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- О ВОЗМОЖНОСТЯХ СОВМЕЩЕНИЯ АНАЛИЗА «ВЛИЯНИЯ НА БЮДЖЕТ» И АНАЛИЗА «ЗАТРАТЫ-ЭФФЕКТИВНОСТЬ» - СОЗДАНИЕ «3D» ФАРМАКОЭКОНОМИЧЕСКОЙ МОДЕЛИ
- ФАРМАКОЭКОНОМИКА САХАРНОГО ДИАБЕТА, РАКА ПОЧКИ, ПОСТИНСУЛЬТНОЙ СПАСТИЧНОСТИ
- СОЦИАЛЬНЫЕ АСПЕКТЫ ТАБАКОКУРЕНИЯ

ON THE POSSIBILITIES OF COMBINING BUDGET IMPACT ANALYSIS AND COST-EFFECTIVENESS ANALYSIS - DEVELOPMENT OF «3D» PHARMACOECONOMIC MODEL

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Summary:
Abstract: *Pharmacoeconomic analysis is becoming more common as a decision-making tool in healthcare of the Russian Federation. On the one hand, this process is accompanied with the complexity of the used methods. In particular, the simultaneous use of both types of analysis (budget impact analysis and cost-effectiveness analysis) is intended. It's important to note that pharmacoeconomic assessment based on these indicators often has controversial character. Thus, the results of one type of analysis can characterize assessed health technology favorably, and the results of other critically. On the other hand, the use of pharmacoeconomic approaches at the system level requires formalization of the decision-making on the basis of pharmacoeconomic evaluations. In this regard, there is a problem of correct interpretation of the results of both types of pharmacoeconomic analysis when making a unified formalized pharmacoeconomic report. In this article, we offer our methodological solution of the stated problem. This solution is a useful tool in making unite 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. The article also presents the concept of a practical embodiment of the described methodology - the creation of «3D» pharmacoeconomic model.*

Key words: *budget impact analysis, cost-effectiveness analysis, multiple-criteria decision analysis, «3D» pharmacoeconomic model.*

In this article the authors for the first time in Russia propose to consider the possibility of synthesis of two most popular methods of pharmacoeconomic analysis - budget impact analysis и cost-effectiveness analysis (utility)»[1] within a single pharmacoeconomic evaluation. The following factors were the prerequisites for beginning the development of the proposed discussion of the methodology.

The demand for tools of pharmacoeconomic analysis in health care decision-making is increasing, mainly due to the strengthening of the managerial decisions role in face of growing fiscal risks due to the high cost of innovative health technologies and limited possibilities of its funding. [6].

The results of budget impact analysis and cost-effectiveness analysis provide the most relevant information for health care decision-making. That is the reason for wide dissemination of these methods. [2-5]. In particular, both types of pharmacoeconomic analysis are present in the project of Resolution of the Government of the Russian Federation «On the development of rules of medicinal drugs lists formation» (on discussion at the moment) in the section on the requirements to the pharmacoeconomic part of dossier to the medicinal product. However, describing the level of pharmacoeconomics implementation in Russian Federation health care system, it is necessary to highlight the national peculiarities of this process.

In developed countries, such as USA, United Kingdom, Australia, Canada, Japan cost-effectiveness analysis is the only type of pharmacoeconomic analysis on the basis of which is given pharmacoeconomic assessment of the technology and which is considered during making decisions about reimbursement of particular technology by health authorities. Results of cost-effectiveness analysis (incremental cost-effectiveness ratio) are then correlated with the received willingness-to-pay threshold value. Thus, in developed countries, health care decision-makers use only one criterion. Although there are debates on the correctness of this way of assessment, on the other hand it excludes the possibility of any contradiction in the received pharmacoeconomic assessment results. In some countries, including Russia, budget impact analysis is widely used in addition to cost-effectiveness analysis due to the insufficient financing and multi-system healthcare management system. What is more, pharmacoeconomic conclusions obtained using budget impact analysis are more valuable for local decision-makers as the practical experience shows.

The forced necessity of the simultaneous use of two types of pharmacoeconomic analysis creates a potential contradictive situation, in which, for example, evaluation of medicines for the possibility of its inclusion in the state program funding using one type of analysis will be positive, but it will be negative using other one of analysis. Moreover, according to our experience of pharmacoeconomic studies conducting, there are a lot of cases when the same technology from the perspective of cost-effectiveness analysis is characterized as strictly preferred (i.e. clinically most effective technology has the minimum value of the cost-effectiveness ratio compared to alternatives), and according to the results of the budget impact analysis this technology is inferior to the alternative enough (i.e. accompanied by high costs compared to the alternative) are often encountered in practice. [2-5] In this connection, the problem of making decisions on the basis of sometimes contradictory pharmacoeconomic conclusions arises. In the discussed draft resolution of the Russian Federation Government «On approval of rules of formation of drugs list «, this problem is solved by the introduction of scoring system in which the points of a negative opinion of one method can be compensated with the positive points of the conclusions of another method. However, the presented approach only formally solves the problem of the conflicting opinions of two different types of pharmacoeconomic analysis, which creates the danger of misinterpreting (loss of meaning) of the findings of each pharmacoeconomic analysis types. However, it is 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, healthcare managers, in practice, especially in the context of the national healthcare system, healthcare decision-makers are the target audience for which pharmacoeconomic evaluation is conducted. The aim of pharmacoeconomic analysis of health technology in accordance with the foregoing is to provide the decision makers with relevant accurate information they need to select the best technologies in the conditions of a particular healthcare system. In this case, the possibility of mistake during integration of the scores of two types of pharmacoeconomic analysis, on our point of view, can lead to the loss of sense of the whole pharmacoeconomic assessment and if its results are misinterpreted, so then these results are presented in a misinterpreted way to healthcare decision-makers.

Given the above discussion, it seemed urgent to find an alternative solution to the problem of consideration of the findings of both main types of pharmacoeconomic

[1]Later in the article for convenience, the term «cost-effectiveness analysis» includes cost-utility analysis as the cost-utility analysis is a special case of cost-effectiveness analysis in which QALY is used as a criterion of the efficiency index. Cost-minimization analysis is also included in general term "cost-effectiveness analysis".

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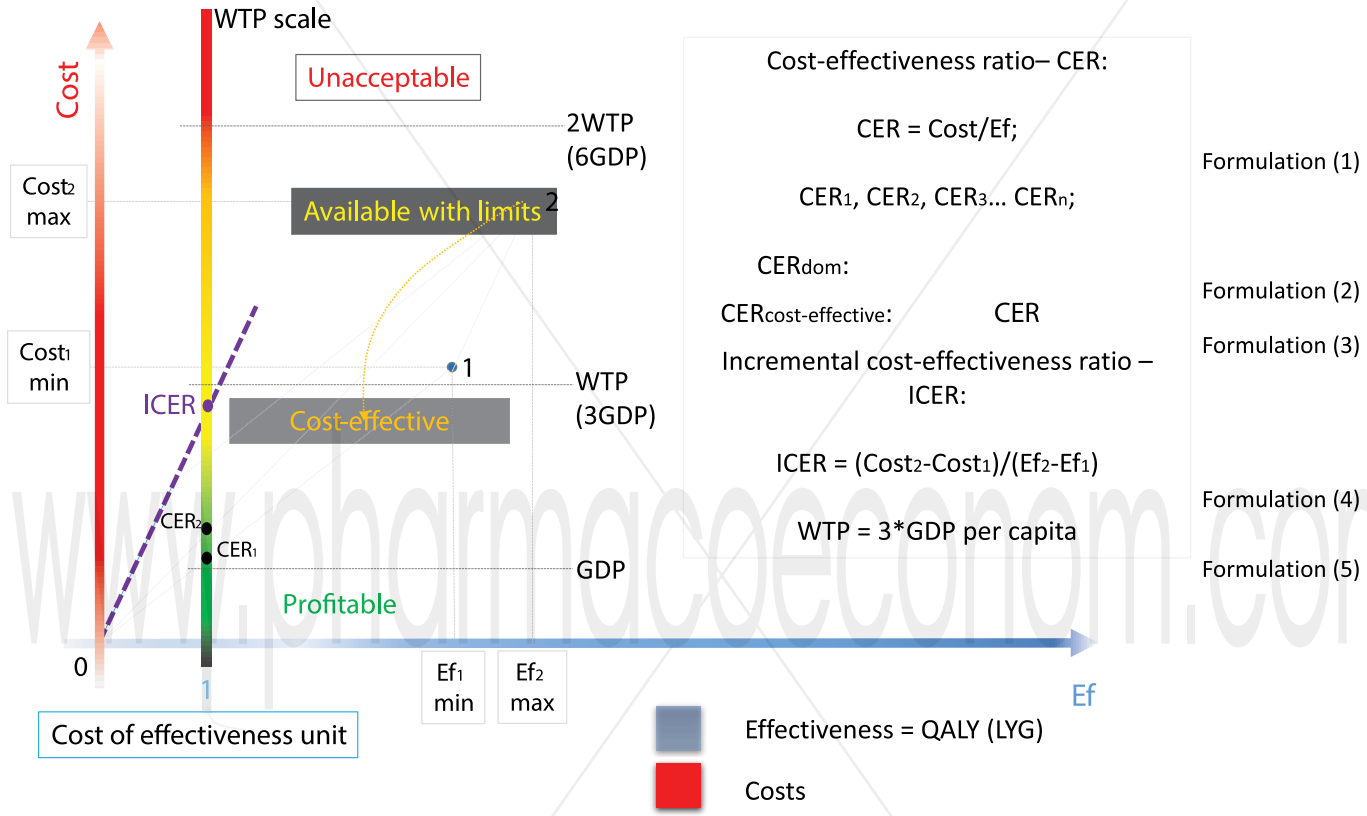
analysis - budget impact analysis and cost-effectiveness analysis, upon condition of absence of distortion of these conclusions. Considering the above discussion, it seems necessary to find an alternative solution of the problem of assessing the findings of both main types of pharmacoeconomic analysis - budget impact analysis and cost-effectiveness analysis without misunderstanding of these conclusions. The investigation was conducted from the perspective of healthcare decision-makers. At the first step of investigation, authors carried out its decomposition, which resulted in the following presentation. . In this case, posted problem can be reformulated as follows: which MCDA method should be used during making decisions on the basis of the results of the budget impact analysis and cost-effectiveness analysis. The choice of MCDA method can be defined by the number and properties of criteria, therefore it is necessary to consider the properties of the budget impact analysis and cost-effectiveness results as MCDA criteria [8-10].

Cost-effectiveness analysis is a pharmacoeconomic method which allows to determine appropriate health technologies using of health outcomes criteria (diagnostics, prevention, rehabilitation) determining cost using comparative assessment of outcomes and costs of two and more health technologies with different effectiveness and results is presented in the same measurement units [1,7,11]. For a visual description of the properties of the cost-effectiveness analysis conclusions, we will consider them on the example of figure 1, which displays a graph and the associated calculations in the form of formulas.

Figure 1. **Graphical representation of cost-effectiveness analysis**



The figure represents a two-dimensional coordinate system in which the effectiveness of the two hypothetically considered health technologies (Ef1 and Ef2) according to selected effectiveness criteria (QALY - quality-adjusted life-year, LYG – life years gained) is plotted on x-axis and is the cost associated with these technologies in monetary terms (Cost1 and Cost2) is plotted on y-axis. Graph represents that technology 2 with better effectiveness requires higher costs compared with technology 1. Technology 1 and 2 are described with blue points on the graph. In the following step, the points corresponding to the technologies 1 and 2 are connected with straight lines from the origin point. Then the point corresponding with the selected single effectiveness criteria is plotted on x-axis, which is representing chosen technology effectiveness according to the chosen effectiveness criteria; perpendicular is restored up from this point. Points (CER1 и CER2) crossing a specified perpendicular with line segments connecting the origin point with the point corresponding to the considered technologies, graphically represent the calculated values of the cost-effectiveness ratios of the analyzed technologies. Therefore cost-effectiveness ratio describes the cost (in monetary terms) of efficiency unit for each technology. If the cost-effectiveness ratio of more effective technology is below cost-effectiveness ratio of the less effective one from the perspective of cost-effectiveness analysis the conclusion of highly preference of more effective technology is should be formed. In the situation that presented in figure 1, more efficient technology is characterized by a higher value of cost-effectiveness ratio, which requires conduction of incremental cost-effectiveness analysis. On the graph the point corresponding to the incremental cost-effectiveness ratios, is also at the intersection with the restored perpendicular and is shown in purple colour. The incremental cost-effectiveness ratio shows the cost of additional efficiency represented by more effective technology. Its graphical calculation is carried out by composition of vectors. Then segment (highlighted in rainbow color), reflecting the gradation of decisions on the incremental cost-effectiveness values according to the «willingness to pay» (WTP) threshold was placed on the perpendicular, restored from a point corresponding to a single value of the effectiveness criteria. WTP is calculated according to the formula (5) (Fig. 1). Based on the proposed grading, technology depending on incremental cost-effectiveness ratio can be characterized as:

- profitable;
- cost-effective (fig. 1);
- available with limits;
- unacceptable.

Thus, the decision criterion based on cost-effectiveness analysis has the following significant characteristics:

- is a non-negative value;
- reflects the value of (additional) unit of effectiveness, ranging health technologies according to the degree of profitability;
- specific value;
- presented in quantitative monetary terms
- quantitative values are characterized by five quality categories: dominant, profitable, cost-effective, marginally acceptable (possible), and unacceptable;
- qualitative categories are more valuable for decision-makers.

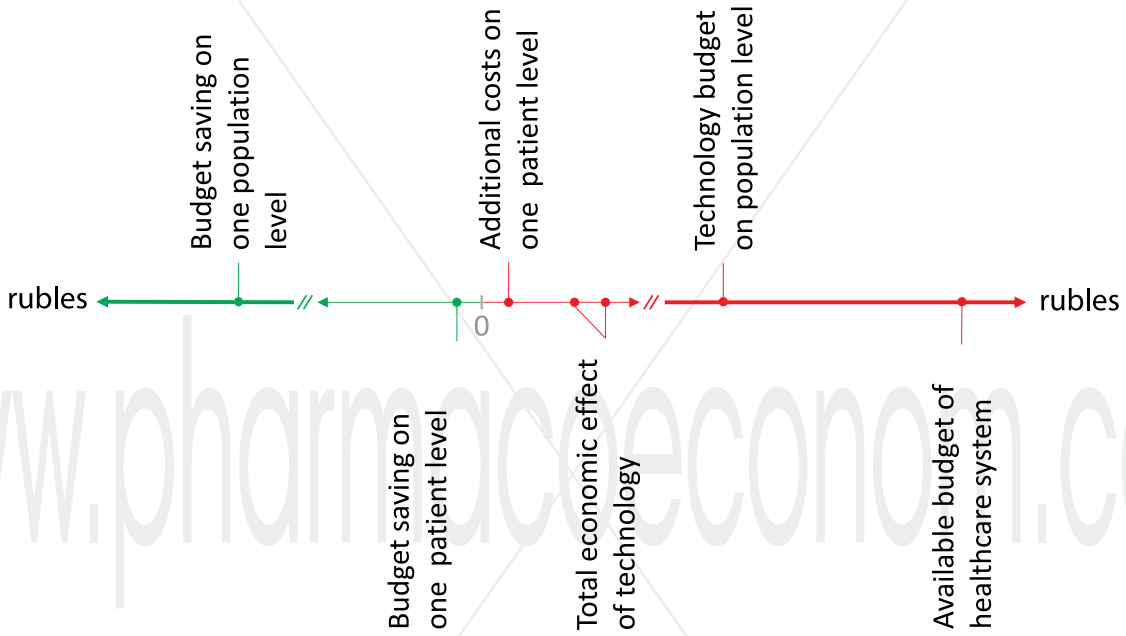
Budget impact analysis in accordance with its naming, allows to determine the effect of health technologies implementation on the healthcare budget. Budget impact analysis begins with determining of the total economic effects provided by the technology on the healthcare budget, which represents the algebraic sum of the costs and savings associated with ones considered by the health technology. The aim of analysis is to determine the advantages of compared health technologies by comparing the calculated values of the total economic effects of each of them.

Technology with lower total economic effect is considered predominant. However, it should be noted that representation of the budget impact analysis results is more diverse in comparison with one of cost-effectiveness analysis. In addition to the above «basic scenario» of budget impact analysis, this pharmacoeconomic tool allows you to define the possible scope of implementation of the studied technologies based on such conditions of the health system, as the amount of available budget and the number of patients in case of full coverage of medical care for all patients. This scenario is called «optimization scenario» of budget impact analysis. Budget impact analysis also helps to implement «investment scenario», which is determined by the required amount of budget to cover the cost of this technology to achieve a given target health outcomes in target patients group [1,11].

When conducting innovation or optimization scenarios budget impact analysis conclusions are not only characterized by qualitative categories (presence/absence of savings), but by the accurate quantitative indicators too. It is also important to note that these figures are not specific, in contrast to the cost-effectiveness ratio, and, therefore, these figures tend to vary (and often dramatically) when you change inputs such as number of patients and amount of technology implementation (which is closely depended on variable costs).

Budget impact analysis is graphically presented in Fig. 2 similarly to the cost-effectiveness analysis (Figure 1). In accordance to the specified figure budget impact analysis corresponds to a one-dimensional structure with scale, which with values in monetary terms (Fig. 2).

Figure 2. **Graphical representation of budget impact analysis**



The green part of the scale reflects the potential savings provided by one of the compared technologies, while the additional costs of more expensive technology, the total economic effects of each of the technologies; the budget required to cover the technology to the given population; the available budget of the health system are reflected on the red part of the scale. Summarizing the above, we can identify the following characteristics of the criterion of the budget impact analysis results when making decisions in health care:

- is a non-negative value;
- defines various parameters of the budget during the health technologies implementation;
- provides a comparative evaluation of the two technologies from the perspective of their impact on the health budget;
- it is not the specific value;
- has a monetary value;
- is more quantitative than qualitative in nature: only for the basic case of budget impact analysis qualitative categorization of the findings is available.

Comparison of properties of budget impact analysis and cost-effectiveness analysis criteria shows that although both criteria are characterized by quantitative monetary form of expression, however, the conclusion on the criterion of cost-effectiveness analysis is more qualitative in nature, and the conclusion on the criterion of the budget impact analysis - quantitative.

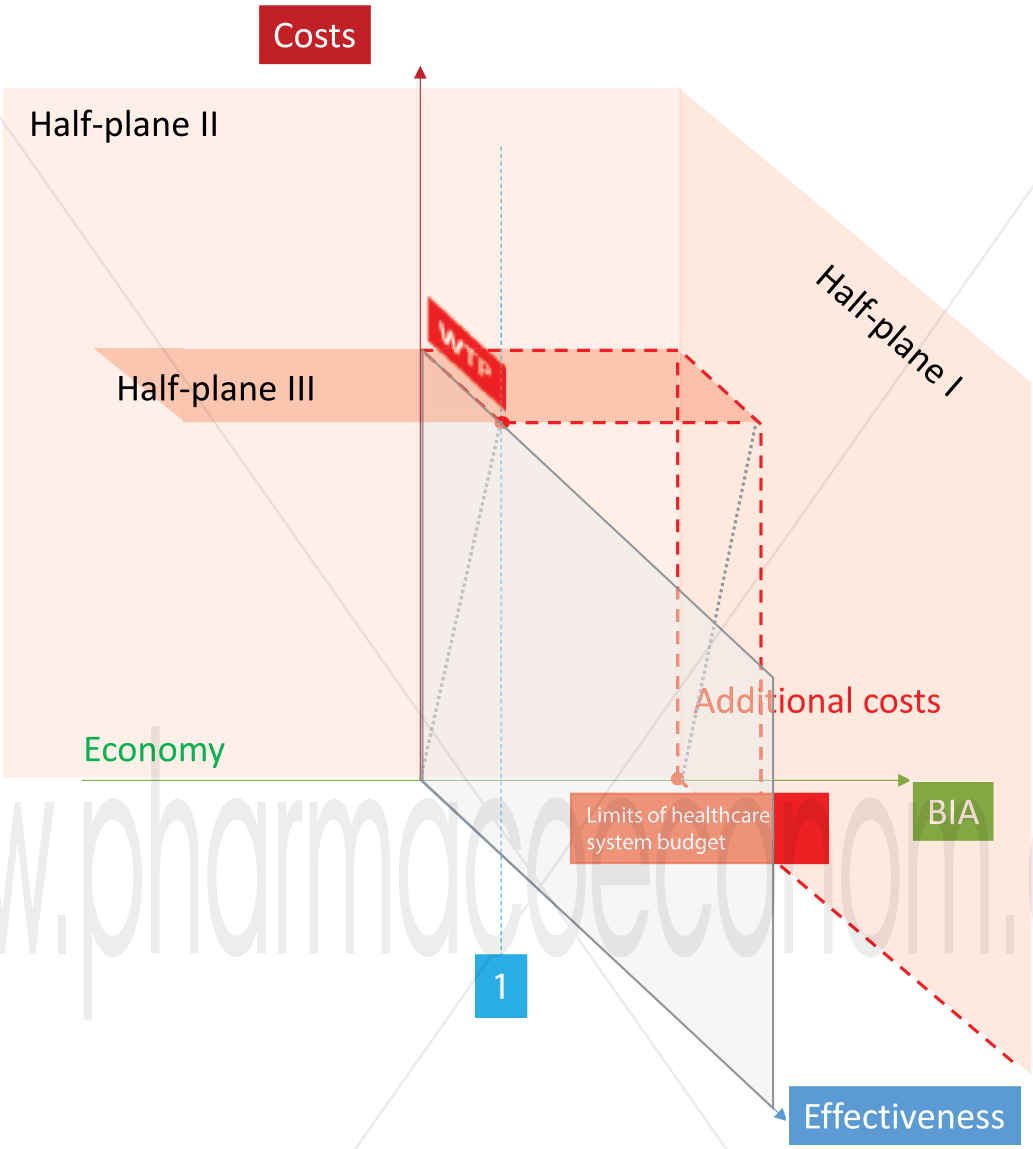
In addition, **sense bearing differences between the described types of pharmacoeconomic analysis should be noted: if cost-effectiveness analysis shows the profitability of the particular technology use, the budget impact analysis deals with availability of technologies based on the capabilities of the healthcare system.**

In this regard, in our opinion, in order to prevent distortion of meaning of both pharmacoeconomic criteria during decision-making more rational may be the use of non-compensatory approach instead of integral (compensatory) approach with scores obtaining. In proposed approach the influence of each criteria (cost-effectiveness analysis and budget impact analysis) will be considered independently. That allows to preserve the logic of methods. Proposed non-compensatory approach[2] is based on the idea of importance for decision-makers, it helps to highlight areas characterizing the possibility of the health technologies approval or disapproval from the pharmacoeconomic analysis perspective. In fact, selection of pharmacoeconomic indexes boundaries characterizing the considered health technology out of scope of which technology will be definitely denied may be most relevant in the first stage. After determining the boundaries of this area, ranking of analyzed technologies according to optimality of pharmacoeconomic profile should be performed in case of the analyzed ones match in the approval area. Then, taking into account high level of relevance of budget impact analysis and cost-effectiveness analysis in the Russian conditions, the boundaries of the specified area should be formed according to the respective values of the two listed pharmacoeconomic tools indicators.

Considering that cost-effectiveness analysis can be presented in two-dimensional spatial representation and budget impact analysis in one-dimensional one, construction of an united area of health technology approval based on two listed criteria involves using of three-dimensional structure (figure 3).

[2]Use of non-compensing approach of multiple-criteria decision analysis applied to the discussed problem is preferable because of the limited number of qualifying criteria (only two).

Figure 3. **«3D» pharmacoeconomic model of health technology approval area used in their inclusion in state funding programs based on pharmacoeconomic criteria: cost-effectiveness analysis and budget impact analysis.**



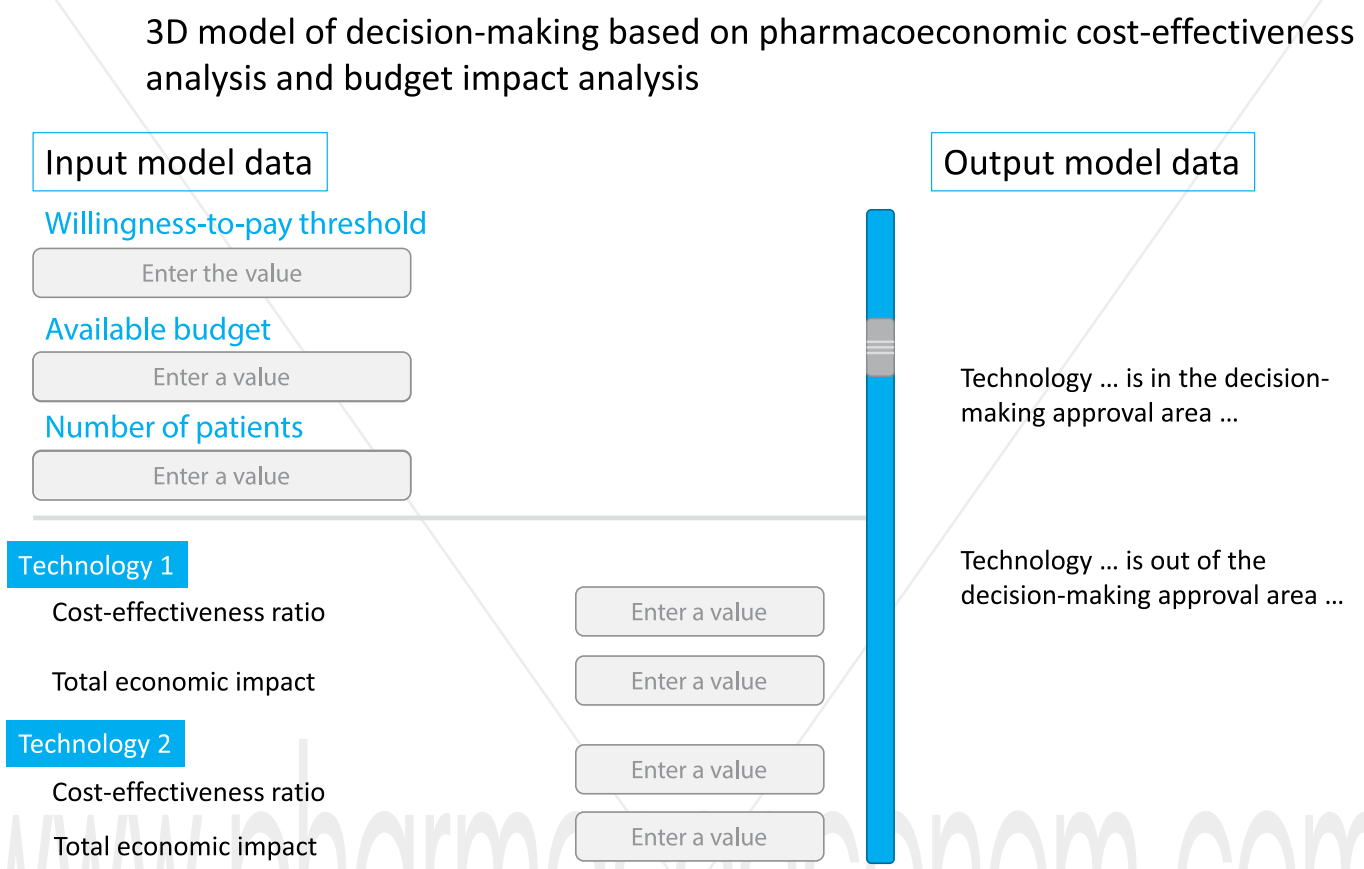
According to figure 4, the health technology is described in the three-dimensional coordinate system from the perspective of two pharmacoeconomic criteria, the axes of which correspond to the effectiveness, costs and results of the budget impact analysis. The approval of health technologies in accordance with the described approach is defined by three half-planes: I, II, and III (figure 3). The first half-plane reflects a health system capacity limit of payment for technologies, the second shows the limitations imposed by the willingness-to-pay threshold in relation to the incremental cost-effectiveness ratio; the third half-plane obviously follows from the impossibility of negative effectiveness axis values (since the point of origin corresponds not to the current practice and efficiency report in relation to it, but for zero values of all three axes).

For practical purposes, according to the authors, the technique should be implemented in the interactive three-dimensional model form, as input data it is possible to make settings that define the area approval boundaries in decision-making and characterizing health technologies from the perspective of two considered criteria. The proposed three-dimensional pharmacoeconomic model allows to formulate a consistent pharmacoeconomic conclusion for evaluated health technologies: whether it is in the scope of approval when making decisions or not (figure 4).

Use of this model preserves the meaning and significance both the first (cost-effectiveness analysis) and the second (budget impact analysis) criterion, it is achieved with non-compensing mechanism of criteria based accounting. In the case of several technologies evaluation under the condition of getting them all in the approval area proposed model makes it possible to rank studied technologies depending on the pharmacoeconomic profile preferences: in our opinion, the ranking should be based on the cost-effectiveness analysis criterion in the described situation.

Thus, for the first time was developed and presented the method of health care decision-making using the criteria of two types of pharmacoeconomic analysis (cost-effectiveness analysis and budget impact analysis) based on the methodology of non-compensative multiple-criteria decision analysis. Characterized by the number of advantages (full account of results of both types pharmacoeconomic analyses during conclusion preparation; formation of a single consistent pharmacoeconomic conclusions; further ranking possibility of the discussed technologies), the technique requires further validation and verification of applicability in real conditions, however, the authors hope that this research will be interesting to the professional community and will initiate a discussion on this topic.

Figure 4. **Basic diagram of three-dimensional (3D) model of decision-making based on pharmacoeconomic cost-effectiveness analysis and budget impact analysis**



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