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- ❑ МЕТОДОЛОГИЧЕСКИЕ ОСНОВЫ АНАЛИЗА  
"ВЛИЯНИЯ НА БЮДЖЕТ"
- ❑ РЕЗУЛЬТАТЫ РОССИЙСКИХ  
ФАРМАКОЭКОНОМИЧЕСКИХ ИССЛЕДОВАНИЙ

## METHODOLOGICAL BASIS FOR BUDGET IMPACT ANALYSIS

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**Abstract:** Budget impact analysis is one of the main methods of pharmacoeconomic analysis and obligatory one for pharmacoeconomic assessment during the apply for inclusion in state reimbursement list in the Russian Federation. Results of budget impact analysis being presented in monetary values are the most convincing ones among the pharmacoeconomic values for healthcare decision-makers. The conduct of budget impact analysis includes such stages as choice of effectiveness criteria, costs analysis. During this type of pharmacoeconomic assessment the following factors are taken into account: time horizon, the peculiarities of choice of patients' models, characteristics of market penetration with health technologies. Budget impact analysis presents wide opportunities for conducted pharmacoeconomic assessment, defining the total economic impact under basic scenario. In the same time budget impact analysis allows to compare the figures of total economic impacts for several technologies, showing the least costly alternatives. If it is necessary using budget impact analysis it is possible to make accurate models describing the budgets of any healthcare programme of ones for treatment of certain nosologies with the function of prognosis and optimization.

**Key words:** budget impact analysis, effectiveness criteria, direct costs, indirect costs, total economic effect, time horizon, federal level, regional level, healthcare facility level, Decree of the Russian Federation Government dated August 28, 2014 No. 871.

included in the analysis. Consequently for BIA there is a great importance of effectiveness criteria related to surrogate points of the second type – mediated clinical effects, such as the frequency of disability, the incidence of complications of the underlying disease, the frequency of side effects of primary therapy, etc. Each of these effectiveness criteria is translated into a monetary value by multiplying the listed values of the frequencies at the nominal value of each event (the onset of disability, treatment of complications, correction of side effect). Thus, the main condition for inclusion of a criterion of efficiency in the budget impact analysis is the ability to translate it into monetary terms. During CEA in general, it is preferred to use end points that reflect the length and quality of life. Endpoint in the BIA analysis are taken into account indirectly, for example as the duration of therapy as defined by the duration of life of the patient on this therapy, or during the inclusion of indirect costs reflecting the loss of society from the premature death of patient.

### Inclusion of costs during budget impact analysis

On the basis of the declared goals of BIA the most important stage in its conducting is an analysis of costs. First, you must define the types of costs to be taken into account in the BIA. The range of costs is determined by the point of view and level of BIA. If the analysis is carried out on federal or regional level, all possible types of costs, respectively, for the country as a whole or individual subjects of the Russian Federation are taken into account. BIA at the level of the health care institutions should include indirect costs and expenses direct costs that are not paid on a budget system of the medical institution (in some cases it may not be included in the cost of providing outpatient care). Whereas for the BIA conducted from the standpoint of the program of drug supply that the only costs for the drugs included in this program are relevant.

### Time horizon during budget impact analysis

During BIA the choice of time horizon is critical. The time horizon defines the period on which the BIA is conducted. The choice of a particular value of the time horizon in the BIA is determined mainly by the following factors:

- Peculiarities of the observed nosology;
- Peculiarities of the studied technology;
- Peculiarities of the financing of the studied budget.

Under the peculiarities of the observed nosology should be meant the duration of the studied disease: whether it is a short-term or chronic; in the latter case it is important to determine what stage of the disease will be considered in the ongoing BIA. It is also necessary to take into account the application of the options of the assessed health technologies, whether it is used constantly (maybe for life), periodically or only a several times. In the case of evaluation of the implementation of innovative health technologies to achieve maximum accuracy of the calculated the actual budget, the calculations must take into account the gradual introduction of the technology in time needed to prepare infrastructure. Thus, the usage of innovative medicinal drug involves the training of medical practitioners, sometimes the implementation of specific diagnostic technologies is needed; all noted processes take time that's why innovative drugs are implemented gradually.

Budget impact analysis along with cost-effectiveness analysis is a basic method of pharmacoeconomic study. In this article the main methodologic issues of budget impact analysis (BIA) are covered. Describing methodology of this type of pharmacoeconomic analysis we will compare it with the main ideas of cost-effectiveness analysis (CEA) for making a comprehensive understanding of usage of these methods.

The objective of BIA in general is to determine the consequences of inclusion of any health technology in monetary terms. Noted consequences are defined as sum (total economic effect) of all costs, connected with the usage of health technology and economy which are associated with it as the result of its effectiveness (formulation (1)). It means that BIA as CER includes effectiveness criteria of studied health technology.

$$S = \Sigma \text{Cost} + \Sigma \text{Econ}, \text{ where:} \quad (1)$$

S – total economic impact of health technology;

Cost – total costs for health technology;

Econ – total economy for health technology.

Formula (1) reveals that from the perspective of mathematics, BIA is a additive function in which number of terms is defined with the set of factors included in the analysis.

### The choice of effectiveness criteria in budget impact analysis

If the result of CEA is a calculated cost-effectiveness ratio representing a cost of effectiveness unit of the studied health technologies, is a specific value (the dimension of cost/efficacy) and does not depend on the number of patients, the result of the BIA is directly determined by the number of patients

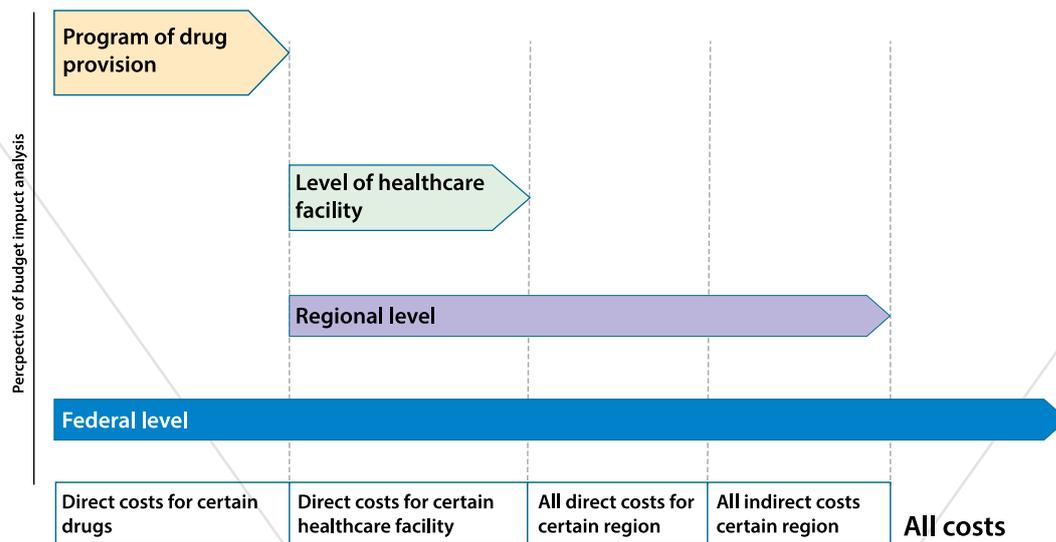


Figure 1. The choice of costs during budget impact analysis

It's also important to define a time period for which budget is forming: is it planned annually or once in several years.

With an increase of the time horizon of the BIA on the one hand its predictive value increases, and on the other hand the complexity of its implementation increases. The results of the BIA for more than a year time horizon should be discounted.

#### Model of patients during budget impact analysis

Budget impact analysis despite of cost-effectiveness analysis not only includes the features of patients from the perspective of the dissemination used data on effectiveness, but the number of patients in the studied group. Thus, the results of BIA can be presented per one patient, reflecting the consequences of implementation of health technology per one patient in monetary terms, the most valued ones for healthcare decision-makers are the results of BIA for the whole population. In this case the provided assessment reflects the actual budget needed for implementation of the studied health technology. Closer attention should be paid to the structure of patient model during conduction of BIA for a long time horizon (one year and more). In this case the following factors should be taken into account for adequacy of conducted analysis: annual income of patients defined with prevalence, and also annual decrease of patients defined with recovery of ones or death; probable transfer of patients among various schemes of treatment, for example due to resistance development.

#### Functional possibilities of budget impact analysis

Cost-effectiveness analysis implies a single scenario of its conduct – the calculation of the values of cost-effectiveness ratio of studied health technology with further comparison of calculated values and, if necessary, the determination of incremental cost-effectiveness ratio. In contrast to the CEA budget impact analysis is a more flexible approach, and in accordance with the specific tasks it can have different scenarios.

The baseline scenario of BIA means determination of the total economic effect of the introduction of the health technology (equation (1)).

If it is necessary, the BIA can be performed on the basis of comparative and competitive approach. This is a pairwise comparison of the total economic impact of introducing two or more health technology among themselves, by subtracting the value of the total economic impact for one health technology from the other (equation (2)).

$$BIA = S(1) - S(2), \text{ where:} \quad (2)$$

- BIA – result of budget impact analysis;
- S(1) – total economic effect of health technology 1;
- S(2) – total economic effect of health technology 2.

As a result of this scenario it becomes possible to determine the application of which health technology is accompanied with the lowest cost.

Optionally, in this scenario, there is the opportunity to undertake an analysis of missed opportunities, which determines the number patients which can be further treated in healthcare technology that requires less cost due to savings resulting from the use of this technology instead of health care

technology, accompanied with higher costs (equation (3)).

$$MA = \Delta S / \text{Cost}(\min) \quad (3)$$

- MA – result of analysis of missed opportunities;
- $\Delta S$  – the difference between the economic impact of two of the compared health technologies;
- Cost(min) – the costs of using least costly health technologies.

BIA allows to determine not only the consequences of the implementation of certain health technologies and to compare them to each other, but also to predict the budget for the treatment of a disease in general. In this situation the integral assessment is carried out to evaluate the total economic impact of health technologies (paid for from considered budget), to reflect the values of their penetration (the proportion of patients receiving a particular alternative health technology), impact of generic replacement for drugs out of patent protection, etc. depending on the task, BIA enables to optimize the budget to determine the ratio in which should be used the alternative health technology to achieve the best results for patients in the frames of the given size of budget. This type of the BIA scenario can be called "optimizing". BIA offers the possibility to solve the inverse problem to determine the needed budget to achieve certain health outcomes. In this case we can speak about "investment" scenario of BIA.

#### Practical usage of results of budget impact analysis

As practical experience shows, the results of the BIA, describing the consequences of implementing health technologies in monetary terms, are closer for understanding and have the greatest degree of credibility for decision makers. This fact is reflected in the preparation of the main normative legal act regulating the requirements for pharmacoeconomic evaluation of medicinal products – regulations of the Government of the Russian Federation N871 dated 28 August 2014 "On approval of Rules of forming of lists of medicinal preparations for medical application and the minimum assortment of medicinal preparations necessary for rendering medical aid." In this document, it is shown the necessity of pharmacoeconomic evaluation in the drug submission for inclusion in the state records: as BIA, as CEA. In addition, the Resolution of the Government of the Russian Federation N871 from 28 August 2014 provides a clear quantitative interpretation of pharmacoeconomic evaluation<sup>1</sup>. So, the minimum passing score on integrated pharmacoeconomic evaluation to the drug for inclusion in the lists of the state is +4. The result of CEA varies from -1 points (with an unwanted profile of the drug from the perspective of this analysis) to +1 point (if the results of CEA are characterized as a strongly preferred) (table 1). At the same time, according to the BIA the drug can be estimated from -10 (the introduction of a medicinal product accompanied by a rise in cost by over 80% compared to drug comparisons) points to +10 (the introduction of the medicinal product is accompanied by cost savings more than 80% compared to drug comparisons) (table. 1). Therefore, in this edition of the document, the results of the BIA have more value and weight in the inclusion of the drug in the state lists, in comparison with the results of CEA.



**Table 1.** Quantitative interpretation of results of budget impact analysis and cost-effectiveness analysis according to the Decree of the RF Government of 28 August N871 of 2014

Criteria	Description	%	Score
2. Advantage of clinical-economic effectiveness of medicinal drug compared with comparison drug (for each of the presented and found studies) <sup>1</sup>	The use of the medicinal product leads to lower overall costs (specify separately the direct and indirect costs) for the provision of medical care within program of state guarantees of free medical care (budget impact)	до 20	+ 2
		20 - 40	+ 4
		40 - 60	+ 6
		60 - 80	+ 8
	Usage of medicinal drug does not require the increase of total costs (note separately direct and indirect costs) for medical aid in the frames within program of state guarantees of free medical care (budget impact)	More than 80	+ 10
			0
	Assessment of costs and effectiveness (ratio of outcomes of medicinal drugs)	Up to 20	- 2
		20 - 40	- 4
		40 - 60	- 6
		60 - 80	- 8
More than 80		- 10	
Assessment of costs and effectiveness (ratio of outcomes of medicinal drugs)	Decrease of score	+ 1	
	Increase of score	- 1	
Final assessment using the scale of advantages of medicinal drug on clinical-economic assessment (ratio of score for each study to the number of studies)			
Final assessment of clinical-economic assessment (sum of scores of presented costs and final assessment on the score of advantages of medicinal drug of clinical-economic assessment)			
Final assessment of clinical-economic expertise of inclusion (not less than + 4) for recommendation for introduction of medicinal drug in the state lists			

This approach is fully appropriate to the list of expensive drugs, where the purchases are made within the respective state drug supply systems, which in turn is characterized by a fixed budget and therefore the necessity for optimal planning and spending. However, for lists of drugs (list of essential medicines) for which there are no corresponding state program of provision of medicines with a limited budget, a larger importance should have the results of cost-effectiveness analysis, which determine the drugs that provide the highest efficiency per unit of input. In other words, the budget impact analysis is the most popular for health technologies that are planned for use within programs with fixed funding. Thus, in future we can expect the differentiation of rules of pharmacoeconomic evaluations for different lists of drugs.

**Quality of performed budget impact analysis**

Describing the methodological basic of BIA a closer attention should be paid to the issue of the quality of conducted study. There is the special importance of the quality of conduct of BIA as the results of this one are the base for decision-making relatively to the usage of certain health technologies in the healthcare system. Results of incorrect BIA can lead to the false management decisions, spoiling the quality of medical aid. The main conditions determining the correctness of the BIA are: relevance (according to the situation in the Russian Federation) and comparability of the source data in the analysis. Data on costs, data on the usage of different types of health technologies, data on the structure of the market, data on the characteristics of the observed budget and data on the patient model (including epidemiologic data)

**Conclusion**

BIA is one of the main methods of pharmacoeconomics and obligatory method of pharmacoeconomic assessment during application of drug for inclusion in state lists in the Russian Federation. Moreover, impact of the drug was introduced by Federal law of the Russian Federation N429-FZ of 22 December 2014 "On amendments to the Federal law "On circulation of medicines" in the basic law on medicinal products is the Federal law of the Russian Federation N61-FZ of 12 April 2010 "On circulation of medicines", as part of a comprehensive evaluation of the medicinal product.

Results of BIA in monetary terms are the most convincing for the healthcare decision-makers among all pharmacoeconomic parameters. The conduct of BIA includes the stages of choice of effectiveness criteria and cost analysis defined with the perspective of observed nosology, assessed health technology and other factors. During this type of pharmacoeconomic assessment the following factors are taken into account: time horizon, the peculiarities of choice of patients' models, characteristics of market penetration with health technologies. Budget impact analysis presents wide opportunities for conducted pharmacoeconomic assessment, defining the total economic impact under basic scenario. In the same time budget impact analysis allows to compare the figures of total economic impacts for several technologies, showing the least costly alternatives. If it is necessary using budget impact analysis it is possible to make accurate models describing the budgets of any healthcare programme of ones for treatment of certain nosologies with the function of prognosis and optimization.

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8. Federal law of the Russian Federation N429-FZ of 22 December 2014 «On amendments to the Federal law «On circulation of medicines».

<sup>1</sup> From the table 1 data, it follows that the Decree of the Government of the Russian Federation N871 requires the budget impact analysis based on comparative competitive approach.

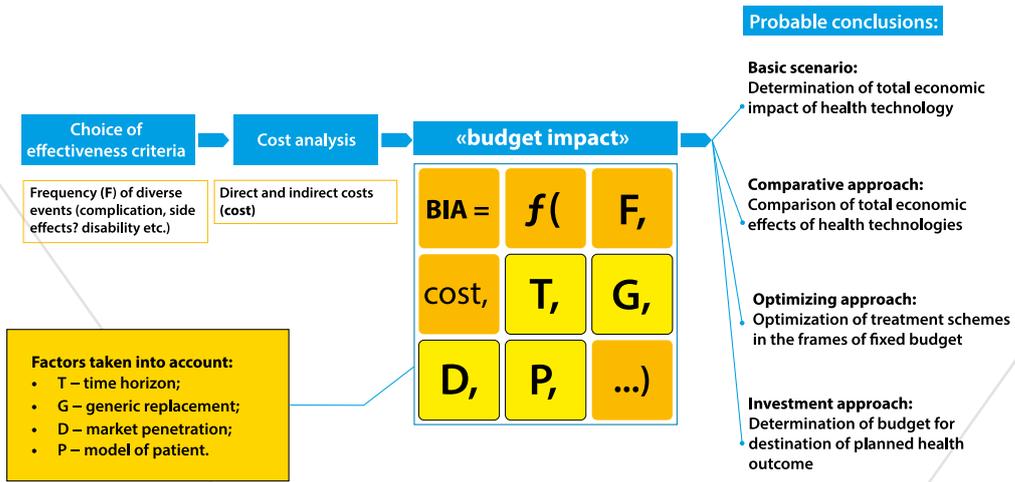


Figure 2. Pattern of conduct of budget impact analysis

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