medical technologies and procedures conducted by the Medical Services Advisory Committee (MSAC). METHODS: Data collection was over a nine month period (August 2008 to April 2009). Twenty in-depth, semi-structured interviews were con- ducted with four stakeholders groups: 1) MSAC committee members and evaluators; 2) economic assessment technology assessment experts; and 3) medical industry re- presentatives and (iv) specialists. Interviews were digitally recorded, transcribed verba- tim and coded using a constant comparative method. RESULTS: The current MSAC decision-making process was described as generally fair and transparent. However stakeholder’s perceived that the burden of proof does vary from the evaluation of pharmaceuticals where “it’s largely resting on the sponsor”. It was pointed that the effectiveness of pharmaceuticals per se can be identified but that of medical devices and techniques has to be placed within the context of the specialist providing the service. The MSAC process is described as more flexible, “idealized” and “idiosyncratic” due to the nature of the technologies being appraised (diagnostics, devices, procedures) and the different types of applicants. Unlike pharmaceuticals these technologies are more likely to be introduced and diffused in the Australian health care system without being evaluated by MSAC. CONCLUSIONS: The results of this study suggest that stakeholder’s perceived that the current process for evaluat- ing non pharmaceutical technologies differs significantly to that of pharmaceuticals. This was thought to be partially as a result of the intrinsic differences in the items under evaluation and partially due to the different institutional arrangements under which the evaluations take place. While differences in assessment for the former reason are generally justiﬁed, differences stemming from the latter may require consideration of whether it is justiﬁed practice, and possible amendment of the process.

A REVIEW OF PHARMACOECOLOGICAL EVALUATIONS OF NEW AND EXISTING TECHNOLOGIES IN IRELAND
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OBJECTIVES: The National Centre for Pharmacoeconomics (NCPE) appraises the cost-effectiveness of new and existing technologies (medicines, diagnostics and devices) which may entail a high budget impact to the health system, in response to requests from the Health Service Executive (HSE). In the case of new medicines, assessments may be conducted prior to reimbursement application but must be completed within 90 days. We describe the pharmacoeconomic evaluation process in Ireland and provide examples of recent appraisals and the subsequent impact on pricing and reimburse- ment decisions. METHODS: The pharmacoeconomic appraisals conducted by the NCPE between September 2006 to December 2009 were reviewed. The recom- mendations and subsequent reimbursement decisions by the HSE were recorded. The duration of the pharmacoeconomic process and the time from marketing authorisation to reimbursement was estimated. The budget impact assessments from the pharmaceuti- cal companies were reviewed and compared for consistency. The NCPE conducted fourteen single technology appraisals during the study period. There is only one example of an existing medicine where cost-effectiveness data was requested to ensure continued reimbursement. All other evaluations were for newly licenced medicines. Eight of the nine medicines assessed were either cost-effective or cost-effective of resources or recommended with certain restrictions, and were funded by the HSE. Of the six medicines that were not considered cost-effective, two were reimbursed after a price reduction was negotiated, two were not reimbursed and the decision for the remaining two medicines is pending. The average duration of the pharmacoeconomic process was 2.7 months. The average time from marketing authorisation to reimbursement was 7 months. The review of budget impact assessments highlighted a high degree of variability between submissions. CONCLUSIONS: The findings of this review demonstrate the efficiency of the pharmacoeconomic process and the acceptance of the NCPE recommendations by the HSE for pricing and reimbursement decisions.

A COMPARISON OF HTA RECOMMENDATIONS ISSUED BY AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT (AHTAPol) IN POLAND AND THE SCOTTISH MEDICINES CONSORTIUM (SMC)
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OBJECTIVES: To compare HTA recommendations of Agency for Health Technology Assessment (AHTAPol) in Poland with HTA recommendations of the Scottish Medicines Consortium (SMC). METHODS: We chose to include examples of both established and emerging entities with different roles and objectives. They include HTA organizations in Australia (PBAC), Brazil (ANVISA), Canada (CADTH), Germany (DAHTA@DIMDI, IQWiG), Korea (HIRA), Sweden (TLV, SBU), Taiwan (CDE), the UK (NICE), and United States (Blue Cross/Blue Shield, CMS, DERP, Wellpoint). RESULTS: There is considerable variation in practices across the HTA organizations. Many of the organizations support and imple- ment certain principles, such as being explicit about their HTA goals and scope; con- sidering a wide range of evidence and outcomes; and seeking all available data. Other principles, such as taking a full societal perspective; having a clear system for setting priorities; explicitly characterizing uncertainty surrounding estimates; monitoring the implementation of HTA findings; and considering the generalizability and transfer- ability of results require much less backing. There is also variation in the degree to which organizations incorporate appropriate methods for assessing costs and benefits. CONCLUSIONS: There is considerable room for improvement for HTA organiza- tions to adopt principles identified to reflect good HTA practices. A broader discussion is needed on principles that do not receive widespread support and implementation.

APPLYING KEY PRINCIPLES FOR IMPROVED HEALTH TECHNOLOGY ASSESSMENT: AN ANALYSIS OF 14 HTA ORGANIZATIONS
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OBJECTIVES: To assess whether 15 Key Principles, previously proposed by our group—the International Working Group for HTA Advancement—could be applied to health technology assessment (HTA) programs in different jurisdic- tions and across a range of organizations and perspectives. METHODS: We investigated the extent to which 14 HTA organizations around the world implicitly support and implement the Key Principles. By “support,” we mean that the organiza- tion backs the principle in written guidelines or other form, regardless of whether they actually follow it. By “implemented,” we meant that published reports and decisions based on reports were consistent with the principles. The HTA organizations were chosen to include examples of both established and emerging entities with different roles and objectives. They include HTA organizations in Australia (PBAC), Brazil (ANVISA), Canada (CADTH), Germany (DAHTA@DIMDI, IQWiG), Korea (HIRA), Sweden (TLV, SBU), Taiwan (CDE), the UK (NICE), and United States (Blue Cross/Blue Shield, CMS, DERP, Wellpoint). RESULTS: There is considerable variation in practices across the HTA organizations. Many of the organizations support and imple- ment certain principles, such as being explicit about their HTA goals and scope; con- sidering a wide range of evidence and outcomes; and seeking all available data. Other principles, such as taking a full societal perspective; having a clear system for setting priorities; explicitly characterizing uncertainty surrounding estimates; monitoring the implementation of HTA findings; and considering the generalizability and transfer- ability of results require much less backing. There is also variation in the degree to which organizations incorporate appropriate methods for assessing costs and benefits. CONCLUSIONS: There is considerable room for improvement for HTA organiza- tions to adopt principles identified to reflect good HTA practices. A broader discussion is needed on principles that do not receive widespread support and implementation.

ELECTROMAGNETIC INTERFERENCES BETWEEN WIRELESS COMMUNICATION TECHNOLOGY AND CRITICAL CARE MEDICAL EQUIPMENT: A HEALTH TECHNOLOGY ASSESSMENT
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OBJECTIVES: Wireless telecommunication technology is commonplace in today’s life including health care environment. Critical care medical equipment such as...
NEW DRUGS EVALUATION IN SPAIN: THE JOINT COMMITTEE OF NEW DRUGS EVALUATION EXPERIENCE


OBJECTIVES: To evaluate the activity of the Joint Committee for New Drugs Evaluation (JCNEDE) in Spain. Analyze the drugs evaluated since the JCNEDE was founded, their scores and their potential correlation with the American CDER-FDA scores. Analyze the time-gaps between the new drugs commercialization and its evaluation publication by the JCNEDE members. METHODS: The JCNEDE Standard Operation Procedures were web-based obtained. The drugs evaluations were collected gathering information from different publications and from the Regional Drug evaluation centers. RESULTS: In total, 215 new drugs were evaluated for reimbursement in Spain since 2003. Commercialization date in Spain were obtained from IMS database. RESULTS: Most of the 60 drugs evaluated had a high prescription potential in the Primary Care (PC) setting and were reimbursed by the Spanish National Health System. The decision algorithm has 4 key criteria to evaluate the new drugs: efficacy, safety, convenience and costs. The drugs were scored ranging from 0 (insufficient experience with the drug) to 4 (relevant therapeutic improvement). 89% of the drugs evaluated had 0–1 scores, and none of the drugs evaluated reached the maximum score.

THE ROLE OF HTA AGENCY IN DRUG REIMBURSEMENT DECISION-MAKING PROCESS IN POLAND (HTA IMPACT)

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OBJECTIVES: The objective of this study was to assess what extent HTA outcomes have been incorporated in drug reimbursement decision-making process in Poland. METHODS: To assess HTA impact, following research questions were investigated: 1) How many different health problems currently prioritized by policy-makers have received HTA Agency's attention? 2) How many different drug technologies with HTA recommendations have been included on the current reimbursement lists? In total, 81 HTA recommendations were dissected by the Appraisal Board of the National Health Agency in Poland concerning drug technologies in the period from September 6, 2007 until February 2, 2009 were studied. The most recent reimbursement lists issued 23 February 2009 by Ministry of Health and 7 July 2008 by National Health Fund were utilized. The list of prioritised health problems issued 23 February 2009 by Ministry of Health was studied as well. HTA recommendations were divided into positive and negative guidance. Drug technologies, appraised by HTA Agency, were classified into two groups: 1) eligible (a drug technology indicated for a prioritized health problem), and 2) not eligible (a drug technology not indicated for a prioritized health problem).

As many as 59% and 54% of different indications were prioritized by Ministry of Health without any input from HTA process. In total, 40 negative and 43 positive HTA recommendations were issued. Only 18 of 43 (42%) drug technologies with a positive guidance were included on the reimbursement lists. At the same time as many as 6 of 40 (15%) of medicines with negative HTA recommendation were listed.

HTA Agency appraised 58 eligible and 25 non-eligible drug technologies. There were 32 positive HTA recommendations in the first group, of which 18 (56%) were included on the reimbursement lists. CONCLUSIONS: The HTA impact on drug reimbursement decisions in Poland is partially achieved and could be further enhanced.

A REVIEW OF THE USE OF PROS IN SUBMISSIONS TO NICE

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OBJECTIVES: To review the use of Patient Reported Outcomes (PROs) in HTA submissions to date, with respect to the types of findings included, and the quality of the PROs. METHODS: A review of the PROs submitted to the NICE website with respect to HTA appraisals that incorporated a PRO as part of the evidence base. RESULTS: Focus was on appraisals that departed from the 2007 reference case, and the use of the EQ-5D. RESULTS: At the time of review, 142 appraisals had been published. 18% of appraisals included a PRO. NICE guidelines were followed in 40% of cases.

As many as 6% and 12% of different indications were prioritized by Ministry of Health without any input from HTA process. In total, 40 negative and 43 positive HTA recommendations were issued. Only 18 of 43 (42%) drug technologies with a positive guidance were included on the reimbursement lists. At the same time as many as 6 of 40 (15%) of medicines with negative HTA recommendation were listed.

HTA Agency appraised 58 eligible and 25 non-eligible drug technologies. There were 32 positive HTA recommendations in the first group, of which 18 (56%) were included on the reimbursement lists. CONCLUSIONS: The HTA impact on drug reimbursement decisions in Poland is partially achieved and could be further enhanced.