Lecture 12. Pharmacoeconomics.

The modern development of healthcare is associated with a steady increase in the cost of medical care, including drug provision.

No country in the world has sufficient financial resources to cover the needs of national health care. Such data is reported by the World Health Organization (WHO).

In Russia, funds for healthcare and compulsory medical insurance are also limited. For the rational distribution of funds, an assessment of the cost and effectiveness of treatment is required.

The need for funds is growing faster than the ability of the company to provide sufficient financing.
This pattern is universal. It is related to factors:
• macroeconomic and inflationary processes
• creation of new expensive medical technologies and innovative medicines
• aging of the population
• an increase in the level of expectation of patients from the conducted treatment.

A large number of alternative therapies and different treatment regimens for the same disease often leads to an irrational use of resources and increases costs.
Different treatment regimens may differ significantly in the cost of treatment and its effectiveness. Choosing the optimal ones among them can be difficult, which in the end can lead to unjustified spending of resources on excessively expensive or ineffective types of interventions.
Therefore, it is necessary to have a clear understanding of the benefits of treatment according to the chosen method and this is the justification for the costs of more expensive modern methods.

Optimal spending of funds is a universal, global problem.
This problem can be solved by clinical and economic analysis. One of the sections of clinical pharmacology is called pharmacoeconomics. In this section, specialists conduct a clinical and economic analysis. This helps to find the right distribution of finances in healthcare.

Pharmacoeconomics is a branch of clinical pharmacology in which costs are analyzed and the results of the use of pharmaceutical products or medical services are evaluated. An economic comparison of the costs and results of using different treatment regimens or medical services makes it possible to make the best choice for use and justify the costs of treatment.

Clinical and economic analysis is a methodology for comparative assessment of the quality of two or more methods of prevention, diagnosis, drug or non-drug treatment. This analysis is based on an assessment of the results of treatment and the costs of its implementation. The purpose of such an assessment is to determine the economic feasibility of choosing and using a treatment method in practice.

One of the variants of clinical and economic analysis is pharmacoeconomical analysis, when the use of drugs (pharmacotherapy) is considered as medical interventions.

In order to obtain objective results during the pharmacoeconomical analysis, the following requirements must be observed:

1. Consider the sources of research funding
2. Determine their analytical perspective
3. Determine the categories of research costs (direct, indirect and intangible).
4. Choose the alternative pharmacotherapy methods to be compared and evaluate their results according to safety and efficacy criteria.
5. Choose an adequate method of pharmacoeconomical analysis.
6. Fully present the results of the study.

What do these factors include?
1. Take into account the sources of research funding (government funding, sponsors, customers – manufacturers).
2. To determine their analytical perspective – this means that it is necessary
take into account who the research is being carried out for: society as a whole; pharmaceutical and insurance companies; healthcare systems, medical organizations and attending physicians; patients);
It influences the choice of methods and the scope of the study.
3. Determine the categories of research costs (direct, indirect and intangible).

All costs in economic analysis are divided into:

- medical, or, direct - direct cost (DC),
- non-medical, or indirect, - indirect cost (IC).
- intangible costs; they are associated with the assessment of the patient's treatment outcome and quality of life after it.

Direct medical costs are the costs of paying for the work of staff (the cost of professional medical services), the costs of maintaining a patient in a medical organization, the costs of hospitalization, the purchase of medicines, the cost of transporting a patient by ambulance, meals, payment for the use of medical equipment, etc.

Indirect costs are associated with: loss of working capacity, loss of working time by family members or the patient himself, economic losses from reduced working capacity, payment of benefits, social assistance, etc. If a person does not go to work, then, ultimately, the national income of the country decreases.

Intangible costs are costs that reflect the assessment of treatment, represent factors that cannot be quantified and that are related to the patient's feelings - pain, suffering, physical, emotional and social aspects of the patient's well-being, quality of life.
This is an attempt to quantify such an indicator as the quality of life.

When calculating the costs of pharmacotherapy, the nature of treatment should be taken into account:

- in case of inpatient treatment, the cost of LP in purchase prices
- for outpatient - in retail prices.

Take into account that the total cost of treatment depends on the characteristics of the patient:

- gender, age;
- stage and severity of the disease
- concomitant pathology.

• the need for therapeutic correction of side effects from treatment.
The medical factor also affects the costs, because it depends on the doctor:
• the success of the diagnosis and treatment of the disease
• choice of tactics and treatment regimens.

• the amount of remuneration depends on the status of the doctor, the level of his competence, authority (the total cost of treatment increases).

When conducting a pharmacoeconomical analysis, it is sometimes possible to limit oneself only to determining the following costs:
• calculating the cost of the drug and the costs of its administration.
• it is possible to calculate the cost of the drug, the cost of its administration, the cost of treating side effects and additional treatment associated with the ineffectiveness of the studied drug.
• it is most appropriate to consider all medical costs (the cost of hospitalization, diagnostic structures, transportation costs, etc.).

4. Choose the alternative pharmacotherapy methods to be compared and evaluate their results according to safety and efficacy criteria.

- The selected methods of pharmacotherapy are compared:
- • with the traditional – typical practice of treating the disease;
- • with the optimal, most effective and safe on the modern
- the level of medicine;
- • with the cheapest pharmacotherapy;
- • with placebo or no treatment.

The choice of an alternative for comparison is based on the pathologies studied and the objectives of the study.
In particular, to compare the effectiveness and safety of treatment for chronic diseases, intermediate indicators are used that reflect the effectiveness of treatment and the quality of life of the patient. These data can be obtained through various questionnaires.

When comparing alternative methods of pharmacotherapy, the following indicators are calculated:
a) if, as a result of treatment, disability develops, then determine the frequency of its occurrence in the study and control groups.
b) if the treatment affects the life expectancy, then the indicator number of saved years of life is used.
c) if treatment affects the duration and quality of life, an indicator of the quality of added years of life is used to assess the latter.

5.Choose an adequate method of pharmacoeconomical analysis.
In world practice, 5 main methods of economic analysis have been developed and are used:
analysis of the "cost of disease treatment" (cost of illness analysis);
cost—effectiveness analysis;
cost—minimization analysis (cost minimization analysis);
cost—benefit analysis (cost-utility analysis);
cost—benefit analysis (cost-benefit analysis).

6. Fully present the results of the study. It is necessary to unify the data of the performed analysis. The report on the results of the study indicates:

- The source of funding for the study
- Its target audience, taking into account the interests of which the study was conducted
- Provide data on all cost categories and the principles of their determination

• Describe the drugs being compared and the methods of their use. Specify the sources of information, assessment of their safety effectiveness, justification of the choice of criteria for their evaluation
• Describe in detail the qualitative and quantitative data of the conducted research
• To make a conclusion about the expediency and preference of using any method of LP treatment based on its clinical and economic assessment

To evaluate any studied drug, the principle of three "E" is used:
• Efficacy – the degree to which the drug can exert its main effect in "ideal" conditions of clinical research
• Effectiveness – the degree to which the drug can exert its main effect in real clinical practice;
• Effeciency – an assessment of how much treatment can improve or worsen the economic condition of the patient and society.
It is this approach to the evaluation of the drug that allows you to make the right choice in favor of the most optimal.

Practical significance. Clinical and economic research is relevant for:

1. A wide range of doctors and patients (the choice of drugs optimal in terms of cost / effectiveness or cost / utility, treatment regimens, this reduces all types of costs)
2. Medical organizations - allows you to optimize costs, reduce the time of hospitalization and quickly transfer the patient to outpatient treatment, because it is less expensive.
3. Managers and specialists of federal and regional health authorities - the use of this data makes it possible to make rational decisions. The data from these studies are used to compile a list of vital and essential medicines and to include these medicines in treatment forms.
4. Insurance campaigns: when conducting a clinical and economic examination of medical interventions and monitoring the expediency of expenses.
5. Pharmaceutical sector – manufacturers to promote drugs in the pharmaceutical market, to position a new drug on the market.
6. Society as a whole - allows to optimize costs, reduce morbidity, disability and mortality in many diseases, improve the quality of life and increase its average duration.

Basic standardized methods of pharmacoeconomical analysis.

The main methods of pharmacoeconomical analysis in the world practice are recognized as:

analysis of the "cost of treating the disease" (cost of illness analysis);
cost—effectiveness analysis;
cost—minimization analysis (cost minimization analysis);
cost-utility analysis (cost-utility analysis);
cost—benefit analysis (cost-benefit analysis).

Cost effectiveness, at the federal level, is compared in the universal indicators QALY and DALY.
QALY (quality-adjusted life years— quality-adjusted life years)
DALY (disability-adjusted life years— years of life, adjusted, adjusted for disability).

1. Analysis of the "cost of disease treatment" (SoI) - The cost of therapy is determined taking into account the direct and indirect costs incurred by the Ministry of

Health during the diagnosis and treatment of a certain disease. This is one of the most common and well-known pharmacoeconomical methods, which makes it possible:
calculate the cost of drug therapy for a specific disease, track the dynamics of costs and make a forecast based on pharmacoeconomical standards;
determine pharmacoeconomical standards (containing two parameters: the minimum set of drugs and their cost), which can serve as the basis of drug technologies (for health authorities and insurance companies), going beyond which indicates the inferiority of the treatment, or its redundancy;

2. Cost—effectiveness analysis (CEA), or cost-effectiveness analysis, consists in comparing LP and treatment programs (protocols) according to identical effectiveness criteria (for example, saved years of life).
It is used to compare two or more interventions (KG), the effectiveness of which is not the same, and the results are measured in the same units, usually natural:
• increased life expectancy
• number of years of life saved
• number of recovered patients
• frequency of eradication
• quantitative indicators of the state of organs, etc.
When comparing treatment methods for chronic non-fatal diseases, such units of measurement as mmHg, mol / l and others are used.

Most often this analysis is carried out when choosing one of the treatment methods in two stages:
• at the first stage, the results of medical interventions are analyzed and average or marginal costs per patient are determined;
• at the second stage, cost-effectiveness coefficients are calculated and compared for each patient's treatment option.
This analysis allows you to determine how much the costs (cost) the costs of this or that intervention correspond to its effectiveness and choose from different alternatives the most preferable one, in which the cost /efficiency ratio will be minimal.
This alternative is called dominant.
The compared methods, comparable in cost and efficiency, are called indifferent.

3. The "cost—minimization" analysis (SMA- cost minimization) consists in determining the actual minimum cost of treatment with the same effectiveness of various treatment methods (two or more). The positive aspect of using this method is the possibility of comparing alternative medical technologies and choosing the cheapest ones.

4. Cost—benefit analysis is used when treatment is associated with improving the quality of life. The method allows you to take into account both the costs and the effects of treatment, the effect is calculated by the number of years of life saved (QALY).

Cost / utility analysis is an economic analysis, the purpose of which is to determine the ratio of two treatment regimens, the result of which is expressed in units of utility (years of quality life - QUALY in points from 0 to 1).
When assessing the patient's quality of life, the following factors are taken into account:

- physical aspect - factors such as pain, ability to move, performing everyday tasks, etc.;
- mental aspect - feelings such as happiness, self-esteem, anxiety, etc.;
- social aspect - interaction with other people in the social sphere, friendship, love, degree of loneliness.

5. The cost—benefit analysis consists in calculating the expected profit, the expected benefit from the introduction of the treatment method, as well as the resulting savings. This analysis is carried out both to compare drugs with each other, and to compare treatment methods alternative to drug therapy.

The results of this analysis are presented in the form of a relative indicator - the ratio of benefits and costs or the absolute difference between costs and benefits in monetary terms.

In addition, additional methods for evaluating the effectiveness of treatment are used in pharmacoeconomical analysis

1. Cost-utility analysis
2. Pharmacoeconomical modeling.
3. ABC/ VEN analysis.

1. Cost /utility analysis is an economic analysis that provides for determining the ratio for two treatment regimens. At the same time, the results are presented in monetary terms. There are two approaches here:
   1. Determining the cost of the loss of working time, but then it turns out that the illness of a disabled child costs nothing.
   2. Determination of the amount that the patient is willing to pay.

2. Pharmacoeconomical modeling, two methods:
A) the construction of a "Decision tree" is a scheme or algorithm for all predicted variants of the course of a particular disease;
B) the "Markov model" is the representation of the disease in the chronic course of the disease in the form of interrelated phases passing over time (Markov cycles for one year) from one to another. In order for the Markov process to stop, at least one health condition must be present in it, from which the patient cannot get out (recovery, complication of the disease, death). They represent this model in the form of a "Markov cycle tree", each state in it is displayed as branches from a Markov node

3. ABC / VEN- analysis is the simplest and most informative method in the conditions of a medical organization, which allows to study the structure of the drugs used and the compliance of the costs of drugs according to their degree of need. ABC / VEN analysis allows you to determine the following for the Ministry of Defense:

1. The expediency of the costs of purchasing LP
2. how to rationalize the purchase of LP
3. which LP should be included in the form first of all
4. whether the financial costs correspond to the data of the analysis of the structure of the disease.

Depending on who the results of the study are intended for, ABC analysis of the following types can be carried out:

- analysis of the purchase of LP for the Ministry of Defense, region, service or department, country
- LP analysis for a certain pathology
- analysis of procurement and application of LP, optimal distribution by FTG

- analysis of the use of certain drugs within one PHTH (for example, antibacterial drugs), or analysis of one drug in the original and generic form.

Formulary treatment system.

In many countries, the formulary system has been adopted as the basis for the activities of medical organizations. This is one of the possible ways to optimize their work. In Russia, a system of cost-effective selection of medicines and the creation of a form is used.

A formulary system is an information and economic system. The purpose of this system is to develop healthcare in a market economy. The formulary system allows you to limit the number of names of constantly used drugs to a certain list of medicines (a formulary list or a list), This greatly facilitates the process of purchasing medicines, reduces the costs of medical organizations and optimizes the process of treating patients.

A formulary system can be implemented if a planned purchase of medicines for the needs of a medical organization is carried out.

possible positive results of the implementation of the formulary system:

• the use of unsafe and ineffective medications is excluded (the number of side effects is reduced);

• the range of purchased medicines is reduced (the costs of the medical organization for the purchase and storage of drugs are reduced);

• the time of the patient's stay in the hospital is reduced (direct cost savings);

• a limited list of medications allows:

☐ implement targeted staff development programs;

create databases that contain complete and objective information about medicines.

• the form is a means of creating and updating quality standards of treatment in a medical organization.

The main functions of the formulary system:

• guaranteed provision of patients with high-quality treatment;

• identification and development of problem-oriented and advanced methods of rational pharmacotherapy of common diseases;

• identification of the most clinically and cost-effective and safe drugs;

• ensuring control over the correct use of drugs and taking measures to prevent and correct pharmacotherapy errors;

• wide dissemination of objective evidence-based medical and pharmaceutical information among all participants in the healthcare process;

• introduction of systematic vocational education.

A form is a list of medications and a guide to their use to ensure treatment standards. This list is restrictive for procurement and use in medical organizations.

The list of medicines for the form is compiled on the basis of:

• agreed and accepted at the international and (or) state level of practical recommendations (standards) of treatment,

• evidence-based data for the implementation of rational pharmacotherapy,

• thorough analysis of the structure of morbidity,

• evidence-based data on the most clinically and cost-effective and safe medicines,

• research data on the level of consumption and the cost of treatment for each disease.

The form is a dynamically developing document with constantly updated and replenished content of individual articles and sections.

The form is restrictive and encourages the use of only those medicines that are included in it.

By using the formulary , it is achieved:

• significant reduction in the range of medicines used,

• increases therapeutic impact

• the process of drug provision is simplified.

The form is not similar to the list of VED, which has a recommendation character. One of the features of the form is the predominant use of generic names of medicines in it, since:

• this name indicates that the drug belongs to a chemical structure and a certain clinical and pharmacological class.

• the use of generic names allows the replacement of bioequivalent drugs containing the same active substance, identical in concentration, dose, dosage form and route of administration; the trade name is not used because it obliges the pharmacist to release only the drug indicated in the prescription.

At the same time, a medical organization can determine the trade names of the drug that are preferred during procurement in order to increase therapeutic benefits and reduce the cost of their purchase.

The system of cost-effective selection of medicines in Russia has been called rational pharmaceutical management. The implementation of this system was carried out under the program of international cooperation.

The World Health Organization has compiled a Program of Vital drugs and has developed criteria for the selection of medicines.

At the same time, priority is given to drugs with proven efficacy and safety. Drugs that have received a good evaluation during clinical trials and meet quality standards are selected. An important criterion for choosing medicines is the affordable cost of treatment.

The structure of the formulary system includes three levels: federal, territorial and the level of the medical organization.

A formulary committee has been established at the Federal level under the Ministry of Health of Russia. This organization analyzes and evaluates data

on the use of treatment protocols in a medical organization, drug interactions, side effects of medications;

results of pharmacoeconomical and pharmacoepidemiological studies;

international experience, national standards of treatment for pharmacotherapy of various diseases;

studies scientific evidence of the clinical and economic effectiveness of medicines

The territorial level includes regional, republican, and regional formulary committees. They include leading specialists of healthcare management bodies and medical organizations.

At the level of a medical organization, formulary committees are also organized to develop a form, which include: deputy chief physician for medical work, pharmacy representative (or responsible for purchasing medicines in a hospital), clinical pharmacologist, department heads, economist, accounting representative.

The main tasks of the formulary committee are:

selection of medicines, their evaluation, safe use and information support in your medical institution

determination of the need for educational programs for advanced training of personnel on the use of medicines.

The formulary list of medicines is approved by the management of the medical organization and distributed to medical personnel. The Chief Physician issues an order on the use and purchase of medicines in strict accordance with the formulary list. From this moment on, the medical organization purchases only the medicines included in the form

When using the formulary list, the following restrictions on the use of medicines should be taken into account:

1. Limitations on diagnosis — determine the indications for the correct prescription of medications. The use of toxic drugs for patients is permissible if the expected effect of the use of drugs exceeds the possible risk of side effects.

2. Restrictions on the level of qualification — determine the circle of specialists who have the right to use these formulary drugs or drugs of the main pharmacotherapeutic groups. For example, only an infectious disease specialist can prescribe some antibiotics for parenteral administration, and only a cardiologist or resuscitator can prescribe thrombolytics.

3. Pharmacological restrictions — determine and approve doses, frequency of administration, duration of treatment for this formulary drug.

THE USE OF INFORMAL LP

In some cases, medications that are not included in the hospital form may be required. For such cases, the hospital's formulary committee establishes rules for the use of non-formulary medications, for a specific patient, including in consultation with the medical commission.

The attending physician fills out a special form and sends it to the medical commission. This commission discusses the appointment of informal medicines and gives permission for the purchase and allocation of the necessary amount of the drug for the patient. The Commission also analyzes all requests for the use of non-regular medicines.

If frequent requests for a certain drug are detected and it is better in effectiveness than the one presented in the form, a decision should be made to replace the formular drug with another.

The practical significance of the formulary system in the work of stationary MO. The form greatly facilitates the work of practitioners,

- it reduces the number of medical errors and
- avoids complications of drug therapy,
- contributes to improving the quality of treatment, reducing mortality.
- As a result, the hospital budget is saved by
- reducing the length of the patient's stay in the hospital,
- repeated hospitalizations
- costs for the treatment of complications of drug therapy.

Finally, the introduction of a formulary system helps to remove ineffective and low-quality drugs from the market. Such drugs will not be included in the forms, and, therefore, will not be purchased.

ECONOMIC ASPECTS OF THE FORMULARY PROCESS

When developing a medication form, it is necessary to take into account the pharmacoeconomical aspects of their use. It is useful to determine the indicator of the cost / effectiveness of drug therapy.

Pharmacoeconomical analysis should include consideration of indirect costs associated with drug therapy.

In some cases, it is advisable to use more expensive LP, provided that this will reduce overall costs. For example, the costs associated with the use of drugs for oral administration are significantly lower than drugs for parenteral administration.

It should be taken into account:

- the cost of a full course of therapy for each medication;
- costs associated with the use of medicines, including the cost of consumables: containers or bottles for intravenous infusions, solvents, syringes, preservatives, transfusion systems, etc.;
- costs associated with the use of these medicines, such as drugs for premedication, medical devices, etc.;
- costs associated with laboratory tests, including the cost of reagents and monitoring equipment;
- costs associated with the storage of LP;
- possible effect of therapy on the duration of the patient's stay in the hospital.