

Medico-social Rationale for Adaptation of Regional Drug Supply Systems to Personalized Pharmaceutical Care for Persons of Different Ages

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Abstract

In this study, we identified indicators of the state of personalized pharmaceutical care for target population groups at the regional level, in a model region, with the aim to develop a differentiated approach to such care. The rationale for the choice of Moscow Region as a model region is based on its specific socioeconomic indicators and a comparison of these with respective average Russian values. A need was shown to modernize patient-oriented pharmaceutical care, especially for certain population groups, such as children, women of working age (mothers), and the elderly. Content analysis of the legislation and regulatory documents applicable to public health care at the Federal and regional levels allowed to demonstrate their shortcomings in relation to the organization of drug supply for target population groups. A situation analysis of the state of drug supply for Moscow Region outpatients and inpatients revealed a room for improvement. Analysis and synthesis of data obtained after the application of statistical tests allowed structuring of indicators that will be used in the development of key elements of a conceptual model of rational drug supply within the framework of personalized health care for the population groups requiring a differentiated approach the most (i.e., target groups).

Keywords: Personalized Health Care, Patient-Oriented Pharmaceutical Care, Regional Drug Supply Systems, Medico-Social Indicators, Conceptual Modeling, Target Population Groups.

Introduction

Personalized medicine is a relatively new field emerging at the current stage of public health care development. The development of personalized medicinal products is known to require a long time and considerable resources. A personified approach to treatment means that a rather large number of hereditary and acquired factors have to be taken into consideration in each individual case, and the health status of patients in different age groups is of great importance [1, 23].

The top national priorities of the Russian Federation, which largely determine the country's future and its socioeconomic development and security, include safe and protected childhood; protection of the health of women of reproductive potential; and prolongation of the active period of life while improving its quality [2-4]. Timely detection of diseases, prophylaxis, diagnosis, treatment, and rehabilitation in each region of the Russian Federation also have special medical and socioeconomic importance [5-8, 24]. The situation requires active use of the opportunities of personalized medicine, which allows more accurate prediction of the risks of certain

disorders, prophylactic measures, and selection of rational pharmacological therapy. Many regional health care authorities are actively involved in the development and implementation of a medico-social concept focusing on improvement of the quality of life in all age groups of the general population. Guidelines based on results of research studies can significantly contribute to boosting the efficacy of undertaken measures and making them less time-consuming. From this standpoint, development and implementation of a methodological basis for a differentiated approach to providing pharmaceutical care at the regional level to children, women of reproductive age, including pregnant and breastfeeding women, as well as the elderly, appear to be of scientific and practical interest.

Study goal: to identify drug supply availability indicators in target population groups through analysis of the current legislation and an experimental study in order to develop a differentiated approach to providing pharmaceutical care at the regional level.

The following objectives had to be met to achieve the study goal:

1) To justify the choice of Moscow Region as a model region in this study;

2) To analyze the characteristic features of the model region;

3) To study the legislation and regulatory documents applicable to public health care and drug supply in different age groups of the Russian population;

4) To perform a situation analysis of the state of drug supply for outpatients and inpatients in the model region;

5) To find resources for the implementation of a differentiated approach to the provision of pharmaceutical care in target population groups using the obtained list of care availability indicators.

Materials and Methods

The study methods were based on the cornerstones of the current management theory, the fundamentals of the legal regulation of health care and the circulation of medicinal products, the principles of personalized medicine, and the publications of leading researchers in pharmaceutical management.

Source data included legislative and regulatory documents of the Russian Federation, Central Federal District (CFD), and Moscow Region; information from the regional State Statistical Service (Mosoblstat), data reported by the Federal Service for Surveillance in Healthcare, materials of sociological studies and experimental data.

The study objects were medical and pharmaceutical organizations of Moscow Region, pharmaceutical and health care professionals employed by them; legislative and regulatory documents in the field of Russian health care and the public drug supply system (twenty regulatory documents published from 1994 to 2017); Rosstat (Federal State Statistics Service) materials; regional demographic and morbidity statistics; data on staff with medical and pharmaceutical education employed by health care and pharmaceutical organizations, on the structure of budget spending and the MMI (Mandatory Medical Insurance) budget allocated to drug supply (for 2010-2018); reports of the Ministry of Health of Moscow Region (for 2010-2017); and data copied from reports of the aforementioned organizations.

Economic-statistical, sociological, and graphical research methods were employed in the study; systemic, situational, historic, retrospective, and content analyses were carried out.

Results and Discussion

In accordance with the employed study algorithm, at the first stage we detected and analyzed the

characteristic features of Moscow Region in order to justify its choice as a model region. Analysis of data obtained from the state statistical bodies, regional demographic and morbidity statistics; reports of the Ministry of Health of Moscow Region and data copied from reports of the aforementioned organizations produced the following geographical, demographic, and medico-social characteristics of the model region.

Moscow Region has a characteristic geographical location, being one of the largest Russian Federation Subjects included in the CFD; it borders seven other Russian regions and a city of federal importance, Moscow.

The area of the Region is 44,329 km², with a mean population density of 167.46 people/km², makes it the largest Russian region (with the exception of the cities of Moscow and Saint Petersburg), which is due to a high proportion of town population. The districts closest to Moscow (Lyuberetsky, Balashikhinsky, Krasnogorsky, and some others) have the highest population density. The total population is 7,508,764 people, as of 1 January 2018.

The overall structure of the Region's population is presented in table 1. Moscow Region has no capital city. It consists of 29 districts and 39 town districts [9].

A specific feature of the model region is a significant scale of workforce commuting (Table 2) [9-11, 25]. A significant proportion of the Region's economically active population find a job and obtain medical and pharmaceutical care in Moscow. Therefore, drug supply in the Region is provided to the "constant", non-commuting part of the population (mainly children and the elderly).

Moscow's location and the availability of federal clinics both in Moscow and in the Region that have always been accessible mean that health centres have developed predominantly at the local and district levels, including central district hospitals. The main types of specialized care are provided in Moscow, because Moscow Region lacks its own inpatient facilities, having none in rheumatology or immunology.

As the data included in Tables 1 and 2 show, the demographic structure of the model region's population is characterized by a predominance of town population, women, and people of working age; the Region has the highest migration flows within Russia's CFD.

Table-1: The demographic structure of Moscow Region's population

| Year | Demographics: population | | | | | | Older than working age, % |
|------|--------------------------|---------|--------|----------|-----------------------------|----------------|---------------------------|
| | Urban % | Rural % | Male % | Female % | Younger than working age, % | Working age, % | |
| 2018 | 81.7 | 18.3 | 46.2 | 53.8 | 17.5 | 57.6 | 24.9 |

Table-2: Comparison of Russian Federation Subjects in the CFD by the proportion of population moving to work in other Regions

| Central Federal District | Proportion of people leaving, % | Central Federal District | Proportion of people leaving, % |
|--------------------------|---------------------------------|--------------------------|---------------------------------|
| Belgorod Region | 4.1 | Moscow | 21.8 |
| Bryansk Region | 3.9 | Oryol Region | 2.0 |
| Vladimir Region | 3.4 | Ryazan Region | 3.3 |
| Voronezh Region | 6.6 | Smolensk Region | 3.6 |
| Ivanovo Region | 3.0 | Tambov Region | 4.0 |
| Kaluga Region | 3.3 | Tver Region | 4.1 |
| Kostroma Region | 2.7 | Tula Region | 4.0 |
| Kursk Region | 3.4 | Yaroslavl Region | 3.5 |
| Lipetsk Region | 3.5 | Moscow | 19.8 |
| | | Total | 100 |

The medico-social specifics of the Region are also reflected by the indicators presented in Table 3.

Table-3: Individual medico-social indicators of the model region

| No. | Indicator, 2017 | Moscow Region | Russian Federation |
|-----|--|---------------|--------------------|
| 1 | Infant mortality (per 1000 live births) | 4.1 | 5.2 |
| 2 | Birth rate (per 1000 population) | 12.0 | 11.5 |
| 3 | All-cause mortality rate (per 1000 population) | 12.4 | 12.4 |
| 5 | Maternal mortality ratio (per 100,000 live births) | 5.4 | 7.3 |

The pharmaceutical care availability level can be assessed using various criteria, including the infrastructure of the pharmaceutical market. In the reported study, the pharmaceutical care availability level was assessed by an organizational criterion, i.e., availability of pharmacies preparing drugs. To do this, we selected pharmacies preparing drugs using data from the Unified License Registry of the Federal Service for Surveillance in Health Care (Roszdravnadzor) [12].

The extremely low number of drug-producing pharmacies has a negative effect on the introduction of a personalized approach to drug supply for target population groups, because a physician is unable to select the drug composition and strength on an individual basis, taking into consideration the patient's age, weight, and comorbidities; the intervals between drug prescription, production, and use cannot be reduced; the use of preservatives cannot be avoided since the formulation has to be stable [13-15].

Since Moscow Region's population is dominated by women, primarily of childbearing age,

organization of drug supply in this population requires special attention. The limited scope of drugs approved for use during pregnancy and of required dosage forms precludes full-scale drug supply for these patients. For instance, thyroid diseases affect female health with regard to the conception potential, the course of pregnancy, threatening miscarriage, etc. A personalized approach to pharmaceutical care in this population will allow to avoid the risks and preclude undesirable outcomes [16,17].

A content analysis of the legislation and regulatory documents applicable to public health care at the Federal and regional levels was carried out at the next stage of the study in accordance with the employed algorithm. For this purpose, we selected, analyzed, and structured, according to a number of criteria, the documents that define the procedure of providing medical, pharmaceutical, social care and drug supply for the target population groups (Table 4).

Table-4: The structure of the legislative and regulatory documents applicable to the organization of drug supply for children, women of working age (mothers), elderly people.

| | Children's health protection | Maternal health protection | Elderly people's health protection |
|------------------------------------|---|----------------------------|------------------------------------|
| Legislative or regulatory document | Constitution of the Russian Federation | | |
| | Federal Law No. 124-ФЗ "On the basic guarantees of children's rights in the Russian Federation" dated 24 July 1998 | | |
| | Federal Law No. 323-ФЗ "On the fundamentals of public health care in the Russian Federation" dated 21 November 2011 | | |
| | Order No. 366H of the Ministry of Health and Social Development of the Russian Federation "On approval of the procedure of providing paediatric care" dated 16 April 2012 | | |
| | Order No. 328 "On approval of the procedure of providing the social services to individual population groups" dated 29 December 2004 | | |
| | Decree No. 890 of the Government of the Russian Federation "On the state support of the development of medical industry and improvement of the supply of drugs and medical devices to the population and health centres" dated 30 July 1994 | | |
| | Federal Law No. 256 "On additional measures of state support for families with children" dated 29 December 2006 | | |
| | Federal Law No. 418 "On monthly payments for families with children" dated 28 December 2017 | | |
| | "Plan of measures to implement the basic provisions of the State Youth Policy of the Russian Federation until 2025" approved by Order No. 2403-P of the Government of the Russian Federation dated 29 November 2014 | | |
| | Decree No. 1351 of the President of the Russian Federation "On approval of the concept of the demographic policy of the Russian Federation until 2025" | | |
| | Federal Law No. 178-ФЗ "On state social assistance" dated 17 July 1999 | | |
| | Decree No. 663/38 of the Government of Moscow Region "On approval of the State Programme of Moscow Region 'Podmoskovye Healthcare' for the period 2014-2020" dated 23 August 2013 (version dated 29 November 2017) | | |
| | Decree No. 1640 of the Government of the Russian Federation "On approval of the State Programme of the Russian Federation 'Healthcare Development'" dated 26 December 2017 | | |

These data show that children, mothers, and families, as well as the elderly, are protected by the state. It should be mentioned at the same time that the number of regulatory documents in this field is small (about 13). We identified the following issues: an extremely low proportion of regional legislative documents regulating the drug supply procedure (only one legislative document), as compared with the Federal level. There are no legislative documents regulating the process of drug supply for elderly patients, with the exception of patients suffering from socially important diseases and entitled to receive drugs free of charge.

A situation analysis of the state of drug supply for Moscow Region outpatients and inpatients was performed from the personalized approach perspective at the next stage of the study in accordance with the employed algorithm.

It has been demonstrated that optimization of the available range of products is particularly important for outpatients. Moscow Region has a rather large number of network pharmacies whose stock lists are approved by their central offices, which has a negative

impact on the availability of drugs needed to treat rare diseases. At the same time, the feasibility of a patient-oriented approach in pharmaceutical care has been increased by the opportunities that have arisen in recent years with drug pre-orders and subsequent purchases following delivery to the consumer's pharmacy of choice.

The study revealed that there are no guidelines for pharmacy employees with regard to pharmaceutical care for the target population groups, which would be indispensable and extremely valuable for the pharmaceutical advice that patients receive from pharmacy employees.

The situation analysis of the drug supply for inpatients revealed a low proportion of pharmacy-prepared formulations, which counteracts with the implementation of a personalized approach to medical and pharmaceutical care.

Afterwards, we analyzed the range of products available for paediatric and elderly patients [18, 19]. It was revealed that the Russian National Paediatric Formulary includes 517 INNs or 3133 TNs (without

division by pharmaceutical form, formulation, or presentation), and 140 of these drugs are not manufactured in the Russian Federation (27.1%), while the State Drug Registry contains no dosage forms for elderly patients at all [20-22].

Summarizing results obtained at all stages of the study, we were able to compile a list of major indicators showing the level of patient-oriented pharmaceutical care at the regional level:

1. Low proportion of drugs for children registered in the Russian Federation.
2. Absence of drugs to be used exclusively by elderly patients.
3. Insufficient amount of drug names approved for use during pregnancy.
4. Extremely small number of guidelines for pharmaceutical care in pregnant women, children, and the elderly.
5. Narrow range of drugs available in pharmacies for treatment of rare diseases and lack of interest of pharmacy personnel in individual drug ordering.
6. Poor development of the network of health centres specializing in providing care to the target population groups.
7. Absence of legislative and regulatory documents defining the contents and principles of personalized pharmaceutical care.
8. Decreasing number of pharmacies preparing medicinal products for human use.

The presented indicator list demonstrates the additional resources of patient-oriented pharmaceutical care for the target population groups and forms the basis for developing a Concept of this type of care at the regional level. Focusing attention on personalized care in the target population groups can help improve adherence to prevention and treatment, thus having a significant effect on the quality of life of people living in the respective Region.

In conclusion, the study of a model region provided medico-social rationale for adaptation of regional drug supply systems to personalized medical and pharmaceutical care for certain population groups, such as children, women of working age (mothers), and the elderly.

Conclusion

1. As part of the reported study, the choice of Moscow Region as a model region was justified based on the geographical, medico-social, demographic, organizational, institutional specifics and the current All-Russian trends reflected by the Region.
2. The current issues in Moscow Region's drug supply system were characterized; drug supply

availability indicators in target population groups were identified in order to develop a differentiated approach to providing pharmaceutical care at the regional level.

3. The study revealed some outpatient and inpatient drug supply problems that require a solution from personalized pharmaceutical care, including a return to pharmacy formulation and broadening the range of dosage forms available for pregnant women, children, elderly patients, as well as preparation of essential guidelines to allow appropriate counseling for drug consumers.

4. The proposed indicator list demonstrates the additional resources of patient-oriented pharmaceutical care for the target population groups, and will form the basis for preparing a Concept of development of this type of care at the regional level.

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