Optimization of Pharmaceutical Care for Children with Joint Diseases

Irina V. Spichak, Yuliya S. Dereglazova,
Olesya G. Pankratova and Alyona S. Spichak
Belgorod State University
Pobedy St. 85, Belgorod, 308015, Russia
dereglazova@bsu.edu.ru

ABSTRACT
The article presents the results of optimization of pharmaceutical care (PC) for children with joint diseases (DJ) in conditions of inpatient and outpatient treatment, at the regional level, which allow to improve the quality of PC for children with DJ; to rationalize the doctors’ prescriptions; to determine the medicinal budget and to optimize the medical supply of children's medical organizations (MO). In addition, the practical significance of the study is in improving the quality of medical care in the medical organizations; ensuring the availability of medical care in the outpatient settings, by facilitating the selection of a set of drugs, in accordance with the possibilities of the family budget; rationalization of labor costs of specialists; ensuring satisfaction of patient with the quality of pharmaceutical care; increasing the responsibility of patients parents when using drugs at home, as well as ensuring timely reference to specialists; reducing the incidence of patients; reducing the period of staying in the conditions of inpatient treatment, etc.

Keywords: pharmaceutical care, medicinal preparations, joint diseases, children, complex pharmacoeconomic research, formulary lists, brand portfolios.

INTRODUCTION
At present, joint diseases in children, united in the group "juvenile arthritis" (JA), have a tendency of steady growth in the population of children and adolescents, that causes a high social and medical significance of the problem. The disease often tends to be chronic progressive, and it is also the cause of the development of childhood disability, which occurs during the first 10 years of illness in 50% of children with joint damages [1-6]. The pharmacotherapy of nosology is sequential. It is based on the long-term course of administration of a great number of medicinal products (M), outpatient and inpatient treatment, and therefore, the timeliness and completeness of pharmaceutical care is often the one of the leading factors in curing of sick child [4,7-10]. However, to date, there are some problems in providing PC for children with joint diseases in the medical organizations: a wide variety of medical organizations for treating DJ in the pharmaceutical market; difficulties in the choice of medicines by doctors for outpatient and inpatient treatment; the absence of formulary lists and brand portfolios of drugs for treatment of DJ in children in the conditions of hospital care and outpatient care (HC and PC); information deficit of medical and pharmaceutical experts in the questions of medicinal care for children with DJ, etc.

The solution of these problems is possible by the forming of complex approaches to optimizing pharmaceutical care for children with joint diseases, based on the system management,
pharmacoeconomics, as well as pharmaceutical information.

METHODOLOGY
The methods of logical, system, structural, graphic and content-analyzes; the methods of strategic management (STEEP- and SWOT-analysis); economic-mathematical methods (grouping, variational statistic, ranking, correlation-regression, value); sociological methods (expert assessments, questionnaires); computer-aided design, are used in the work.

MAIN PART
At the heart of comprehensive analysis of literature sources, the status and problems in providing of pharmaceutical care to children with joint diseases were studied. It was indicated high medical and social significance of juvenile arthritis, due to the increase in the incidence rate among the children's population of the Russian Federation, the tendency to chronic progressive course and the risk of early disability. It has been established, that the pharmacotherapy of children with this pathology is complex and involves the use of significant assortment of medicines, long-term, expensive treatment and rehabilitation. However, to date, having a large number of proposals of the pharmaceutical market, medical specialists are suffered from information deficit in the process of medicines prescription for the treatment of children with joint diseases in the conditions of hospital care and outpatient care; and pharmaceutical specialists have a lack of information in the field of pharmaceutical counseling. This is largely due to the lack of restrictive lists of medicines for treatment children with joint diseases. The solution of these problems is possible by the forming of complex approaches to optimization of PC for children with DJ, based on system management, pharmacoeconomics, as well as pharmaceutical information. The system of studies, aimed at optimizing pharmaceutical care for children with joint diseases has been developed, in order to provide an integrated approach to the solving of problems, on the basis of system analysis and targeted modeling.

The research system includes 3 blocks (Figure 1). The analysis of PC potential for children with joint diseases (based on the example of the Belgorod region) was carried out within the framework of the first block, in accordance with the developed research system. It includes 6 stages: pharmaceutical care analysis from the position of system management; the analysis of the macro-environment factors, affecting the pharmaceutical care of children; the analysis of the micro-environment factors, affecting the PC of children with joint diseases; the audit of the HC and PC internal environment in the field of pharmaceutical care for children with joint diseases; comprehensive assessment of macro- and microenvironment factors through the implementation of SWOT-analysis and compilation the matrix of opportunities and threats; definition of complex measures for optimization of pharmaceutical care for children with DJ in the region. In the analysis of pharmaceutical care from the position of system management, the main participants were identified: parents, doctors and pharmaceutical workers. In the framework of the macro-environment analysis, the socio-economic characteristic of the Belgorod Region was given; STEEP-analysis of environmental factors was carried out. The impact of environmental factors was estimated as average. In the course of the evaluation of microenvironment factors, marketing analysis of Russian and regional pharmaceutical markets of medicinal preparations for the treatment of DJ in children was carried out. So, in particular, the macrocontour of the Russian market of preparations for juvenile arthritis treatment includes 5 groups, according to the ATC-classification, 620 preparations, 14 international non-proprietary names (INN), 25 trade names (TN) of preparations. In this structure, anti-inflammatory and antirheumatic medicines are leading (89.0%), among them the leading position is occupied by acetic acid derivatives (92.8%), monocomponent composition (97.0%). Domestic medicinal preparations are dominated on the basis of production (60.0%), the company-manufacturer is “Ozon”, LLC (25.0%).
Solid pharmaceutical forms (50.7%), in particular, enteric-coated tablets (65.0%) are dominated in the structure of assortment.

The average index of the assortment renewal is 45.0%. The meso-contour of the regional pharmaceutical market of the Belgorod region was determined. It was established, that it entered the boundaries of the macrocontour, was similar in its parameters to the main parameters, and used the opportunities of the Russian market by 87.5%.

At the next stage, the sociological study of the services consumer - a child with joint disease - was carried out. Medico-social portraits of children with juvenile arthritis - patients of children's hospitals - were developed. So, in particular, the hospital patient is a boy (53.7%); at the age of 12 to 18 (35.6%); resident of the region (69.0%); living in a full family (78.0%); sent to a hospital from consultative polyclinic (66.2%); with clinical diagnosis "reactive arthritis" (63.8%); who was treated for an average of 14.5 days; having concomitant disease cardiopathy (33.6%).

In sociological survey of 60 parents of children with a joint diseases, the main consumer criteria for choosing medicines were identified, in the process of pharmacotherapy of children with joint diseases in outpatient settings: high pharmacotherapeutic efficacy (61.2%), safety (22.4%), price (7.5%), and easiness of use - dosage form (DF) and the frequency of admission (6%).

The next stage was a comprehensive SWOT-analysis. It has been established, that the PC potential for children with DJs in the Belgorod region is currently under moderate favorable conditions, which is largely due to the indirect influence of stress factors of the external environment. Among the main threats to the development of pharmaceutical care for children...
with joint diseases are the following: the difficulty of choosing of medicinal preparations by the inpatient and outpatient doctors, due to the lack of information for prescribing drugs, the absence of restrictive lists of medicinal preparations for the treatment of juvenile arthritis in medical organizations, the lack of interaction in the system: "pharmacist-patient (patient’s parent)"; the lack of preventive materials for children, etc. In order to solve the identified problems, the "Optimization Program of Pharmaceutical Care for Children with Joint Diseases in the Belgorod Region for 2016-2017" was developed. It includes 7 vectors of action: the rationalization of legal framework for the provision of pharmaceutical care for children with joint diseases; optimization of pharmacological support for children’s medical organizations; improvement of pharmaceutical information on prescription of medicines, etc. The methodical approach for a comprehensive pharmacoeconomic research of medicinal care for children, simultaneously in the outpatient and inpatient settings, was developed for the first time, aimed at the implementation of the second block of the research system. The advantages of this approach are the following: the possibility of studying the sequence and succession of treatment; identification of tendencies in the process of formation of medicines assortment and performance of comparative analysis; optimization the expert examination of drugs, due to a clear delineation of requirements for pharmacotherapy, depending on the conditions of medical care; and, as a consequence, the formation of the most rational restrictive lists of medicinal preparations. The methodological approach provides for the simultaneous and consistent implementation and comparative analysis of the research stages: the formation of the information base of medicinal preparations; structural analysis of medicines assortment; ABC-analysis of medicines assortment; multifaceted expertise of assortment; formation of the restrictive lists of medicines for the treatment of children in outpatient and inpatient settings; normative and cost analysis and determination of the medicinal budget of the hospital department. Within the framework of methodical approach, the technology for carrying out a multifaceted expertise of the medicines assortment was developed for the first time. It includes multi-stage sequential evaluation of the medicines assortment, conducted by pharmaceutical and medical specialists, according to a great number of criteria. The technology of multifaceted expertise of medicines assortment helps to optimize the selection of drugs in restrictive lists and provides for the implementation of the following actions: pharmaceutical evaluation of medicines from the position of their characteristics, VEN-expertise, analysis of conformity to consumer preferences, evaluation of cost criteria. At the first stage, pharmaceutical expertise (PE) of the medicinal preparations is implemented by highly competent pharmaceutical specialists (the representatives of the MO formulary committee). Pharmaceutical expertise includes: the analysis of medicines assortment characteristics; the selection of medicinal preparations, which maximally meet the requirements of the expertise; elimination of drugs, which have limitations to the prescription; and formation of summary analytical information about the assortment, with the purpose of medical experts training, for carrying out the subsequent VEN-expertise. The technology of pharmaceutical expertise includes sequential execution of the following stages: determination of criteria for pharmaceutical expertise of medicinal preparations assortment for specific conditions of the analysis; the analysis of the list of medicinal preparations characteristics, selection and justification of the choice of their use under specific research conditions; identification of barrier (restrictive) characteristics of medicines; removal from the expertise such medicines, which do not fully comply with the criteria; creation of information materials on the characteristics of medicinal preparations, for optimization of VEN-expertise of the medicines assortment by doctors. At the second stage, VEN-expertise of the medicines assortment is
carried out by highly qualified specialists in order to segment the assortment of medicines, according to the criteria optimality: "pharmacotherapeutic efficiency" - "safety", to justify inclusion of medicines in restrictive lists. The goal of the third stage is to analyze the medicines assortment for compliance with consumer preferences, that means an assessment of the correspondence of medicinal preparations characteristics to consumer criteria, identified during the sociological survey of services consumers. At the fourth and final stage, the cost criteria are evaluated by comparing the cost of medicinal preparations and the cost of treatment (according to the results of the ABC-analysis).

Methodical approach was applied in the course of comprehensive pharmaeconomic study of medicinal care for children with juvenile arthritis in outpatient and inpatient settings of children's hospitals in the Belgorod region.

At the initial stage of the study, it was conducted the content analysis of 900 case histories of children with juvenile arthritis - the patients of hospitals, and 86 outpatient cards - the patients of polyclinics. In the course of the analysis, two types of juvenile arthritis were diagnosed: juvenile chronic arthritis (JCA) and reactive arthritis (RA). As a result, further research in the inpatient setting was carried out for these nosological forms of juvenile arthritis.

An information array of was formed. It included 72 TN, 48 MNN, 2575 packages of pharmaceutical drugs for outpatient institutions, and 106 TN, 78 MNN and 1565 packages of drugs for hospitals.

The structure of the assortment and consumption of drugs for the treatment of these nosologies were defined. They are mainly formed from 6 groups, according to the ATC-classification. Among them the following are dominated: "Remedies, affecting the digestive system and metabolism"; "Remedies, affecting the musculoskeletal system"; "Hormones of systemic action", etc.

Further, the analysis was made for the compliance of the outpatient assortment with consumer characteristics. With the help of medical experts, inconsistencies in the use of medicines for pharmacotherapeutic efficacy (25.7%); security (67%); easiness of application (37.7%) were defined. The analysis for the criterion "affordable price" showed, that every third prescribed drug is expensive. Then, with the help of the ABC-analysis, the medicines assortment was segmented according to the frequency of prescription and the costs for the treatment course. Thus, it was found out, that in the inpatient setting, the high consumption group "A" for the treatment of juvenile arthritis occupied 22.05% of the total assortment volume. It was formed with preparations, having the range of assignment coefficient (Ca) from 17.4 to 2.3 and included 15 preparations - Diclofenac, Meloksikam, Metipred, Sulfasalazine, etc. The average consumption group "B" (22%) consisted of 15 medicinal preparations with a range of Ca from 2.1 to 0.3 - Diprospan, Voltaren, Methotrexate, etc. Low consumption group "C" (54.4%) included 38 preparations with Ca from 0.3 and lower - Nexium, Movalis, Indomethacin, and others.

At the next stage, the technology of multifaceted examination of the medicines assortment was used for the first time. At the first stage, the inpatient and outpatient assortment was analyzed in detail - 80 and 72 M for the treatment of juvenile arthritis, respectively, from the position of their characteristics. For the examination, 19 M characteristics were defined, while only 57% were reflected in the "Instructions for use".

In the course of the analysis, in particular, it was found that more than 90% of all medicines do not have a child dosage and only 30% of them have the possibility of dividing, with minimizing the risk to the child's body. Only 6% of drugs have a children's dosage form. It was revealed, that 67% of medicines from outpatient assortment were prescribed. According to the results of pharmaceutical expertise, about 20% of medicines were removed from the assortment, having restrictions for use. Analytical information materials on the characteristics of preparations of the selected assortment, for the training of medical experts, for conducting VEN- expertise were also formed.
At the next stage, the VEN-expertise was carried out, for the purpose of segmenting the medicines for the treatment of juvenile arthritis, according to the rate of clinical relevance, economic feasibility and compliance with consumer criteria. 47 highly qualified doctors-experts, the specialists of 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 average weighted values, the assortment of medicines was divided into main medicines (V), important, or substitute drugs (E) and non-essential (impractical) (N) drugs. So, in particular, the group "V" includes 20 preparations: Movalis (tablets), Voltaren (solution for injection), etc.; the group "E" includes 21 preparations: Dolgit (gel), Diprospan (solution for injection) and others; the group "N" includes 36 drugs: Magnesium orotate (tablets), Metamizol sodium (solution for injection), etc.

At the final stage, 5 preliminary formulary lists of medicinal preparations have been developed for the treatment of children with RA, associated by urogenital, enterogenic and nasopharyngeal infections; polyarticular and oligoarticular arthritis in the inpatient setting. Three brand portfolios of medicines for the treatment of children with juvenile poly-/ oligoarticular arthritis in outpatient setting. Three brand portfolios of medicines for the treatment of children with juvenile poly-/ oligoarticular arthritis in outpatient setting - high-cost ("Comfort"); medium-cost ("Standard") and low-cost ("Economy") for a course of 1 month treatment.

The fourth and final block of the study is devoted to the formation of pharmaceutical informational and methodological materials for all participants of the PC: methodical recommendations on optimization of pharmaceutical counseling by drugstores, about the preparations for treatment of joint diseases in children; methodical recommendations on the rationalization of prescriptions and the choice of medicines by doctors for the treatment of a child with a joint diseases in a hospital and polyclinic; pharmaco-economic maps and pharmacotherapeutic stands for parents of children with joint diseases, providing the possibility of self-selection of medicines complex, based on its price availability; valeological video materials for informing children about the problem of joint diseases.

CONCLUSION
The significance of the study is to develop methodological approaches to the complex pharmaco-economic study of medicinal care for children, in the conditions of outpatient and inpatient treatment; the technologies of multifaceted expertise of preparations assortment, with participation of pharmaceutical experts and doctors.

DEDUCTIONS
1. The system of studies on optimization of PC for children with DJ has been applied;
2. Marketing analysis of the Russian and regional pharmaceutical markets of preparations, for the treatment of DJ in children was carried out;
3. Sociological study of schoolchildren in Belgorod, parents of children with DJ, pediatricians and children's rheumatologists was performed;
4. Comprehensive pharmaco-economic study of medicinal care for children with juvenile arthritis has been implemented;
5. Preliminary formulary lists of preparations for the treatment of juvenile arthritis in hospitals and brand portfolios of drugs for the treatment of juvenile arthritis in outpatient setting were formed;
6. Pharmaceutical information-methodological materials for participants of PC (pharmaceutical workers, doctors-specialists, parents and children with joint diseases) were developed.

REFERENCES