, or drugs prescribed and dispensed by proprietary brand name. For both simvastatin and atorvastatin, the proportions of prescription items in the different preparation classes were compared each year. **RESULTS:** Proprietary simvastatin prescription items as a proportion of all simvastatin prescription items decreased each year, from 2.87% in 2007 (843,000 proprietary items) to 1.76% in 2012 (752,000 items), representing a proportional decrease of 39% in the 6-year period assessed. Proprietary atorvastatin prescription items as a proportion of all atorvastatin prescription items were close to 100% between 2007–2011 (approximately 11 million proprietary items each year), but fell to 30.55% in 2012 (3.9 million items), coinciding with the expiry of atorvastatin's patent in May 2012. **CONCLUSIONS:** In England, prescribing of high-cost proprietary items for these two examples of lipid-modifying drugs has decreased since 2007, suggesting that the BCBV prescribing indicator for statins is being met. Such reductions, particularly as seen with atorvastatin in 2012, are likely to have a significant budget impact.

CV4

IMPACT OF SHORT PERIODS WITH IMPROVED OR WORSENERD INR CONTROL ON LIFE EXPECTANCY AND QALYS IN PATIENTS WITH ATRIAL FIBRILLATION

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OBJECTIVES: Warfarin-treated patients with poor international normalized ratio (INR) control, measured with time in therapeutic range (TTR) or the standard deviation of transformed INR (SDT_{INR}), have an increased risk for clinical events. To what extent only a short period with an altered INR control may influence outcomes remains unknown. This study assessed the impact of transient periods of improved or worsened INR control on life expectancy and quality-adjusted life years (QALYs) among warfarin-treated patients with atrial fibrillation (AF) using both metrics. **METHODS:** Warfarin-treated patients with AF, registered in the patient record system Journalia during years 1985–2000, were included. Information on all-cause mortality was collected from the Cause of Death Register. Scenarios where patients were assumed to have a transiently altered INR control during 30 days were modeled statistically using hazard functions, and the impact on remaining life expectancy and QALYs was assessed. **RESULTS:** When using SDT_{INR} , a 70-year old man within the 2.5th worst INR control percentile was estimated to gain 10.8 days of life or 0.0168 QALYs from a 30-day improvement in INR control to that of an average 70-year old man. Correspondingly, 15.5 days of life or 0.0196 QALYs would be lost if a 70-year old man within the 2.5th best INR control percentile would have an average INR control during 30 days. The magnitudes were smaller when TTR was used to determine INR control. **CONCLUSIONS:** Even short periods of altered INR control is expected to have impact on life expectancy and QALYs among patients with AF.

MEDICAL DEVICE & DIAGNOSTIC RESEARCH

MD1

COMPARING VIRTUAL COLONOGRAPHY WITH CONVENTIONAL COLONOSCOPY FOR COLORECTAL CANCER SCREENING: WHAT ARE THE DRIVERS OF COST-EFFECTIVENESS?

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OBJECTIVES: The majority of recent cost-effectiveness reviews concluded that computerized tomographic colonography (CTC) is not a cost-effective Colorectal Cancer (CRC) screening strategy yet. The objective of this review is to examine cost-effectiveness of CTC versus optical colonoscopy (COL) for CRC screening and identify the main drivers influencing cost-effectiveness due to the emergence of new research. **METHODS:** A systematic review was conducted for cost-effectiveness studies comparing CTC and COL as a screening tool and providing outcomes in life-years saved, published between January 2006 and November 2012. The following databases were searched: PubMed, Science Direct, Cochrane Library and the York Centre for Reviews and Dissemination databases. The search methodology was in line with PRISMA guidelines, including the use of the PICOS review system. **RESULTS:** Nine studies were included in the review. There was considerable heterogeneity in modelling complexity and methodology. Different model assumptions and inputs had large effects on resulting cost-effectiveness. The most important assumptions that influenced the cost-effectiveness of CTC and COL were related to CTC threshold-based reporting of polyps, CTC cost, CTC sensitivity for

large polyps, natural history of adenoma transition to cancer and importantly, adherence. CTC was found to be cost-effective in three studies, assuming the most favourable scenario. **CONCLUSIONS:** CTC has the potential to be a cost-effective CRC screening strategy when compared to COL. There is a strong need for a differential consideration of patient adherence and compliance to CTC and COL. Recent research shows that laxative-free CTC screening has the potential to become a viable alternative screening method for CRC as it can improve patient uptake of screening. 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 EMN¹ (Project grant No. 13EX1013B).

MD2

MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES: EVIDENTIARY REQUIREMENTS ACROSS GLOBAL MARKETS

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OBJECTIVES: With tightening health system budgets, medical devices (MDs) are being increasingly scrutinized for their impact on overall health care cost. The evidence bar for implantable MDs is particularly high since most implantable devices are not reimbursed separately by payers, but via direct bundled payments to the provider. To characterize that trend, the objectives of this study were to: 1) Identify specific evidence criteria that maximally impact the payer decision, 2) Note differences in HTAs across global markets, and finally 3) Outline differences in evidence requirements between drugs and devices. **METHODS:** A multimarket review of implantable MD HTAs and reimbursement decisions published from 2008–2013 was conducted. Identified by HTA Watch, HTAs included those from Australia, Belgium, Canada, France, Germany, Italy, the UK and the US. They spanned a variety of indications, including cardiovascular, orthopedic, neurological, trauma, among others. HTAs and reimbursement decisions were characterized for clinical and economic evidence requirements and apparent correlations and/or impacts on ultimate agency recommendation. **RESULTS:** Evidence criteria evaluated by HTA agencies and payers primarily included: 1) Availability of supportive randomized controlled trials (RCTs), 2) Safety, 3) Efficacy/long-term outcomes, 4) Cost/cost-offsets/budget impact, and 5) Quality of-life improvement. In contrast to drug HTAs, clinician training and learning curve effects were often evaluated. Importantly, agencies recognized the challenge in demonstrating statistically- and clinically-significant evidence of improvement in outcomes. As such, many MDs were recommended on a restricted basis to specific patient subpopulations or on a coverage based on continued evidence development. While requirements considered most critical were largely uniform across global markets, regional nuances impacted the ability to obtain favorable reimbursement of implantable devices. **CONCLUSIONS:** Similar to drugs, MDs face rising hurdles in terms of demonstrating value, both clinical and economic. Optimal global market access for implantable MDs hinges on monitoring evolving evidentiary requirements and on carefully planning to collect evidence early in the developmental cycle.

MD3

DECISION MAKING UNDER UNCERTAINTY: COVERAGE WITH EVIDENCE DEVELOPMENT IN THE CONTEXT OF MEDICAL DEVICES

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OBJECTIVES: Coverage with evidence development (CED) is increasingly being used to provide provisional coverage for promising, but unproven, interventions, while additional data are generated. This study aimed to explore the application of CED in the context of devices. **METHODS:** First, a literature review was conducted on international CED schemes and the CED approach more generally. In total, 50 articles were gathered and reviewed. Second, semi-structured telephone interviews were conducted with different expert groups (payers/HTA bodies, industry, and academics/policy analysts) to better understand the use of CED in different jurisdictions; identify and explore device CED case studies; and, gather expert opinion on the challenges associated with the CED approach and potential strategies to improve current policy and practice. A total of 25 experts were invited to participate, of which 20 (80%) agreed and were interviewed. **RESULTS:** Canada, the UK, and US have the most experience with CED applied to devices; Germany and The Netherlands have both recently introduced new CED policies for devices and procedures. Devices that have undergone CED in these jurisdictions include ICDs, stents, TAVI, laparoscopic surgery, and spinal cord stimulators. While there are distinct differences in the national approaches to CED, common challenges were identified: 1) establishing a clear framework for initiating, overseeing, and stopping CED studies, 2) identifying and applying appropriate study methods, 3) funding CED studies, 4) incentivizing studies, and 5) applying new evidence to inform coverage decisions. **CONCLUSIONS:** Devices are viable candidates for CED, given some of their unique characteristics and often uncertain evidence base at the time of coverage determination. However, improvements are needed, including enhanced clarity and predictability of CED selection criteria and processes, greater stakeholder collaboration, new models to fund studies and collect data, better incentives for physicians to engage in studies, and strengthened requirements for use of new evidence in coverage policies.

MD4

QUALITY CRITERIA FOR THE DEVELOPMENT OF IMPLANT REGISTRIES

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OBJECTIVES: During the last few years, there has been a steady increase in the number of implant registries, mainly in the field of arthroplasty. The benefit of a registry depends on its content and quality. However, there are no further data requirements, legal and financial issues or requirements for the organizational