

credible interval: 1.4 to 14.8). Results of synthesizing IPD using information on a covariate account for possible ecological bias and show a clear improvement in accuracy over estimated treatment-covariate interactions, when compared to results obtained from synthesizing AD. **CONCLUSIONS:** Including evidence at IPD level in the MTC is advisable when exploring participant level covariates; even when IPD are only available for a fraction of the studies forming the evidence base. Our findings suggest that adjusting for covariates impact produces intervention effect estimates of higher accuracy, which is valuable for estimating subgroup effects or adjusting for inconsistency.

PODIUM SESSION II:

DISCUSSION ON DECISIONS AND THE IMPACT OF NICE AND OTHER REGULATORY BODIES IN THE UK

N11

THE UK NICE SINGLE TECHNOLOGY APPRAISAL PROCESS: A QUALITATIVE STUDY BASED ON MANUFACTURERS' SUBMISSIONS

Kaltenthaler E

University of Sheffield, Sheffield, UK

OBJECTIVES: International health technology assessment is increasingly interested in the rapid review of technologies. In the UK NICE Single Technology Appraisal (STA) process, manufacturers present the clinical and cost effectiveness of new technologies in their evidence submissions. These submissions are critically appraised by Evidence Review Groups (ERGs) who produce a report which forms part of the evidence considered by the Appraisal Committees. Early on in the process the ERG requests more information from the manufacturer via a clarification letter. The purpose of this research was to analyse ERG reports and clarification letters in order to develop guidance for manufacturers based on common problems or issues identified in manufacturer submissions (MS). **METHODS:** A thematic analysis of the first 30 completed ERG reports was undertaken using a framework approach. Twenty one of the available associated clarification letters were analysed using a set of open codes to analyse data. Both sources of evidence were used to identify common issues and concerns. **RESULTS:** Inadequate reporting of processes was identified in 90% of reports; criticisms of data used, especially in the model was mentioned for 67% of the reports and issues with the conduct of the systematic review in 57%. The population and comparator represented the key items in the decision problem assessed by the ERGs as being inadequately addressed by manufacturers. The majority of clarification points related to the economic data analysis. Issues identified included clarification of data sources and selection, queries about modelling decisions and requests for additional analyses. Internal inconsistencies between the clinical and economic sections of the MS and inconsistencies within the economic section of the MS were also identified as particular problems. This analysis was used as the basis for the development of 12 recommendations for manufacturers. **CONCLUSIONS:** These recommendations may help to improve the quality of manufacturers' submissions.

N12

THE IMPACT OF NICE GUIDANCE ON THE DIFFUSION OF MEDICAL DEVICES

Cabo R¹, Sorenson C², Lynch P³, Eggington S⁴

¹GE Healthcare, Bucks, England, UK, ²London School of Economics and European Health Technology Institute for Socio-Economic Research, London, UK, UK, ³Medtronic, Tolochenaz, Switzerland, ⁴Medtronic International, Tolochenaz, Vaud, Switzerland

OBJECTIVES: Health technology assessments (HTAs) have the potential to influence the diffusion of medical devices into health care systems. This study investigates the impact the National Institute for Health and Clinical Excellence's (NICE) technology appraisals have on the diffusion of implantable devices in the UK (UK). **METHODS:** The analysis focused on the impact of NICE guidance on volume sold of three medical devices: drug eluting stents (DES), implantable cardioverter defibrillators (ICD), and spinal cord stimulators (SCS). UK sales data (2005-2010) for each device were collected from Eucomed and other industry sources. Diffusion patterns before and after publication of NICE guidance were analyzed from an aggregated market-level perspective. A linear regression model was fit to the time series data to illustrate the relationship between the NICE decision and volume. **RESULTS:** The results from the statistical analysis show that NICE guidance has different effects on diffusion across products. NICE guidance had a step increase impact in adoption of DES and SCS ($p=0.026$ and $p=0.00$, respectively). The model suggests that the NICE review did not predict the diffusion of ICDs. Descriptive analysis demonstrated that for SCS and ICDs the NICE decision had a positive effect and no impact on DES diffusion on volume over time. Overall the units sold were positively and significantly correlated with time post-NICE guidance. **CONCLUSIONS:** The study indicates that NICE guidance influences the adoption of medical devices. Positive recommendations were associated with an increase in units sold despite a decrease in units sold experienced before the final recommendation. Additionally, the analysis suggests that there may be a lag between a positive NICE decision and adoption of guidance recommendations in practice. Lastly, there were no consistent trends on NICE's effect on the rate of diffusion. More research is needed to clearly understand the dynamics of HTAs on technology adoption.

N13

ECONOMIC EVALUATION IN NICHE MARKETS: THE ROLE OF THE UK'S ADVISORY GROUP FOR NATIONAL SPECIALISED SERVICES FOR RARE DISEASES AND DISORDERS

Khan N¹, Kiss N¹, Pang F²

¹Oxford Outcomes Ltd., Morristown, NJ, USA, ²Shire Human Genetic Therapies, Inc, Basingstoke, UK

OBJECTIVES: The Advisory Group for National Specialised Services (AGNSS) is a new committee that advises health ministers on which orphan services, including orphan drugs, should be nationally commissioned. The aim of this paper is to provide a description of AGNSS priorities, budget, and synergies with the National Institute for Health and Clinical Excellence (NICE), and an analysis of the decision-making framework used by AGNSS to recommend new drugs and technologies. **METHODS:** A web-based search was conducted for articles and information related to the specialized services of the National Health Service (NHS) and NICE. All documents, including AGNSS meeting minutes were analyzed to provide a comprehensive understanding of the AGNSS program. **RESULTS:** Beginning in 2010 and each year thereafter, AGNSS will recommend approximately 60 highly specialized services and a small number of new drugs and technologies that affect fewer than 500 patients in England. Drugs and stand-alone technologies first must be submitted to NICE. Based on prevalence, disease severity, resource impact, and clinical benefit, a subset of these are referred to AGNSS for consideration. AGNSS can recommend "accept" or "accept with conditions" when the application meets the quality, innovation, productivity, and prevention criteria, or will recommend to "defer" or "reject" otherwise. Currently, AGNSS has identified eight priority areas for 2011-2012. The total program budget in 2010/11, excluding three high-cost drug categories, is expected to be about £348 millions. Additionally, the planned budget for high-cost drugs such as enzyme replacement therapy, paroxysmal nocturnal hemoglobinuria (PNH), and cryopyrin-associated periodic syndromes (CAPS) is £128,879, £27,592, and £3,080 million, respectively. **CONCLUSIONS:** Under the current NHS framework, access to orphan drugs can be denied if they surpass NICE implicit willingness to pay thresholds. The introduction of AGNSS offers an alternative evaluation mechanism, one that potentially offers the flexibility necessary to comprehensively review orphan drugs and services.

N14

THE ASSOCIATION BETWEEN FINANCIAL IMPACT AND THE LIKELIHOOD OF RECOMMENDATION OF MEDICINES FOR USE IN ENGLAND AND WALES

Mauskopf JA¹, Chirila C¹, Birt J², Boye KS², Bowman L², Grainger D³

¹RTI Health Solutions, Research Triangle Park, NC, USA, ²Eli Lilly and Company, Indianapolis, IN, USA, ³Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To estimate the relationship between the maximum possible financial impact (MPFI) of a new medicine on the UK (UK) National Health Service (NHS) and the probability of the drug being recommended for use in England and Wales by the National Institute for Health and Clinical Excellence (NICE). **METHODS:** Data were abstracted from the NICE guidance document and costing template for decisions made about drugs between January 2001 and March 2011. MPFI was calculated by multiplying the population eligible for treatment with the new drug based on the UK marketing indication by the upper bound estimate for the annual cost of treatment. Descriptive, logistic, and recursive partitioning decision analyses were used to estimate the relationship between the MPFI of a new medicine and the probability of recommendation for use with or without restrictions. Multivariable analyses controlled for other clinical and economic variables that have been shown to be correlated with the probability of recommendation for use, including the cost per quality-adjusted life-year (QALY) gained. **RESULTS:** In all analyses, MPFI was an important predictor of the recommendation for use, in addition to cost per QALY. In the univariate analysis, the mean MPFI was £140 million for medicines not recommended and £92 million and £31 million for those recommended with and without restrictions, respectively. In the logistic analysis, the coefficient on the MPFI variable was statistically significant. In the recursive partitioning decision analysis, the second split of the data for classifying recommendations, after cost per QALY, was for submissions with an MPFI above or below £130 million. **CONCLUSIONS:** In England and Wales, besides cost-effectiveness ratio, MPFI on the NHS may be an important determinant of whether a new drug is recommended for use with or without restrictions.

PODIUM SESSION II:

MERGING PRO AND UTILITY ASSESSMENT: DOES THE GAP INDEED GET SMALLER?

UT1

COMBINING DCE AND TTO INTO A SINGLE VALUE FUNCTION

Van Hout BA¹, Oppe M²

¹University of Sheffield, Sheffield, UK, ²iMTA, Rotterdam, The Netherlands

OBJECTIVES: To develop a method that enables estimation of a single value function using data from discrete choice (DC) and time trade off (TTO) questionnaires and to analyse the informative value of an additional TTO question versus that of an additional DC. **METHODS:** Separate DCE and TTO studies are designed with varying numbers of health states (EQ-5D) to be valued. The DC states do not hold a time dimension. An optimal Federov design is chosen for the TTO states, a Bayesian approach is followed for the DC states. The base line is blocked design of 20 blocks with 10 DCE's and 20 blocks of 5 TTO's. Responses are simulated to both study-types using prior expectations about answering behaviour, including 10% of individuals who do not trade time when judging TTO states. Models are estimated separately as well as simultaneously. For the latter all information is combined using a likelihood approach assuming a generalised linear model underlying the answers to the DC comparisons as well as to the TTO questions. The informative value of adding an additional DC or TTO is measured by the average precision surrounding the model parameters. **RESULTS:** While the TTO data offer sufficient data to identify a value function, the DC data need normalizing constants. Combining both approaches by estimating a single likelihood function takes care of this