Research Article

Methodical approach to conducting a comprehensive pharmacoeconomic study of drug care in medical organizations

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ABSTRACT

Aim: The problem of rational pharmacotherapy in outpatient and inpatient therapy is one of the most significant to date, due to the occurrence and progression of most pathologies. **Method:** In this regard, it is important to develop a methodological approach to conducting a comprehensive pharmacoeconomic study of drug care in inpatient and outpatient settings of medical organizations (MO), assessing the continuity of treatment, the results of medical prescriptions, as well as the implementation of methodological, managerial, and economic support for pharmacotherapy. The main objective of comprehensive (hereinafter tandem) pharmacoeconomic study is to develop restrictive lists (formulary lists of drugs for stationary conditions and brand portfolios of drugs for outpatient) that are optimal according to the criteria "pharmacotherapeutic efficacy" – "characteristics of drugs" – "compliance with consumer expectations" – "price." **Result and Discussion:** The methodical approach provides for simultaneous and sequential execution and comparative analysis of the research stages: Formation of the database of the drugs; structural analysis of the drug assortment; ABC analysis of the drug assortment; multidimensional examination of the assortment; and regulatory cost analysis and determination of the drug budget of the inpatient department. **Conclusion:** A methodical approach has been developed for conducting a comprehensive pharmacoeconomic study of drug care simultaneously in outpatient and inpatient settings. This approach may be of interest when optimizing the issues of succession and sequence of treatment in medical organizations (MOs) for pharmacotherapy of patients with different nosologies.

KEY WORDS: Brand portfolios, Comprehensive pharmacoeconomic research, Drug assistance, Drugs, Formulary lists

INTRODUCTION

The problem of rational pharmacotherapy in outpatient and inpatient therapy is one of the most significant to date, due to the occurrence and progression of most pathologies.[1-3] At present, there are separate methods for conducting pharmacoeconomic studies of drug care of various nosologies in the hospital or clinic, differing in a number of significant positions.[4-6] None of them allows conducting complex research, assessing the continuity of the pharmacotherapy process at each stage of drug assistance.[7,8]

The need for the formation of an integrated methodological approach is also due to the preferential differences in the trends of medicinal prescriptions and the formation of the range of drugs for the treatment of various nosologies under outpatient and inpatient treatment.[9,10]

In this regard, it is important to develop a methodological approach to conducting a comprehensive pharmacoeconomic study of drug care in inpatient and outpatient settings of medical organizations (MO), assessing the continuity of treatment, the results of medical prescriptions, as well as the implementation of methodological, managerial, and economic support for pharmacotherapy.

MATERIALS AND METHODS

The methods of logical, system, graphical analyzes, the works of leading scientists in the field of management

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and economics of pharmacy, and pharmaceutical production were used in this work.

RESULTS AND DISCUSSION

In the course of a large-scale study of drug assistance provided during pharmacotherapy in outpatient and inpatient conditions, a methodical approach was developed to conduct a comprehensive (hereinafter tandem) pharmacoeconomic study. The advantages of this approach are: The ability to study the sequence and continuity of treatment during outpatient treatment, and then inpatient treatment, identify trends in the formation of the range of drugs and conduct a comparative analysis, optimize the examination of drugs by specialists due to a clear distinction between the requirements for pharmacotherapy depending on the conditions of care, and, as a result, the formation of the most rational restrictive lists of drugs.

The main objective of comprehensive (hereinafter tandem) pharmacoeconomic study is to develop restrictive lists (formulary lists of drugs for stationary conditions and brand portfolios of drugs for outpatient) that are optimal according to the criteria "pharmacotherapeutic efficacy" – "characteristics of drugs" – "compliance with consumer expectations" – "price."

The methodical approach provides for simultaneous and sequential execution and comparative analysis of the research stages: Formation of the database of the drugs; structural analysis of the drug assortment; ABC analysis of the drug assortment; multidimensional examination of the assortment; and regulatory cost analysis and determination of the drug budget of the inpatient department [Figure 1].

Within the framework of the methodological approach, the technology of multidimensional expertise of the drug assortment was developed for the first time, which implies a multi-stage, consistent assessment of the drug assortment conducted by pharmaceutical and medical experts according to a significant number of criteria. The technology of multidimensional expertise of the drug assortment helps to optimize the selection of drugs in restrictive lists and provides for the implementation of pharmaceutical evaluation of drugs from the point of view of their characteristics, VEN-expertise, analysis of compliance with consumer preferences, and evaluation of cost criteria [Figure 2].

The goal of a multidimensional examination of drugs assortment is the rationalization of drugs restrictive lists (official lists and brand portfolios).

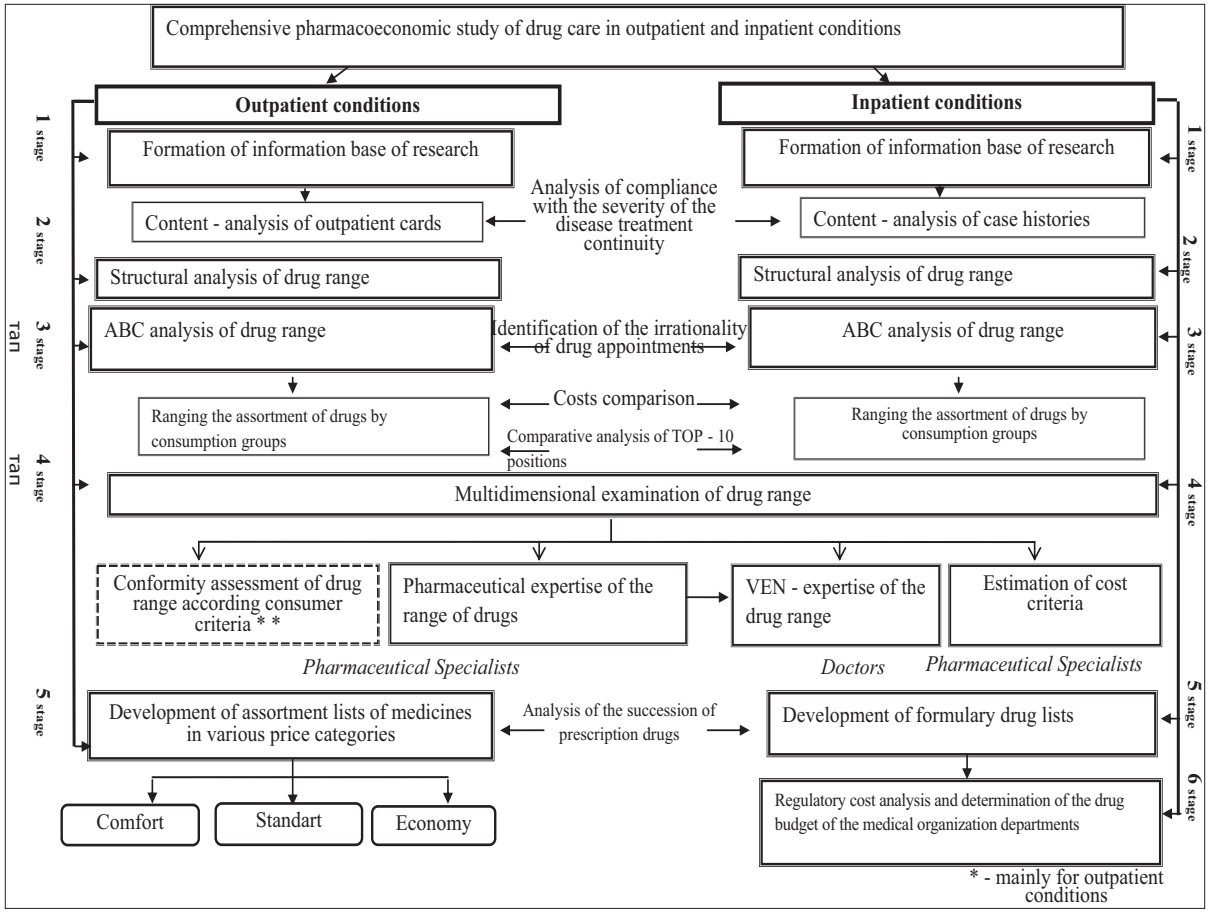

Figure 1: Methodical approach of an integrated pharmacoeconomic study of drug care in medical organizations

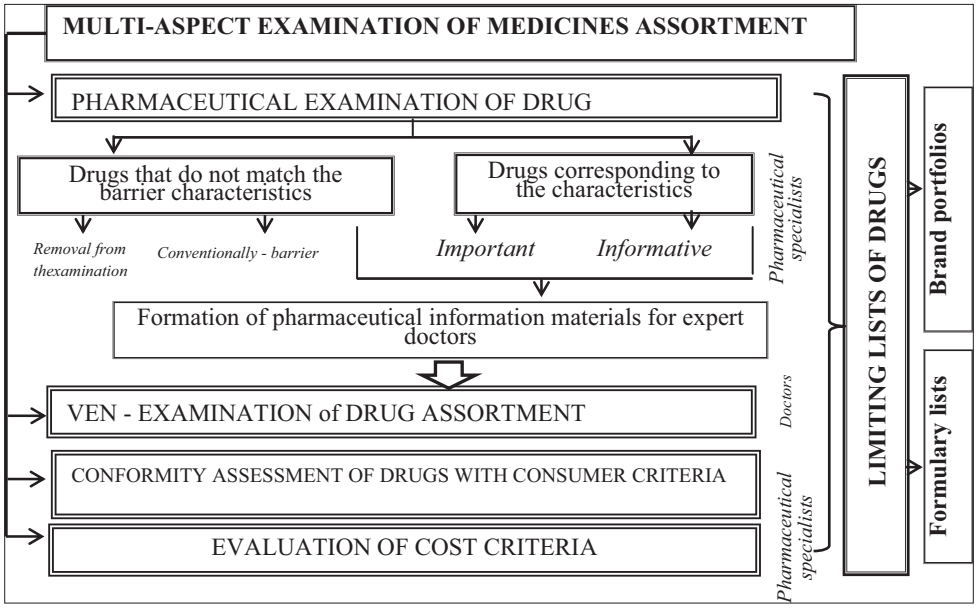

Figure 2: Stages of a multidimensional examination of the range of drugs

Conducting a multidimensional examination of drugs assortment involves the consistent participation of highly competent experts – pharmaceutical and medical specialists.

At the first stage, the highly competent pharmaceutical specialists (representatives of the MO formulary commission) implement the pharmaceutical expertise (PE) of the drug assortment. PE implies characteristics analyses of the drug range; selection of drugs that best meet the requirements of the examination; elimination of drugs that have limitations to the purpose and the formation of a summary of analytical information on the range for the preparation of expert doctors for the subsequent VEN-examination.

The technology of PE includes the sequential implementation of the following steps: Determination of the criteria for PE of the drugs range for specific conditions of analysis; analysis of the list of drugs characteristics, the choice and justification of the choice of their use under specific conditions of the study; identification of barrier (restrictive) drugs characteristics; removal of drugs from the expertise that does not fully meet the criteria; and the formation of information materials on the characteristics of the drugs to optimize VEN-expertise of the medicines range by doctors.

At the second stage, highly qualified medical specialists carry out VEN-expertise of the drug assortment with the purpose of segmenting the drug assortment, according to the optimality of the criter "pharmacotherapeutic efficacy" – "safety," to justify the inclusion of the drug in restrictive lists. The purpose of the third stage is to analyze the assortment of pharmaceutical products for compliance with consumer preferences, which implies an assessment of the correspondence of the characteristics of pharmaceutical products to consumer criteria identified in the course of a sociological study of consumers of services. At the fourth and final stage, the evaluation of cost criteria is carried out through a comparative assessment of the cost of drugs and the cost of treatment (according to the results of the ABC analysis).

The methodical approach was tested in the course of a comprehensive pharmacoeconomic study of drug assistance to children with juvenile arthritis (JA) in the outpatient and inpatient conditions of children of the Belgorod Region MOs.

At the initial stage of the study, a content analysis was conducted of 900 case histories of children with JA – hospital patients and 86 outpatient cards – polyclinic patients. The analysis revealed the diagnosis of 2 types of JA: Juvenile chronic arthritis and reactive arthritis (ReA), as a result of which further research under stationary conditions was conducted on these nosological forms of JA.

We have formed an information collection of drugs which amounted to 72 trade names, 48 international non-proprietary names, 2575 drug packages for ambulatory institutions and 106 trade names, 78 international non-proprietary names and 1565 drug packages for hospitals.

We have identified the structure of the range and consumption of drugs for the treatment of these nosologies which are mainly formed at the expense of six groups according to the ATC classification, among them dominate: "Agents affecting the digestive system

and metabolism;" "Agents affecting the musculoskeletal system;" "Hormones of systemic action," etc.

At the same time, during the implementation of a detailed intragroup analysis implemented with the help of rheumatologists and pediatricians, we identified individual cases of irrationality in the prescription of a number of drugs, in particular, therapeutic polypharmacy, prescription of drugs that have limitations for use in childhood, etc. Further, an analysis was conducted on the compliance of the outpatient range with consumer characteristics. With the help of expert doctors, discrepancies between prescriptions of medicines on pharmacotherapeutic efficacy were revealed (25.7%); security (67%); and ease of use of drugs (37.7%). Analysis by the criterion of "affordable price of drugs" showed that every third prescribed drug is expensive. Then, using the ABC analysis, the drug assortment was segmented according to the frequency of prescription and the cost of treatment. Thus, it was revealed that in stationary conditions, the high consumption Group "A" for the treatment of JA takes 22.05% in the total range of the product, formed by drugs with a range of prescription rates (PR) from 17.4 to 2.3 and includes 15 drugs – Diclofenac, Meloxicam, Metipred, Sulfasalazine, and others. The average consumption Group "B" (22%) is formed by 15 drugs with PR from 2.1 to 0.3 – Diprospan, Voltaren, Methotrexate, and others. The low consumption Group "C" (54.4%) includes 38 drugs with PR of 0.3 and below – Nexium, Movalis, Indomethacin, etc.

At the next stage, we first implemented the technology of multidimensional expertise of the drug assortment. Thus, at the first stage, the inpatient and outpatient assortment is analyzed in detail – 80 and 72 drugs for the treatment of JA, respectively, from the viewpoint of their characteristics. For the examination, 19 drug characteristics were identified, while only 57% are reflected in the "Instructions for Use."

In the course of the analysis, in particular, it was established that more than 90% of all medicines have no infant dosage and only 30% of them have the possibility of dividing while minimizing the risk to the child's body. Only 6% of preparations have a children's dosage form. It was revealed that 67% of the outpatient drug assortment is prescribed; however, in 8 out of 10 cases they were asked to go to the pharmacy without a documented prescription. According to the results of the pharmaceutical examination, about 20% of medicinal drugs with limitations to the purpose were removed from the range. Analytical information materials on the characteristics of the selected assortment preparations for the preparation of expert doctors for VEN-expertise have also been formed.

At the next stage, we carried out a VEN-examination with the aim of segmenting the drug of the investigated range for the treatment of JA according to the degree of clinical significance, economic feasibility, and compliance with consumer criteria. Forty-seven highly qualified expert doctors – specialists from children's hospitals and polyclinics of Belgorod, Kursk and other cities of Russia took part in the examination. The average coefficient of expert competence was 0.85. Based on the weighted average estimates obtained, the drug assortment was segmented into major drugs (V), essential, or substitution drugs (E), and secondary (inexpedient) (N) drugs. Hence, in particular, 20 drugs are combined in the "V" group: Movalis (in tablets), Voltaren (solution for in.), Sulfasalazine (in tablets), Calcium – D3-Nicomed (in tablets), etc.; in Group "E" – 21 drugs: Dolgit (gel), Diprospan (solution for in), etc.; and in the Group "N" – 36 drugs: Magnesium orotate (in tablets) and Metamizole sodium (solution for in), etc.

At the final stage, we developed five indicative lists of drugs for the treatment of children suffering from ReA, associated urogenic, enterogenic, and nasopharyngeal infections; polyarticular and oligoarticular arthritis in stationary conditions. Three assortment portfolios of drugs for the treatment of children with juvenile poly/oligoarticular arthritis on an outpatient basis — high-cost ("Comfort"); average cost ("Standard"); and low cost ("Economy") for a course of treatment for 1 month.

The developed brand portfolios and formulary lists were introduced into the activities of the Health Department of the Belgorod Region and the nurseries of the city of Belgorod, as evidenced by 8 acts of implementation.

CONCLUSION

1. Using the approaches of rational pharmaceutical management, a methodical approach was proposed to conduct a comprehensive pharmacoeconomic study of drug assistance to children simultaneously in outpatient and inpatient conditions, allowing to evaluate the continuity of treatment, the tendency of assortment formation to rationalize the subsequent development of restrictive drug lists. The approach involves the parallel implementation and comparative analysis of the following stages: The formation of an information base on drugs; structural analysis of the range of drugs; ABC analysis of the range; multidimensional examination of the range of drugs; the formation of restrictive lists of drugs for the treatment of children in outpatient and inpatient settings; regulatory cost analysis and determination of the drug budget of the inpatient department;

2. Conducting a comprehensive pharmacoeconomic study allows us to solve a number of issues: To carry out a comparative analysis of the range of drugs prescribed for outpatient and inpatient treatment, taking into account the sequence and continuity of treatment; to conduct a multidimensional examination of drugs with the involvement of specialists of different profiles (pharmaceutical specialists, doctors); and to involve in the examination of drugs high-skilled ambulatory and inpatient specialists to differentiate drugs according to the conditions of medical care; develop restrictive lists of drugs that best comply with the principles of rational pharmacotherapy in outpatient and inpatient settings.
3. In the framework of the methodological approach, we first developed a technology for multidimensional examination of the drug assortment, which implies a multi-stage, consistent evaluation of the drug assortment, which is carried out by pharmaceutical and medical specialists, including four steps: PE from the position of their characteristics, VEN-expertise of the drug assortment, analysis of compliance with consumer preferences, and evaluation of cost criteria;
4. We also carried out an approbation of the methodological approach in the course of optimization of drug assistance to children with JA in the outpatient and inpatient conditions of children's MOs in the Belgorod Region;
5. As a result of the study, we developed: Five indicative drug lists for treating children with arthritis in stationary conditions; three assortment portfolios of drug for the treatment of children with juvenile poly/oligoarticular arthritis on an outpatient basis.

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