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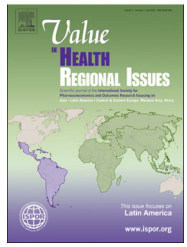

Concept of Combining Cost-Effectiveness Analysis and Budget Impact Analysis in Health Care Decision Making

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ABSTRACT

Objectives: The objective of this study is to cover the ways of solving the problem of understanding the results of two key methods of pharmacoeconomic analysis – budget impact and cost-effectiveness. It is important to note that pharmacoeconomic assessment based on this evidence often has controversial character. The results of one type of analysis can characterize assessed health technology favorably, and the results of other critically. Pharmacoeconomic evidence is often a crucial part of decision-making in healthcare, that's why clear understanding of combination of this two types of analysis is highly in demand. **Methods:** Authors propose methodological solution of the stated problem. This model is a useful tool in making unified pharmacoeconomic report based on cost-effectiveness analysis and budget impact analysis results. Use of this model preserves the meaning and significance of each type of pharmacoeconomic analysis. **Results:** Three-dimensional pharmacoeconomic model proposes full account of both types of pharmacoeconomic analyses during conclusion preparation, the formation of a single consistent pharmacoeconomic conclusion. Though further validation of a tool is needed, presented model can be interesting for the professional community. **Conclusions:** The proposed model of combining budget impact and cost-effectiveness analysis can be used by healthcare decision-makers for obtaining reliable and transparent pharmacoeconomic data.

Keywords: budget impact analysis, cost-effectiveness analysis, health care decision making, health economics, health technology assessment, pharmacoeconomic model.

Introduction

In this article, the authors propose to consider the possibility of combining the two most widespread methods of pharmacoeconomic analysis—budget impact analysis (BIA) and cost-effectiveness analysis (CEA)—in the same pharmacoeconomic study. Decision making based on pharmacoeconomic evaluations at the state level requires transparent rules and clear definitions of obtained results. The demand for tools of pharmacoeconomic analysis in health care decision making is increasing, mainly because of the high cost of innovative health technologies and limited possibilities of their funding [1]. The BIA and CEA results provide the most important data for health care decision makers. BIAs are an essential part of a comprehensive economic assessment of a health care intervention and are increasingly required by reimbursement authorities as part of a listing or reimbursement submission [2,3]. A BIA is supposed to be complementary to more established types of economic evaluations, mainly CEA, by providing decision makers with additional information on the financial consequences of covering and reimbursing new technologies. Thus, the outcomes of a BIA should reflect scenarios that consist of a set of specific assumptions and data inputs of interest to the decision makers rather than a scientifically chosen "base" or "reference" case as is usually done in a CEA [4]. In particular, both types of pharmacoeconomic analysis are present in the Resolution of the Government of the Russian Federation (No. 871) "On the development of rules of medicinal drugs lists formation" in the section on the requirements to the pharmacoeconomic part of the dossier to the medicinal drug.

Nevertheless, describing the level of pharmacoeconomics implementation in the Russian Federation health care system, it is necessary to highlight the national peculiarities of this process. In several developed countries, such as the United Kingdom, Australia, Canada, and Japan, CEA is the only type of pharmacoeconomic analysis on the basis of which pharmacoeconomic assessment is conducted and which is considered during making decisions about reimbursement of a particular technology by health authorities. Results of the CEA (incremental cost-effectiveness ratio [ICER]) are then compared with the willingness-to-pay (WTP) threshold value. Thus, in developed countries, health care decision makers use only one criterion.

Conflicts of interest: The authors have no conflicts of interest to declare.

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Although there are debates on the correctness of this way of assessment, there is no possibility of any contradiction in the received pharmacoeconomic assessment results. In some countries, including Russia, BIA is widely used in addition to CEA because of the insufficient financing and multisystem health care management system. Furthermore, pharmacoeconomic conclusions obtained using BIA are more valuable for local decision makers as practical experience shows.

The forced necessity of the simultaneous use of two types of pharmacoeconomic analysis creates a potential contradictory situation, in which, for example, evaluation of medicines for the possibility of their inclusion in the state program funding using one type of analysis will be positive, but it will be negative using the other type of analysis. Moreover, according to our experience of conducting pharmacoeconomic studies, there are many times when the same technology is characterized as strictly preferred from the perspective of CEA (i.e., the clinically most effective technology has the minimum value of the cost-effectiveness ratio compared with the alternative), but it is inferior to the alternative according to the results of the BIA (i.e., accompanied by high costs compared with the alternative). Such situations are often encountered in practice [1]. In this connection, the problem of making decisions on the basis of possibly contradictory pharmacoeconomic conclusions arises. In the Russian Federation Government decree "On approval of rules of formation of drugs list," this problem is solved by the introduction of a scoring system in which the points of a negative opinion of one method can be compensated by the positive points of the conclusions of another method. Nevertheless, the presented approach only formally solves the problem of the conflicting opinions of two different types of pharmacoeconomic analysis, which creates the danger of a misinterpretation (loss of meaning) of the findings of each pharmacoeconomic analysis type. It is, however, important to note that although pharmacoeconomics allows to consider the problem of choosing the appropriate health technologies from the point of view of all stakeholders—patients, society, doctors, business, and health care managers—in practice, especially in the context of the national health care system, health care decision makers are the target audience for which pharmacoeconomic evaluation is conducted. The aim of pharmacoeconomic analysis of health technology in accordance with the decree is to provide the decision makers with relevant accurate information they need to select the best technologies in the conditions of a particular health care system. In this case, the possibility of mistake during integration of the scores of the two types of pharmacoeconomic analysis, in our point of view, can lead to the loss of sense of the whole pharmacoeconomic assessment and its results being misinterpreted. Hence, the results will be presented in a misinterpreted way to health care decision makers.

Given this discussion, it seemed urgent to find an alternative solution to the problem of consideration of the findings of both types of pharmacoeconomic analysis, BIA and CEA, upon the condition of absence of distortion of these conclusions. It then seems necessary to find an alternative solution to the problem of assessing the findings of both BIA and CEA without misunderstanding these conclusions.

Methods

This methodological study was conducted from the perspective of health care decision makers. In the first stage, authors carried out its decomposition, which resulted in the following presentation.

CEA is a pharmacoeconomic method that allows to determine appropriate health technologies using health outcomes criteria (diagnostics, prevention, and rehabilitation) and to determine costs using comparative assessment of outcomes. Costs of two or more health technologies with different effectiveness and results are presented in the same measurement unit [5]. For a visual description of the properties of the CEA conclusions, see Figure 1, which displays a graph and the associated calculations in the form of formulas.

The figure represents a two-dimensional coordinate system in which the effectiveness of the two hypothetically considered health technologies (Ef_1 and Ef_2) according to selected effectiveness criteria (quality-adjusted life-years and life-years gained) is plotted on the x-axis, and the cost associated with these technologies in monetary terms (Cost1 and Cost2) is plotted on the y-axis. The graph shows that technology 2 with better effectiveness requires higher costs compared with technology 1. Technologies 1 and 2 are indicated by blue points on the graph. In the following step, the points corresponding to technologies 1 and 2 are connected with straight lines from the origin point. Then, the point corresponding to the selected single value of the

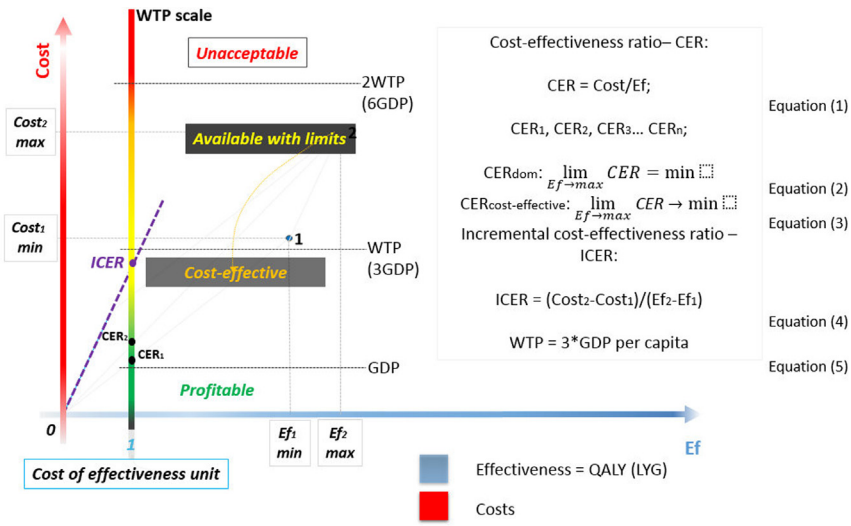

Fig. 1 – Graphical representation of cost-effectiveness analysis WTP - willingness-to-pay, ICER - incremental cost-effectiveness ratio, CER - cost-effectiveness ratio, GDP - gross domestic product, QALY - quality-adjusted life year, LYG - life years gained.