

Proposal of Polish Guidelines for Conducting Financial Analysis and Their Comparison to Existing Guidance on Budget Impact in Other Countries

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ABSTRACT

Background: Financial analysis (budget impact analysis, BIA) is increasingly required by decision-makers to ascertain the macroeconomic consequences of new product reimbursement in addition to proof of cost-effectiveness. Poland is in the process of drafting country-specific guidelines for BIA, positioned as complementary to economic evaluation in decision-making

Objectives: The aim of this article is to present the Polish project and compare it with currently available guidance.

Methods: A checklist was developed that focuses on issues that are unique to BIA. An analysis of the differences between different national guidelines and their Polish counterparts was subsequently undertaken.

Results: The Polish project of BIA guidelines is composed of two sections. The first section presents the objective, the use of BIA, the responsibility for the preparation, and

the target audience. The second section presents important methodological aspects that researchers should keep in mind when carrying out BIA. In comparison to existing guidance the Polish project appears to be more detailed. It includes more precise recommendations on perspective, time horizon, and reliability of data sources; reporting of results; rates of adoption of new therapies; and the probability of redeploying resources.

Conclusions: Although there is an increased demand for BIA, there is only limited guidance on how such studies should be undertaken. It is hoped that the Polish guidelines can contribute to the development of such analyses and deliver benefit for Polish health-care decision-makers and beyond.

Keywords: financial analysis, budget impact analysis.

Introduction

In 1970, Toffler [1] described a world of “Future Shock,” in which advances in technology outpaced society’s ability to cope with them. The many resultant problems included ethical, economic, and societal challenges about how to allocate the benefits of this brave new world of high technology. In the field of health care this challenge brings into sharper focus the concept of the provision of quality health care at an affordable cost. The rapid growth of health-care expenditures, coupled with slowdown in the growth of the general economy, has led to increased interest in health-economic and financial evaluation of health-care programs. Both of these approaches independently inform health-care decision-makers: the health-economic evaluation, which demonstrates the cost-effectiveness, or value

for money, of new intervention, may assist the prioritization of interventions, advocating efficiency maximization as a central objective; the financial analysis, budget impact analysis (BIA), which provides insight into the budget impact of the inclusion of the new intervention, addresses the issue of affordability. The cost-effectiveness and affordability has been widely labeled as the “fourth and fifth hurdle” to market, in addition to the traditional three hurdles of safety, efficacy, and quality, required for the licensing of new medical technology.

If medical decision-making is going to be based on economic data, guidance must be forthcoming. Without it, such decisions run the risk of degenerating into ill-informed negotiations based on evidence of a variable quality. For several years a growing number of countries have developed guidelines that outline issues in the design and carrying out of health-economic studies [2–19]. Unfortunately, although an increasing number of agencies have recognized the potential for BIA, guidance for

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such analysis has been slow to develop. Existing guidance are generally limited in detail, unclear, and variable in terms of defining what constitutes a BIA.

Poland is in the process of drafting country-specific guidelines for BIA, positioned as complementary to health economic evaluation in decision-making. The aim of this article is to present the project of Polish guidelines for conducting BIA and compare it with existing international guidance, highlighting areas of agreement and dissent.

Background

Pharmaceutical pricing and reimbursement in Poland have been based until recently on the traditional clinical trial outcomes, efficacy, safety, and quality parameters, used for registration. The main response to rising costs over the past decade has been the introduction of cost-containment policies, such as reference price system, based on classification of pharmaceuticals into groups of interchangeable drugs and setting the fixed refund price according to the lowest priced drug in the cluster.

At the end 2001, Poland implemented the new Pricing Law [20] to improve the functionality of the existing pricing and reimbursement system and to bring Poland into line with the EU's Transparency Directive. In this regulation, requirements for justification of the proposed price and description of impact of the drug on direct treatment costs are specified [20]. The first one can be interpreted as the first step toward taking advantage of health economic evaluation the second one addresses the problem of affordability. The lack of clear interpretation and the lack of suggestions about approaches/calculations as part of legal framework raised issues in both filling out and evaluation of applications submitted for reimbursement. In an attempt to bridge this gap, proposals for guidelines for conducting health economic evaluation and guidelines for conducting BIA have been prepared by representatives of academy and government. The Polish projects, after consultation with international experts, were published in a Polish professional pharmacoeconomic journal [21,22], presented on Web sites (<http://www.farmakoeconomika.edu.pl> and <http://www.decyzjemedyczne.org.pl>) and during Polish and international meetings. Polish Society for Medical Decision Making, the professional association for physicians, initiated consultation with representatives from all medical faculties, the Polish Medical Chamber, associations of health care managers, and associations of local and international manufacturers.

The aim of the projects is to stimulate the provision of standardized, reliable, and good quality information for target audience—policy makers and purchasers of health care services. Among other things, the guidelines recognize the obstacle and difficulties in conducting health economic and budget impact studies and the lack of available data and by serving as reference material stimulate the development in accordance with the worldwide trend toward economic system of reimbursement.

Positioning of BIA in Relation to Health Economic Analysis

BIA should be positioned as complementary to health economic evaluation and viewed as working in parallel [23]. The health economic analysis evaluates, from the societal perspective, the possible inclusion of a drug in light of the criterion of cost-effectiveness after determining the therapeutic added value. The financial analysis looks at the budgetary macroconsequences on the possible inclusion of the drug. Insight into these budgetary consequences was necessary in making the choice within the unavoidable budgetary restrictions. The two methods might work together by firstly identifying cost-effective drugs, then by assessing potential budget impact of the possible inclusion of a drug or by reversing this sequence and carrying out the financial analysis first so there and then it could be immediately determined whether there was a sufficient budget available for reimbursement.

The Reason for Special Guidelines for Conducting BIA

The need for carrying out the financial analysis has been mentioned in Appendix 1 of the project of Polish guidelines for conducting health economic evaluations, but since the health economic guidelines themselves deal purely with the scientific methodology of health economic research, it was believed that the recommendations regarding financial analysis should be treated as separate guidelines. This arrangement does not imply any difference in the relative importance of the two analyses, but was chosen to accentuate the difference between the two analyses and to stress that financial analysis should not be regarded as a variant of the health economic analysis conducted from a purchaser perspective. Admittedly both of them may share many of the same data, but they differ in their scope and reporting of the results.

The main advantage of special guidelines for carrying out financial analysis is to establish principles for best practice in designing and implementing financial analysis. For the financial

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