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ABSTRACTS

RESEARCH PODIUM PRESENTATIONS – SESSION I

STUDIES ON HTA AGENCIES

AG1

THE GERMAN NICE OR THE GERMAN NASTY? AN ANALYSIS OF IQWIG DECISIONS AND REQUIREMENTS FOR AN 'ADDED BENEFIT'

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OBJECTIVES: IQWiG (The Institute for Quality and Economic Efficiency in Health Care or Institut fuer Qualitaet und Wirtschaftlichkeit im Gesundheitswesen) assesses the added benefit of new medicines in Germany, with stringent evidence requirements. To inform future submissions, all IQWiG decisions from January 2011 to May 2015 were assessed, and the effect of the clinical evidence base on the submission outcome was examined. **METHODS:** All completed IQWiG drug appraisals from January 2011 to May 2015 were included in the analysis. Multiple-technology appraisals, non-drug intervention appraisals, and incomplete assessments were excluded. The recommendation ('added benefit' or 'no added benefit'), indication, underlying rationale, and evidence base presented were extracted. **RESULTS:** Between 2011 and May 2015, IQWiG published 132 drug appraisals, including 30 resubmission/addendums. 50/132 (38%) of the appraisals were deemed to offer an added benefit (14% in all subpopulations; 24% in some subpopulations only), while 82/132 (62%) of appraisals received a 'no added benefit' decision. Only 2/34 (6%) of appraisals lacking head-to-head evidence received an 'added benefit' decision, compared with 47/84 (56%) of appraisals reporting head-to-head evidence against an appropriate comparator and 0/14 (0%) of appraisals reporting head-to-head evidence against an inappropriate comparator. Oncologics, infectious disease drugs, and cardiovascular drugs had the highest proportion of submissions receiving an 'added benefit' decision. Over time, the proportion of submissions receiving a 'no added benefit decision' has increased, from 50% (4/8) in 2011, to 52% (12/23) in 2012, 65% (26/40) in 2013, 64% (27/42) in 2014, and 68% (13/19) so far in 2015. **CONCLUSIONS:** Over half of drugs appraised by IQWiG since 2011 have been given 'no added benefit' status, and direct evidence against an appropriate comparator remains a priority for a favourable decision. In contrast, NICE has rejected just 15% of technology appraisal submissions since its inception in 2000, highlighting the differences between the two agencies.

AG2

DO EVIDENCE REVIEW GROUPS BIAS NICE DECISIONS?

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OBJECTIVES: NICE designates one of nine independent academic centers as an Evidence Review Group(ERG) or Assessment Group(AG) to systematically review the clinical efficacy and cost-effectiveness of a product or products based on a manufacturer-submitted dossier or on published evidence. The ERG/AG's report is integral to NICE's decision-making process. This presentation explores whether NICE appraisals—particularly final reimbursement decisions—vary based on which ERG/AG was consulted. This evaluation is important from policy and industry perspectives as it can demonstrate whether NICE's choice of ERG/AG is a potential source of bias in the technology appraisal process. To explore this topic, we examine clinical and economic factors within NICE appraisals influenced by different ERG/AGs. **METHODS:** Reimbursement decision, therapeutic area (TA), manufacturer base-case ICER, NICE's most plausible ICER, and clinical and economic rationales for decision were extracted from NICE technology appraisal guidances from 2003-present. These factors were compared across ERG/AGs. **RESULTS:** NICE reviewed a total of 305 indications, with 72% resulting in positive decisions. Eleven different ERG/AGs were commissioned. There was no difference in rates of positive decisions between the different ERG/AGs (p=.69) though there was a wide range (mean = 72% [71% - 89%]). BMJ had the lowest rate of positive decisions and Warwick Evidence had the highest. There were differences in the number of oncology drugs reviewed by ERG/AG: Kleijnen Systematic Reviews assessed the most (60%) while Aberdeen HTA Group evaluated the fewest (4.6%). The presentation will show rates of positive decisions and clinical and economic rationales for decision by ERG/AG while controlling for TA. The presentation will also compare the most plausible ICERs and manufacturer base-case ICERs by ERG/AG. **CONCLUSIONS:** This study is the first systematic investigation of the influence of ERG/AGs on NICE reimbursement decisions. We will examine the components of the clinical and economic assessments as well as reimbursement decisions by ERG/AG.

AG3

THE CANCER DRUGS FUND IN ENGLAND – UNDERMINING NICE OR EFFICIENT AND GOOD VALUE FOR MONEY?

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OBJECTIVES: Since its inception in 2010, the National Cancer Drugs Fund (NCDF) has become an important market access route for cancer medicines in England and became fully established in April 2011. The objective of this analysis was to review the decisions made by the NCDF to date, in the context of NICE decisions, and identify how recent and proposed changes to the NCDF might impact on future decisions and the evaluation process for oncology products. **METHODS:** The NCDF list was analysed and compared against those appraised by NICE to obtain the percentage that are rejected by NICE as well as those that are never assessed by NICE. Trends across indications and the number of drugs represented on the NCDF were also analysed. Policy documents and consultations on proposed process changes to the NCDF were also reviewed. **RESULTS:** As of May 2015 there are 38 drugs covering 67 indications approved on the NCDF list, many of which have been rejected by NICE. Recently implemented and proposed changes such as a change to the definition of rarity when scoring the median drug cost per patient, and the appeal process, could have significant implications for pharmaceutical companies and patients on gaining reimbursement for oncology products. **CONCLUSIONS:** The existence of the NCDF suggests that NHS England sees cancer as having more value than other diseases. Evidence suggests that the NCDF has been a success in providing access to medicines for patients but could be seen as undermining the NICE evaluation process. Recent changes in the NCDF appear to try and close this gap.

AG4

INFLATION, INFLEXIBILITY AND IRRELEVANCE – THE NEED FOR INFLATION TO BE ACCOUNTED FOR IN ICER THRESHOLDS

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OBJECTIVES: Many obligate cost-utility Health Technology Assessment (HTA) bodies formally or informally reference incremental cost-effectiveness ratio (ICER) thresholds as key criteria that new medicines must satisfy to receive reimbursement approval. One such body, the National Institute of Health and Care Excellence (NICE), in 2004 defined its ICER threshold at £20,000 per quality added life year (QALY), rising to a maximum of £30,000/QALY if specific exceptional circumstances applied. Nevertheless, this basic threshold range has remained unaltered and has not accounted for inflation, the rate at which the general level of prices for goods and services rises. This research aims to model how the NICE threshold would vary if it fluctuated in line with the UK inflation rate and what effect this could have on appraisal outcomes. **METHODS:** Annual UK historical and forecast inflation rates were sourced from rateinflation.com (2004- 2016), upon which the effects on the NICE thresholds were modelled. Base-case ICERs were extracted from NICE Single Technology Appraisal (STA) reports for oncologics from 2006-July 2014. **RESULTS:** Annual UK inflation rates varied from 0.4% to 4.5% (average 2.4%). Cumulatively, this amounts to a 29% decrease in the value of UK currency in this period. This means that in 2016 the NICE thresholds would need to rise to £26,100 and £39,150 to be monetarily equivalent to their 2004 levels. 60 NICE STA reports with base-case ICERs were extracted (average $68,636/QALY, range: US$5,390-234,009/QALY), 27 of which (45%) were not recommended. 35% (23/65) had a base-case ICER below £30,000 but this increased to 52% (34/65) if the £39,150 threshold is utilised. **CONCLUSIONS:** The cumulative effects of inflation over time can be substantial. HTA bodies are artificially raising this threshold by not accounting for this fall in the currency purchasing power over time. ICER thresholds should be subject to periodic updating to account for inflation.

CANCER OUTCOMES RESEARCH STUDIES

CA1

ANALYSIS OF THE RELATIONSHIP BETWEEN PATIENT-REPORTED OUTCOMES (PROS) AND CLINICAL OUTCOMES IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) PATIENTS WITHOUT PRIOR CHEMOTHERAPY

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OBJECTIVES: PROs are used in prostate cancer clinical trials to measure therapeutic impact. We explored the temporal relationship between changes in PROs

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