WHAT IS THE FUTURE IN THE IMPLEMENTATION OF HEALTH TECHNOLOGIES IN SPAIN? THE EFFECTIVENESS OF A QUALITATIVE STUDY EXPLORING 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 process countrywide; 4) information: open and consistent management across, and within, sectors; 5) information/recommendations were included in 50% or less of the submissions per disease group. Of the recommendations, 63% vs. 57%. The study revealed that an ICER was above 186 200 Euro per quality-adjusted life year. In 65% of positive recommendations, an ICER was below threshold in 44% of negative recommendations. CONCLUSIONS: The negative and positive HTA guidance with major restrictions prevailed in Poland. These results should serve the Spanish Health Authorities to more effectively implement the health technologies in the NHS.

A COMPARISON OF REASONS FOR RECOMENDATION 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-tions/rejection between NICE, SME, CADTH, and PBAC 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, SME, CADTH, and PBAC, in England/Wales, Scotland, Canada, and Australia, respectively. Reasons for 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 recommendation reasons in malignant 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 recommended 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.

PhP85

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 2007–58/16/2008, 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-elines 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 men-tioned 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-effectiv-ity (6 cases), use as second line (5 cases), use if intolerant to other treatment (3 cases), submission within specific periods (2 cases). Among recommendations with minor 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 186 200 Euro per quality-adjusted life year. 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.

PhP86

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 technology 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 analysis” and limits of “English Language” and “published within the last 6 years”. Additional 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.

PhP87

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 conducted 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 submissions to NICE, SME and CADTH between 1 November 2005 and 31 December 2008 were included. Only interventions appraised by at least two agencies were of interest. Extracted data included the guidance issued, the name of the intervention, the guidance issued by 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 the cases, the first body to conduct appraisals was the SME. In contrast, only 4% of the submissions were submitted to
NICE first. Nineteen of the 46 submissions were appraised by NICE; 10% of the cases were first assessed by NICE, 60% were appraised by NICE second, and in 30% of the cases, NICE were the last in the sequence to appraise. It is interesting to note that the rate of acceptance by the SMC was approximately 63% regardless of whether the intervention was appraised by the SMC or CADTH first. In contrast, the acceptance rate for CADTH was observed to be much higher when interventions were appraised by the SMC first compared to when CADTH conducted the first appraisal; 76% and 20% respectively. CONCLUSIONS: The SMC have generally received submissions before NICE and CADTH. In comparison, NICE were rarely the first to appraise an intervention. Reviewing the sequence in which submissions are appraised by each of these bodies and the influence of this on the guidance issued may inform future strategic planning of submissions.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP90

THE IMPACT OF AN ELECTRONIC PRESCRIBING SOLUTION ON THE SELECTION AND PRESCRIBING OF COST-EFFECTIVE THERAPEUTIC OPTIONS

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OBJECTIVES: To assess the impact electronic prescribing system in the use of an on a provider’s prescribing of low cost generic drugs through lowering cost channels. METHODS: Generic, brand, mail retail, and cost-per-day (costs) for over nine million adjudicated prescriptions dispensed between July 2002 and December 2005 were incorporated into independent multivariate logistic and general linear models to compare prescriptions from 468 providers prescribed before and after using an electronic prescribing system and 281 to non-use controls. Separate models for ACE Inhibitors, ARB and ARB Combinations, H2 Antagonists, HMG inhibitors, NSAIDs, PPIs, and SSRIs classes included independent variables for: provider degree, specialty, and electronic prescribing system use (no, little and regular use prescribed >50 prescriptions/month); patient sex, age (continuous), and regimen status; claim and market and distribution channel (except mail/retail models). Significance was a p-value 0.01. RESULTS: Generic and mail prescriptions were generally more likely to be prescribed from providers with regular use (ORs: 0.87±0.01) and less likely from those with little or no use (ORs: 0.67±0.23) than prescriptions from the pre-period of providers who became regular users (OR ~ 1.00), with most significant and few exceptions. Costs were generally lower for providers with regular use (CEs: $0.3±0.04) and higher for providers with little or no use (CEs: $0.13±0.14) than prescriptions from the pre-period of providers who became regular users (CE ~ $0.00), with some significant and some exceptions. CONCLUSIONS: Similar underlying patterns found across multiple classes provide support for linking regular use of electronic prescribing systems to providers being even more likely to prescribe generics and having them dispensed through mail, both of which likely lower overall cost. Additional research should be performed to better assess the robustness of these findings as participation expands and in more therapeutic classes.

PHPS9

IDENTIFYING KEY DECISION PATHWAYS IN HEALTH TECHNOLOGY ASSESSMENT AROUND THE WORLD

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OBJECTIVES: Health technology assessment (HTA) is a process tool used to evaluate emerging and emerging health technologies (e.g., pharmaceuticals, medical devices, and diagnostics), and to determine how these technologies will impact health care service delivery and society. Despite the growing importance of HTA as a tool to govern the adoption process for emerging technologies, a systematic and hierarchical approach to characterize the decision-making process used by various countries has not been developed. The objective of this study was to model the decision pathway that describes the underlying decision-making structure and process for HTA in eight selected countries. METHODS: Members of the International Society for Pharmacoeconomics and Outcomes Research Special Interest Group for HTA performed research online to identify resources that described health systems and decision pathways for the following countries: Australia, Canada, France, Germany, Spain, Sweden, UK, and the United States. Once proposed decision structures were reviewed by committee members with that country’s familiarity, decision models were developed for each country and validated for clarity and accuracy. RESULTS: The HTA decision-making hierarchy developed for each country identified the decision maker as the payer (i.e., person or organization) who makes the final decision for coverage and payment for an intervention. The evaluator was defined as a person or organization that provides input into the decision-making process via HTA development, but did not make the final decision for coverage and payment. The decision-making process referred to the HTA evaluation process, as defined in the public domain, for emerging technologies in consideration for coverage and payment. CONCLUSIONS: Each of the countries examined utilized a unique decision-making structure and maintained detailed processes for HTA input to the final decision maker. Decision pathways for HTA in the countries examined continued to evolve in response to societal needs for emerging technologies.

PHPS9

APPLES AND ORANGES: COMPARATIVE EFFECTIVENESS IN THE UNITED STATES AND OTHER COUNTRIES

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OBJECTIVES: Health technology assessment (HTA) started in the United States (US) to quantify the benefits, harms and costs associated with new technologies. Paralleling methodological advances, applied HTA processes were instituted in many countries to inform decisions about adopting new technologies. Within the context of discussions regarding a new center for comparative effectiveness in the US, we compared HTA of medications in six jurisdictions: Australia, Canada, England and Wales, the Netherlands, Scotland and Sweden. The objective was to identify characteristics of HTA processes and agencies that may inform the structure and operation of a US center for comparative effectiveness. METHODS: We identified characteristics of each health care system and HTA processes, including: the medications reimbursement processes; whether recommendations are mandatory; and structure and transparency of the process using the accountability for reasonableness framework. RESULTS: For Australia, England and Wales and the Netherlands, reimbursement decisions are made nationally, while in Canada, Scotland, and Sweden, formularies are maintained regionally. HTA processes range from manufacturer-prepared single product submissions to comprehensive assessments based on de novo analyses. While six jurisdictions have quasi-governmental HTA agencies, the Netherlands relies largely on a reference-pricing system. Sweden has two HTA agencies: one for rapid assessment of single medications and another which undertakes multiple-technology assessments involving other funding silos. Scotland, and to lesser extents England and Wales and the Netherlands, have implemented various technology assessment processes, e.g., by point scoring; transforming evidences to a single number to make them comparable; and reasoning for recommendations. CONCLUSIONS: The US health care system is fragmented and characterized by insured populations with different health needs. Characteristics directly relevant to a US center include having: non-mandatory recommendations; and transparent two-tiered processes. Collecting better evidence on real-world treatment effects – as is being done in some jurisdictions – would increase the number and types of stakeholders who could apply the information for decision-making.