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What Influences Recommendations Issued by the Agency for Health Technology Assessment in Poland? A Glimpse Into Decision Makers' Preferences

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ABSTRACT

Objective: This study aimed to evaluate the factors that are associated with positive (supporting public funding) and negative recommendations of the Agency for Health Technology Assessment in Poland. **Methods:** Two independent analysts reviewed all the recommendations publicly available online before October 7, 2011. For each recommendation, predefined decision rationales, that is, clinical efficacy, safety, cost-effectiveness, and formal aspects, were sought, either advocating or discouraging the public financing. In the analysis, we used descriptive statistics and a logistic regression model so as to identify the association between predefined criteria and the recommendation being positive. **Results:** We identified 344 recommendations—218 positive (62.8%) and 126 negative (37.2%). Negative recommendations were better justified and also the comments were less ambiguous in accordance with the recommendation (except for clinical efficacy). In general, the specified criteria supported the decision (either positive or negative) in 209 (60.8%), 107 (31.1%), 124 (36.0%), 96 (27.9%), and 61 (17.7%) recommendations, respectively, and ran contrary to the actual decision in the remaining ones. Threshold

values for either cost-effectiveness or budget impact distinguishing positive from negative recommendations could not be specified. The following parameters reached statistical significance in logistic regression: clinical efficacy (both explicitly positive and explicitly negative evaluations impacted in opposite directions), lack of impact on hard end points, unfavorable safety profile, cost-effectiveness results, and formal shortcomings (all reduced the probability of a positive recommendation). **Conclusions:** Decision making of the Agency for Health Technology Assessment in Poland is multicriterial, and its results cannot be easily decomposed into simple associations or easily predicted. Still, efficacy and safety seem to contribute most to final recommendations.

Keywords: decision making, health technology assessment, incremental cost-effectiveness ratio, reimbursement.

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Introduction

Health technology assessment (HTA) agencies play a vital role in the decision-making process, whether or not to reimburse given health technologies. These agencies are expected to be guided by medical, economic, and ethical criteria and to account for limited resources and sometimes limited evidence regarding the profile of assessed technologies. Therefore, there are many possible drivers for the final decision.

The aim of the current scientific project was in general to detect the criteria that can be considered important for the Agency for Health Technology Assessment in Poland (AHTAPol), and in particular to try to find the characteristics of HTA reports that are associated with positive and negative recommendations.

The AHTAPol was established in 2005 by the Ministry of Health as a first of its kind of institution in Central and Eastern Europe. Since 2009, the AHTAPol is defined as a legal and

independent entity playing a key role in reimbursement decision making. The most important role of the AHTAPol is to prepare recommendations for and support decision making by the Ministry of Health on financing health care services from the public budget. The AHTAPol assesses and appraises all medical technologies, drugs, devices, and other services that are claiming public funding. The role of the AHTAPol covers the assessment and appraisal of the HTA reports including systematic review of clinical findings, economic evaluation, and budget impact analysis, majority of which are submitted by the pharmaceutical industry. Assessment is provided by a team of analysts and based on the Polish HTA guidelines (first issued in 2007 and reviewed in 2009) [1]. Appraisal is completed by the Consultative Council (transformed into the Transparency Council with the beginning of 2012), a team of highly qualified and experienced specialists, and the president of the AHTAPol. Final judgment is made in the specific context of the alternative options available, social

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consequences, health care delivery organization implications, national health priorities, and social and ethical aspects. Based on AHTAPol recommendations, reimbursement decisions are made by the Ministry of Health following negotiations with pharmaceutical industry representatives.

Recommendations issued by the AHTAPol have evolved over time. The new types of recommendations (i.e., conditional, temporal, combined, and others [2]) were introduced. Legal background of recommendations has also changed and currently statements by the Consultative Council and final recommendations by the President of the AHTAPol are issued [3].

The current article can be located in the line of research established by a classical article of Devlin and Parkin [4] and a study by Towse [5]. Devlin and Parker analyzed past decisions made by the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom to determine factors that were associated with positive decisions, and in particular the threshold level for the incremental cost-effectiveness ratio (ICER). In their study, they managed to detect that the threshold level probably lies above approximately 35,000 GBP. The study of Devlin and Parker motivated subsequent articles. And so, Tappenden et al. [6] tried to identify the preferences of the members of NICE Appraisal Committees by using a questionnaire-based study. They concentrated more on the ethical issues, that is, on the impact of such variables as baseline quality of life or age of the beneficiaries. Dakin et al. [7] introduced multinomial approach to these kinds of studies, accounting for conditional approval by NICE.

Methods

Material

The analysis covered all recommendations and statements of the Consultative Council of the AHTAPol issued following two separate regulations (the Ordinance of the Minister of Health dated September 10, 2009, and the Act on Healthcare Services Financing From Public Funds) and available on the official Web site of the agency (<http://www.aotm.gov.pl>) before October 7, 2011. It may be somewhat misleading that we call “a recommendation” both the text published by the AHTAPol and the final conclusion thereof. We do not call the latter “a decision” because this is made only by the Ministry of Health and need not agree with the AHTAPol recommendation. At the same time, we decided to analyze recommendations, not decisions, because the decisions are not accompanied by any justifications and thus would be difficult to spot any regularities.

Inclusion and exclusion criteria

All recommendations and statements were included with the exception of collective recommendations for dental interventions (covering not a single technology but a group of technologies). Some recommendations were explained either poorly or not at all—then the recommendation was excluded altogether.

Analysis—Data Extraction and Interpretation

Only recommendations’ texts were analyzed, neither HTA reports nor critical appraisal, which in most cases were not available on the official Web site of the AHTAPol. For every recommendation, the following data were extracted: medical technology being evaluated, medical therapeutic area in which the technology reimbursement was appealed, and the year of issuing the recommendation. Different types of AHTAPol recommendations (e.g., supporting or rejecting funding, conditional, temporary, and combined) were redefined into statements of limited or no financing technology (negative recommendations) or ones supporting financing or increase in funding (positive recommendations).

Each recommendation was evaluated independently by two researchers by using predefined criteria listed below (language specialist with experience in auditing of HTA reports and HTA specialist). Disagreements were resolved by discussion. For every recommendation (positive or negative), it was classified whether the final recommendation was supported or discouraged by each criterion. Table 1 presents the data interpretation. Consistency was found if for a particular criterion positive and negative findings were reported and explicitly referred to support positive and negative recommendations, respectively. For other situations, we interpreted the criterion as not reflected in the final judgment. Following pilot analysis of the AHTAPol recommendations, clinical, economic, and formal criteria used to judge final statements were distinguished. In a few recommendations, rationales used to judge final statement could not be classified as the above-listed criteria and were not defined separately.

Clinical criteria

The importance of general relative efficacy and safety over comparators in decisions’ reasoning by the Consultative Council was recognized in pilot analysis. Thus, the clinical criteria were further split into three subcriteria: the efficacy (benefit over the comparator used in the analysis—an active treatment or placebo), safety, and the impact of the technology on clinical hard end points (which were treated separately as anticipated significant driver of clinical decision making). Hard end points were defined following reviewed Polish guidelines for HTA as clinically significant end points, playing an important role in a given disease, that is, deaths, cases or recoveries, quality of life, adverse effects (divided into serious and nonserious), or medical events [1]. The issue of difference between the efficacy, studied in clinical trials, and effectiveness, observed in real life settings, was not taken up explicitly in any recommendation; thus, it was not addressed in our analysis.

Economic criteria

Economic criteria were also further split into two subcriteria: cost-effectiveness and the impact on the payer’s budget. The evaluation of the technology’s cost-effectiveness significance was based on values for cost per quality-adjusted life-year (QALY) or life-year gained (LYG) reported in the recommendations and assumed cost-effectiveness threshold of three times the gross domestic product per capita (~83,239 PLN) [7]. The

Table 1 – Data interpretation for predefined criteria determining the AHTAPol recommendations.

	Positive recommendations		Negative recommendations	
Criterion	Positive data (consistent impact on final judgment)	Negative data (not driving final judgment)	Negative data (consistent impact on final judgment)	Positive data (not driving final judgment)
AHTAPol, Agency for Health Technology Assessment in Poland.				

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