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PHARMACOECONOMIC ASPECTS OF FURTHER IMPROVEMENT OF PHARMACEUTICAL CARE FOR PATIENTS WITH DEPRESSIVE DISORDERS

In modern society among general medical problems the most urgent are the problems of depressive disorders. According to WHO, at the beginning of the XXI century depressive disorders accounted for about 40% of total mental pathology. Every year depression affects about 200 million people, and this figure is rapidly growing. Every eighth person, at least once in life, requires specialized antidepressant therapy (WHO, 2000). Among general population of patients seeking for medical or psychological help, depressive disorders are recorded in 65% of cases. In 148 economically developed countries (Sweden, Spain, the USA, Australia, Japan), this figure reaches 20-29%.

Actuality of problem is caused by the prevalence of depression, its impact on the quality of life and social functioning of the person. Depression reduces and depresses mood, which is often accompanied by anxiety, insomnia, weakness, and loss of appetite, adynamia and other symptoms [12]. In order to be considered as a disease, the depression should have a severe form and duration of at least 2 weeks. A very important aspect of depressive disorders is a risk of suicide. Approximately 2/3 of patients diagnosed with depression are inclined to suicide attempts and 10-15% commit suicide [5].

According to WHO the "epidemic threshold" of suicides makes 9 people per 100,000 population, but in our country, this figure is much higher, it ranges about 40. Thus, the most inclined to suicidal behavior in people aged 21 to 60, the crucial point is at the age from 41 to 50, so from psychological crises suffer mostly working-age population of the country. This all leads to major economic losses.

For the last 40 years depression is successfully treated with psychopharmacological drugs, but only every third case is recognized by doctors and only one in four patients is assigned adequate treatment. Now in the present conditions of limited financing of specialized health facilities, arises the acute question of rational choice of drugs for the treatment of depression

Medical and pharmaceutical care requires the development of a rational approach to the provision of the population with life-saving drugs in resource-limited health care institutions. For this purpose, the leading countries of the world use the results of health technology assessment and economic evaluation of the cost-effectiveness of pharmacotherapy.The use of different medicines and their reasonable choice for inclusion in formulary lists, standards, and protocols of treatment are considered. That technology is called "pharmacoeconomics" [1].

The history of the development of terminology with respect to the concept of "pharmacoeconomics" began in 70s-80s. The analysis of cost-effectiveness of treatment with drugs was understood under the notion. Later, in the early 90s, the term "clinical and economic analysis" was introduced.

That brought the use of pharmacoeconomic approaches beyond pharmacotherapy and allowed to use it in all types of medical technologies. During last decades, the world medical community uses the term "health technology assessment", which is synonymous to the term

"clinical and economic analysis" and involves pharmacoeconomy which is pharmacological evaluation of technology.

Currently, the problem of economic estimation of efficiency of application of both separate drugs and drug regimens in Ukraine is one of the most actual issues because it is connected with the necessity to impose rational approaches with limited resources of health care institutions. Rapid development of the pharmaceutical industry and medical services market is taking place [2,3].

The results of the following methods of pharmacoeconomic analysis are used more often. Among them are:

− "*Cost of illness*" is the calculation of all direct and indirect (average) costs for diagnosis and treatment of disease at the level of state or region in order to identify patternsand trends of using funds and optimization of priorities in health care financing;

− "*Cost-minimization*" is when treatment has similar and equal results that allows to compare the costs for selecting a cheaper alternative of medical technologies;

−"*Cost-effectiveness*" is the method of comparing of two or more alternative medical technologies when measured in costs and results of treatment of each of them;

−*"Cost-benefit*" –It is more complex analysis when the costs and benefits of medical technologies are calculated only in financial terms, evaluating the saved money due to the reduction of disability days and duration of hospital treatment. This method is used to assess benefits of vaccinations, early diagnosis, prevention of diseases;

– *"Cost-utility"* –This method is used while analyzing the effectiveness of treatment on the basis of indirect assessment of patient's quality of life (physical, psychological, social functioning) using alternative treatment regimens. Due to the special questionnaires the quality of life indicators are compared and the number of years of life of standardized quality is determined with the help of index calculation of QALYs (Quality Adjusted Life Years).

In connection with the introduction in Ukraine of pilot projects on the reimbursement of medicines, using elements of the evaluation system of medical technologies promising is the development of unified approaches to conducting and interpreting the results of pharmacoeconomical analysis.

Currently the pharmacoeconomy of developed countries actively uses the method of "risk-sharing". It is used for cost estimation in the application of innovative products and the effectiveness of these medicines. The study is carried out in a particular population during a specific period. Its aim is risk sharing of the financing of overpriced treatment and insufficient evidence on efficacy of innovative drugs between the state and manufacturer.

The application of this method in the implementation of state financing of innovative therapy or medical technology is a relatively new phenomenon in the world of pharmaeconomy. Currently it is widespread in some countries. At the same time, this method can be considered by other countries, in particular, while funding expendable areas of medical care.

Often the results of the method of "risk sharing" is used in the form of an agreement between the manufacturer and the government to reduce the risk in the financing of state procurement of drugs when the high cost of treatment has not yet been confirmed by a high level of evidence of its effectiveness. This method is constantly used since 1997 in the UK, Italy, Portugal, France and only for certain medical technologies it is used in Germany, Belgium, Estonia, Hungary, Lithuania, Slovenia.

The results of "budget impact analysis" are used by managers in the national health programs for budget planning, forecasting the size of insurance payments, the introduction of new medical technologies. It should be noted that the methodology of conducting and providing the results of this analysis is still in the formative stage. The most important sections are still in need of further theoretical elaboration, including the conditions of national health care.

There are two models of analysis of impact on budget: static and dynamic. Static model provides a simple calculation of the costs by changing one or two factors, leaving all the rest

unchanged. This may be sufficient if an alternative and reference scenarios are quite similar, but the probability is well known.

The dynamic model takes into account such uncertainties as the probability of clinical outcomes, as well as indirect effects (e.g., more attention is given to the diagnosis of patients, changes in the use of resources, involvement of patients in the payment).

In cases when the introduction of new medical technology requires additional costs for the obtaining more helpful treatment the analysis of “willingness to pay” is used. For its implementation the “willingness to pay threshold” is applied. It reflects the amount in national currency that the society is willing to spend for the achievement of certain therapeutic effect for this category of patients.

The obtained results may vary depending on the country and methods of determination. In carrying out of this method acquires importance the analysis of the indicator "threshold willingness-to-pay" for one year saved quality of life of the patient. It can be calculated by:

− GDP (Gross domestic product), per capita of population multiplied by three (it’s the technique recommended by the Commission on Macroeconomics WHO);

− incremental values of the indicators of "cost-effectiveness" ("incremental cost – effectiveness ratio" – ICER) or "cost - utility " ("incremental cost – utility – ICUR);

− survey data groups of consumers of medical and pharmaceutical services or experts, such as random evaluation of closed and open questions, joint analysis, conditional evaluation etc.

The use of multi-criteria approach for decision-making on reimbursement of drugs can be replaced by “cost-effectiveness” analysis in cases when it is advisable to use more criteria than baseline, among which are such measure as price and proven effectiveness.

The purpose of multi-criteria analysis is the choice of the most available and important indicators for making proper decisions in the health care. The advantages of multi-criteria analysis are:

− allows to find the optimal solution in the terms of excess disordered arguments for making a decision;

− provides a consistent and repeatable decision-making process through the use of common approach to different contexts of decision-making;

− delivers more clear decision-making process, i.e. evidence and other factors are taken into the account, and the decision-making process is understandable to external observers.

Thus, the results of the economic evaluation of medicines will allow to justify the choice of the most rational treatment regimens for patients with depressive disorders. That will enable to make reasonable managerial decisions to identify priorities in the financing of medical and pharmaceutical care of these patients.

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