data are unavailable or insufficient, indirect comparison is increasingly used across therapy areas, reflected by recent NICE guidance. To maximise quality of submissions, analyses must use validated methodology, manage heterogeneity appropriately and clearly justify decisions and usage of methods and comparators. Rationale for use of indirect comparisons is also required.

WHAT IS THE FUTURE IN THE IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT (HTA) IN POLAND? TO EXPLORE KEY DECISION-MAKERS’ PERSPECTIVES

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OBJECTIVES: To explore key decision-makers’ agreement on desirable scenarios to effectively implement health technologies in the public sector in the future. From 2006 onwards, the Spanish government has undertaken several initiatives to establish a reliable mechanism for implementing technologies in the National Health System (NHS). METHODS: A naturalistic, qualitative, two phases study was conducted. The current situation of implementing health technologies in Spain was explored on an earlier study. Based on the present circumstances, both phases of this study sought to explore and determine the level of agreement amongst key decision-makers on suitable strategies to improve the existing conditions. Phase One: semi-structured interviews explored their views on desirable scenarios to more effectively implement health technologies in the public sector. Phase Two: the Delphi method determined the level of agreement amongst participants on key messages consistently endorsed during the interviews. Two rounds of questionnaires were required to consolidate consensus level. RESULTS: A total of 35 interviews were conducted, including managers, researchers and evaluators across country. Several categories of information emerged and were assessed in the Delphi process amongst 26 participants. Most responses (87.5%) agreed on: 1) decision making: based on a demonstrated incremental cost-benefit ratio, 2) desirable attributes: efficiency and cost-benefit, safety and efficacy: 3) unified processes countrywide; 4) information: open and consistent management across, and within, levels of decision, with the health technology evaluation agencies (HTEA), and the industry; 5) education: continued training of decision-makers; 6) evaluation models: organized HTEA, coordinating efforts, following up transparent, participatory and methodologically robust processes agreed across Europe; 7) financing mechanisms; more flexible, collaborative formulas to avoid blocking the implementation of cost-beneficial technologies; and 8) the industry’s role: expert, legitimate provider, “trainer of trainers” CONCLUSIONS: These findings should serve the Spanish Health Authorities to more effectively implement the health technologies in the NHS.

A COMPARISON OF REASONS FOR RECOMMENDATION AND REJECTION ACROSS FOUR HEALTH TECHNOLOGY APPRAISAL SYSTEMS CATEGORISED BY DISEASE

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OBJECTIVES: Reasons provided by the health technology appraisal (HTA) agencies for the guidance issued vary across the board. Following interest from a previous ISPOR presentation, we sought to further investigate the reasons for recommenda- tion/rejection between NICE, SMG, CADTH, and PRAC with a specific focus on disease-specific reasons. METHODS: A previously developed database was updated with data from submissions appraised between 31 May and 31 December 2008 by NICE, SMG, CADTH, and PRAC, in England/Wales, Scotland, Canada, and Australia, respectively. Results of opposing decision outcomes were included and were categorised by disease based on the BNF (cardiovascular system, CNS, endocrine system, gastro-intestinal system, infections, malignant diseases and immunosuppres- sion, musculoskeletal and joint diseases, nutrition and blood, obstetrics, gynaecology, and urinary tract disorders, respiratory system, and skin). Reasons for acceptance/rejection were analysed across the disease categories. RESULTS: In total, 83 submissions were included for analysis. Across all HTAs, the most common rejection reasons for skin disease interventions included “not more effective than comparators” and “not cost-effective”; these reasons were demonstrated in 100% of the submissions for interventions relating to skin disorders. The most common rejection reasons in malign- nant diseases and immunosuppression included “not cost-effective” and “concerns over the economic model” (100% for both). The majority of the reasons for rejection were reported in 50% or less of the submissions per disease group. Of the recom- mended interventions, those for the treatment of skin disease were all “more effective than placebo and comparators” as well as having a lower cost. Interventions for infectious diseases and obstetrics, gynaecology, and urinary tract disorders demonstrated a wide range of reasons for rejection. CONCLUSIONS: Sub-group analysis categorised by disease provides further insight into the primary reasons for rejection and recommendation across HTA bodies. Analysing trends within these submissions highlights potential obstacles for new interventions within a specific disease area.

REVIEW OF HTA RECOMMENDATIONS FOR DRUG THERAPIES IN POLAND ISSUED FROM SEPTEMBER 6, 2007 UNTIL OCTOBER 28, 2008 BY THE CONSULTATIVE COUNCIL (APPRaisal COMMITTEE) OF AHTAPOL IN POLAND

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OBJECTIVES: Review of HTA recommendations issued by the Consultative Council of AHTAPol in Poland. METHODS: Fifty-nine drug recommendations, January 2007–May 2008, from September 2007 until October 2008, available online, were analyzed. Appraisals were grouped into positive and negative recommendations. The clinical and non-clinical reasons for rejection of use were studied. The positive guid- ances were divided into recommendations with major, minor and without restrictions. RESULTS: Thirty-two HTA reports received negative recommendations; 26 on the grounds of clinical evidence and 6 because of non-clinical issues. Among 26 recom- mendations, insufficient clinical effectiveness data was the most frequently stated reason (18 cases). In other eight guidelines, the argument of poor efficacy or safety was raised. Among non-clinical aspects, unacceptable cost-effectiveness ratio was given four times. The unacceptable budget impact and risk of off-label use were ment- ioned each one only once. Twenty-seven HTA reports received positive recommenda- tions, of which 18 for use with major restrictions, 7 with minor restrictions and 2 without additional restrictions. Among those 18 recommendations, several restrictions were imposed simultaneously. The most common was prescription restricted to specific subpopulations (15 cases), followed by the need for an improvement of cost-effective- ness (6 cases), use as second line (5 cases), use if intolerant to other treatment (3 cases), recommending within specific period (2 cases). Among recommendations with minor and without restrictions, lowering price was mentioned five times and use by specialist twice. The appraisal of cost-effectiveness analysis was included more frequently in positive rather than negative guidelines; 63% vs. 37%. The study revealed that an ICER was above 100,000 PLN/case, threshold, accepted by AHTAPol, in 65% of positive recommendations. An ICER was below threshold in 44% of negative recommendations. CONCLUSIONS: The negative and positive HTA guidances with major restrictions prevailed in Poland. Clinical rather than pharmacoeconomic aspects were the most common reason for an appraisal recommendation.

PUBLICATION TRENDS OF BUDGET IMPACT ANALYSES OVER THE PAST SIX YEARS

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OBJECTIVES: Budget impact analyses (BIAs), along with cost-effectiveness analyses, are an essential part of a comprehensive economic assessment of a new health technol- ogy and increasingly required by national regulatory agencies and managed care organizations. This study describes the characteristics and growth of BIAs published in the literature over the past 5-6 years. METHODS: An initial search was conducted using PubMed, a service of the U.S. National Library of Medicine. Approximately 800 citations were retrieved using key words of “budget impact” and “budget analy- sis” and limits of “English Language” and “published within the last 6 years”. Addi- tional articles were obtained through ancestral and related article searches. All relevant BIA articles were identified through an initial title review and secondary abstract review and included in this study. RESULTS: We identified 32 BIAs published between 2003 and 2008. The number of studies published each year were 1 (2003), 3 (2004), 5 (2005), 6 (2006), 7 (2007) and 10 (2008), showing a steady upward trend. The publishing journals had impact factors ranging from 1.985 to 5.888. Just over half of published studies (18/32) assessed budget impact of a health technology in the United States, while the remaining studies were performed in European countries, Canada and Brazil. Although the majority of published BIAs (22/32) examined budget impact of a specific drug, several studies assessed budget impact of various procedures e.g. surgical, endoscopic. Fourteen (44%) of the published BIAs were performed in conjunction with a cost-effectiveness analysis. CONCLUSIONS: Despite increased demand for and recent growth in number of published BIAs, the absolute number of BIA studies published in peer-reviewed journals remains limited. Future studies should examine whether the quality of published BIAs has improved over time and examine changes in practices following the recently published recommendations of the ISPOR Task Force on good research practices for BIAs.

THE IMPACT OF THE SUBMISSION SEQUENCE – WHICH APPRAISING BODY TO SUBMIT TO FIRST?

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OBJECTIVES: The outcomes of health technology assessment (HTA) appraisals con- ducted by appraising bodies vary greatly and are influenced by a range of factors. The aim of this research was to determine whether the sequence of agencies in which HTAs are submitted has an impact on the guidance issued. METHODS: Data from submis- sions to NICE, SMG and CADTH between 1 November 2005 and 31 December 2008 were included. Only interventions appraised by at least two agencies were of interest. Extracted and information included the guidance issued the name of the intervention, the guidance issued and the date of guidance. In addition, a correlation between the sequence of submission and guidance issued was assessed. RESULTS: A total of 46 interventions were submitted to at least two appraising bodies. In 76% of cases, the first body to conduct appraisals was the SMC. In contrast, only 4% of the submissions were submitted to...