

The Pharmaceutical Provision of Patients with Cardiovascular Diseases in the Republic of Dagestan

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ABSTRACT

Drug coverage is a part of medical care. The purpose of this article is to examine the problems of drug provision and a development of measures to improve accessibility of medicines for patients with CVD in the Republic of Dagestan. The analysis of indicators of morbidity and mortality from cardiovascular diseases in the Republic of Dagestan allowed the author to conclude that activities implemented in the framework of socially significant target program "Improving medical care for patients with vascular diseases in the Republic of Dagestan for 2012 - 2014 years", have led to reduce mortality from circulatory diseases in the population of the region. At the same time, the average duration of life after the detection of CHD remains low, which suggests the lack of effectiveness of the system of rendering medical aid to patients with CVD. A mandatory component of the health system, a member of the program of state guarantees is the medication provision of the population. The study of the level and quality of provision of medicines of patients in the Republic of Dagestan gives the basis to speak about the low level of availability of essential drugs for patients with the most severe pathology of CVD. In the framework of this article were identified the main systemic problems of drug supply of the population with circulatory diseases in the Republic of Dagestan, demanding the immediate solution. These include: lack of financial security TPSG, a lack of effective system of public procurement of medicines, low availability of medications for CVD patients living in rural areas.

Key words: Cardiovascular disease (CVD), diseases of the circulatory system (DCS), the territorial program of state guarantees (TPSG), medications (drugs), drug supply, availability of drugs, quality of medical care, medicines.

INTRODUCTION

Among the most common and dangerous diseases of modern times are cardiovascular disease (CVD). In this group of disease includes: ischaemic heart disease; disease of blood vessels of the brain; peripheral arterial disease; rheumatic heart disease - damage to the heart muscle; congenital heart disease; deep vein thrombosis and pulmonary embolism. 2015 year is declared in Russia the Year of combating cardiovascular diseases, which are the main cause of mortality today¹. Mortality from cardiovascular diseases in Russia is 2.9 times higher than the rate of mortality from cancer. Therefore, the provision of timely and

quality medical aid to patients with vascular diseases and deaths from such diseases are now a priority.

For people suffering from various cardiovascular diseases, drugs for the heart are vital. They take them not only for treatment but also as prophylaxis, to maintain their body in a normal healthy rhythm².

Problems of maintenance drugs are associated with a constitutional right to health, which includes the development of additional measures for safety of citizens at carrying out of clinical trials, the establishment of barriers from the circulation of

counterfeit drugs, implementation of measures for safe use of pharmaceuticals and improving the quality of medical activities.

The modern drugs are able to normalize the human body by normalizing, for example, blood pressure. Cardiologists argue that people suffering from heart disease, according to a specific schedule and in appropriate quantity should take the prescribed medications regularly. Abruptly discontinuing medication can have a detrimental effect on health and cause a sharp jump in blood pressure.

Therefore, one of the most important tasks of governments is the provision of vital drugs, increasing their availability for patients with cardiovascular diseases.

However, in many regions of the Russian Federation the problem of ensuring the quality and affordability of medications (late appointment a free for drugs, insufficient number of drugs for beneficiaries and pharmacies serving them) do not lose their relevance.

Particularly acute issues of providing drugs have the regions with underdeveloped economies. One such region is the Republic of Dagestan. The main problems with the drug provision of patients with CVD in the Republic of Dagestan are short of budget financing, deficiencies in management, requirements planning, rational distribution of medicines, as well as insufficient control over the quality and safety of the medicinal help to the population of the Republic.

METHODOLOGY

The purpose of this study is to develop recommendations on drug provision of the population of the Republic of Dagestan with the current trends.

To achieve this objective it is necessary to undertake the following tasks:

- to examine the dynamics of morbidity and mortality from CVD in the population of the Republic of Dagestan;
- to analyze the current state of drug supply in

the region;

- to identify problems and to develop practical recommendations on improvement of the mechanism of provision of medicines of the population of the Republic of Dagestan.

This work is based on the methodological approaches, providing a systematic study of the challenges of meeting the needs of the population with CVD in accessible, quality and effective medicines.

This article used a variety of methods of system analysis of complex socio-economic objects, including statistical and comparative analysis, normative and graphical methods that allow to comprehensively conduct research.

The information base of the research is normative-legal acts and analytical materials of the Ministry of health of the Russian Federation and the Republic of Dagestan, statistical data of Federal state statistics service of the Russian Federation and Dagestanstat.

Morbidity and mortality from CVD in the population of the Republic of Dagestan

In the Republic of Dagestan, as in the whole of the Russian Federation, cardiovascular disease (CVD) remain the leading cause of disability and premature death.

At the same time, the prevalence of diseases of the circulatory system (CVD) in the region remains one of the lowest among the subjects of North Caucasus Federal district and the Russian Federation as a whole (figure 1).

In four years, registered an increase of 7.35% of newly diagnosed patients with CVD: 68 thousand people in 2010 to 73 thousand people in 2013. The incidence of CVD among children has increased by 1.3 thousand people, i.e. by 23.2%. This dynamics is observed as a result of the Dagestan medical examination of the adult population, thereby improving the detection of heart diseases at earlier stages.

Diseases of the heart and blood vessels in the Republic of Dagestan, as elsewhere in the

world, are on the first place in structure of causes of death. At the same time, in recent years due to the ongoing events in the Republic there is a decrease in the level of mortality from circulatory diseases (table 1).

Mortality from circulatory diseases in the Republic of Dagestan for 4 years decreased by 15.9%. When compared with mortality at working age in Russia and the North Caucasus Federal district in Dagestan it is almost 3 times lower than the national average and 1.9 times less than in the North Caucasus Federal district.

The effectiveness of the organization and delivery of health care to patients with cardiovascular diseases in the territory of the Republic of Dagestan aim of the Republican target program “Improving medical care for patients with vascular diseases in the Republic of Dagestan for 2012 - 2014 years”⁵.

Activities undertaken in the framework of the socially important programs, have reduced mortality from diseases of the circulatory system of the population.

However, it should be noted that official medical statistics do not reflect the true situation with the morbidity of the population. For example, the results of research of the National Institute of

public health named after N. A. Semashko, held in the framework of the WHO project, have shown that the real prevalence of arterial hypertension in 3 times exceeds the indicator of official statistics. The average duration of life in our country after the detection of ischemic heart disease and cerebrovascular diseases in men 10 years, in women – about 12 years, and 18.4% of patients, i.e. almost one in five who have the disease of the circulatory system, die within a year of onset⁶.

These negative trends suggest the failure of public policy measures aimed at reducing the impact of negative factors on the health of the population and the low efficiency of system of medical care, leading to increased dissatisfaction of patients with CVD.

The legal basis for the medical provision of population of the Russian Federation

Integral part of medical care is the provision of medicines. In the Russian Federation the unified state policy in the field of provision of medicines citizens throughout the country.

Drug coverage is a mandatory component of the health system and is also included in the program of state guarantees. System of drug supply of the Russian Federation consists of three segments: retail (63%), reduced (21%) and hospital (16%)⁷. The retail segment is financed by own funds

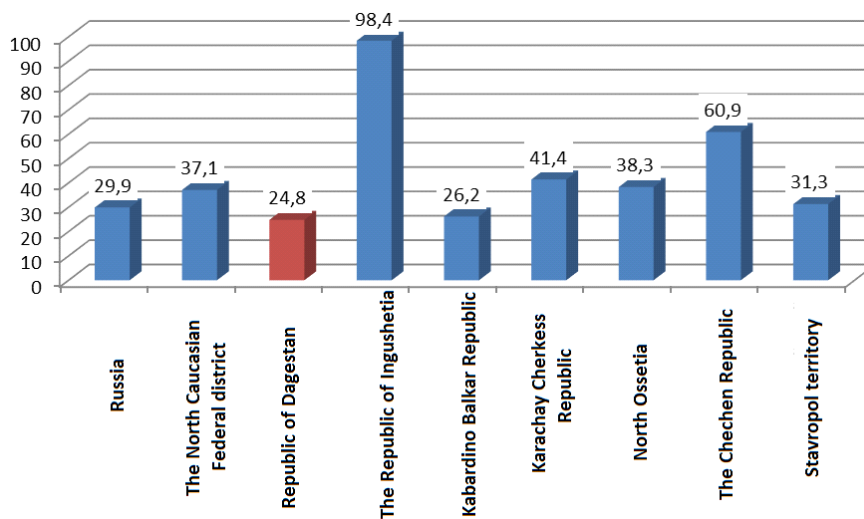


Fig. 1: The prevalence of CVD in the subjects of the North Caucasus Federal district and the average for the Russian Federation (data of 2013), cases on 1 thousand of population³

of patients, and the grace hospital at the expense of state funds. Hospital segment (provision of medicines in a hospital) is divided into the provision of medicines within the program and outside the MMI (mandatory medical insurance) program MMI (PSG – program of state guarantee) and is financed mainly at the expense of the mandatory medical insurance Fund.

The organization provide various categories of citizens drugs are regulated by the Federal law of 21 November 2011 No. 323-FL (edition of 28.12.2013) "About bases of health protection of citizens in the Russian Federation"⁸.

The main law regulating the Russian Federation, the circulation of medicines is Federal law of 12.04.2010 1 61-FL "On circulation of medicines"⁹. According to article 9 of this law, the state control (supervision) in the sphere of circulation of medicines includes:

- 1) licensing control in the field of production of medicines and pharmaceutical activities (carried out by the Ministry of industry and trade of the Russian Federation);
- 2) Federal state supervision in the field of medicines.

In 2014, were enacted several pieces of legislation that made significant changes in the field of drugs and introduced the application of measures administrative and criminal exposure for violation of its requirements. Strengthened criminal and administrative liability for import, manufacture and

sale of forged, counterfeit, substandard and unregistered medicines¹⁰.

On the basis of the Federal laws were accepted and began working many normative-legal acts at the Federal level. Among governmental acts can be mentioned, in particular the Resolution of the Government of the Russian Federation of 15 April 2014 N 294 approved the program of state guarantees of free rendering to citizens of medical care ¹¹. In this document was stated, in accordance with what document citizens are provided with medicines, and describes the sources of payment of various drugs. The state guarantees free drugs at the expense of funds of the Federal budget, means of budgets of subjects of the Russian Federation and local budgets and extrabudgetary sources.

According to Russian law, the procedure and scope of provision of free medical care approved annually by the subjects of the Russian Federation in the framework of Territorial programs of state guarantees (TPSG). Territorial program of state guarantees of free rendering to citizens of medical aid in the Republic of Dagestan for 2014 and the planning period of 2015 and 2016 defines the standards of volume and cost, the per capita norms of financial security, as well as the procedure for the formation and structure of tariffs for medical aid.

In accordance with Federal law No. 323-FL of 21.11.2011 "On fundamentals of protection of

Table 1: Indicators of population mortality from circulatory diseases (cases per 100 thousand population)⁴

Index	2010 year	2011 year	2012 year	2013 year	Change	
					+/-	%
In Russia	805,9	753	737,1	698,1	-107,8	-13,4%
NKFD	486,9	464,4	460,4	449,5	-37,4	-7,7%
Republic of Dagestan	278,3	256,7	239,4	234,1	-44,2	-15,9%
Republic of Ingushetia	230,3	188,2	198,9	184,5	-45,8	-19,9%
Kabardino Balkar Republic	571,3	568,5	545,4	552,8	-18,5	-3,2%
Karachay Cherkess Republic	611,8	600,0	583,6	567,1	-44,7	-7,3%
Republic of North Ossetia-Alania	697,8	682,4	689,8	684,1	-13,7	-2,0%
The Chechen Republic	334,9	274,6	288,0	262,7	-72,2	-21,6%
Stavropol territory	714,3	701,1	709,9	698,5	-15,8	-2,2%

citizens in the Russian Federation¹² and Territorial program of state guarantees of the Republic of Dagestan, financial provision of pharmaceutical care to the citizens within the list of vital and essential drugs (VED) is carried out by Territorial Fund of compulsory medical insurance of the Republic of Dagestan. Funding is provided in accordance with the basic program of compulsory medical insurance and the healthcare modernisation programme, under tariffs approved by the basic and additional tariff agreements. The financing of the territorial CMI program at the expense of tax revenues and insurance contributions of employers (12%), insurance contributions for mandatory medical insurance of unemployed population (27%), funds of the Federal mandatory medical insurance Fund (58,9%), and miscellaneous income (2%).

Speaking on state guarantees regarding provision of medicines free of charge to all citizens of the Republic of Dagestan drugs are provided

only in the conditions of hospitalization (including day hospital) in accordance with approved standards of medical care and essential drugs List. Free outpatient drugs are provided only some (privileged) category of citizens within the state programs.

Current status of drug supply patients with CVD in the Republic of Dagestan

Drug provision of specialized health facilities in the territory of the Republic of Dagestan and unified on the basis of centralized procurement according to their demands and distribution of drugs procured under the targeted programmes. Policies of drug supply in areas of specialized services are formed by the head lead agencies.

As of 1 January 2015 in the implementation of the programme of mandatory medical insurance on the territory of the Republic of Dagestan involved 203 state medical institutions and medical organizations and 15 other form of

Table 2: Indicators of certain categories of citizens with medicines support in 2011-2014

Indicator	2011 year	2012 year	2013 year	2014 year
The number of beneficiaries, retained the right to social services (SS), pers.	33251	30096	30024	48054
Drug supply volume, thousand rubles	405333,1	415839,7	337365,1	430324
Number written out preferential recipes.	289524	222450	142 558	102498
The volume of the handled preferential recipes, thousand rubles.	405333,1	415839,7	253239,9	341757,4
Registered recipes on the delayed service	0	0	0	0

Table 3: Dynamics of the average cost of a prescription and the average per capita income of the population of the Republic of Dagestan in the years 2011-2014

Indicator	2011 year	2012 year	2013 year	2014 year
Per capita monetary income of population (monthly), roubles	18278,1	20729,9	21716,5	23400,5
Increase/decrease of average population incomes, % to the previous year	116,6%	113,4%	104,8%	107,8%
The average size of the appointed monthly pensions, rubles	6336,5	7050	7793,5	8530,8
Increase/decrease in the average size of the appointed monthly pensions, % to previous year	108,6%	111,3%	110,5%	109,5%
Maximum average cost of a prescription on the RD, in rub.	2217	1869	1776,3	3334,2
The rate of increase/decrease of the maximum of the average cost of a prescription in RD, %	127,3%	84,3%	95,0%	187,7%

ownership [13]. The number of the beneficiaries amounted for 48054 of people, an increase compared to the previous year on 18030 of people, or on 60%.

According to Roszdravnadzor in the Republic of Dagestan in 2014 delivered medicines worth 430324,4 thousand rubles, which is 27.6% higher than the last year (table 2) [14]. In the framework of preferential drug provision were prescribed 102498 recipes (in 2013 - 142558), (according to the monitoring the implementation of the program that provides the necessary drugs (PND) of the Ministry of health of the Republic of Dagestan were served all the recipes 100%) in the amount of 341 thousand rubles 757,4. The balance at 1 January 2014 – 85573,41 thousand.

The main indicator of the quality and timeliness of the medicinal help to preferential categories of citizens is the number of recipes that are on a delayed provision in pharmacies. During the period under review the registered recipes on deferred maintenance and not served recipes in the Republic of Dagestan are absent.

During the last four years the maximum average cost of a prescription for the Republic of Dagestan has risen for nearly 50.4%: from 2217 rubles in 2011, up to 3334,2 rubles in 2014. According to this indicator among the constituent entities of the Russian Federation the Republic of Dagestan is in the last place (in Russia as a whole the figure is 945 rubles) [15].

In 2012-2013 in the Republic of Dagestan there was a decline in the average value of prescription – the reducing of the recipes cost (in 2012 – 1869 rubles, in 2013 – 1776,3 rubles). In 2014 there was a significant increase in average cost per prescription (+15578,9 rubles, i.e., to 187.7% compared to the previous year). In 2014, the average income of the population has only increased 107.8%, and the average size of the appointed pensions - on to 109.5% (table 3).

According to the results of sociological research of medical support for patients with cardiovascular diseases, more than 60% of

cardiologists see the key to success in the treatment in a regular intake of necessary drugs [16].

However, currently the purchase of expensive drugs necessary for treatment of patients with the most severe CVD pathology (e.g., acute myocardial infarction) for the majority of the population of the Republic, and especially to those over working age, mostly not possible. Thus, the average size of the appointed monthly pensions in the Republic of Dagestan in 2014 amounted to 8530,8 rubles at subsistence level for pensioners 6640,0 rubles [17]. The cost of the necessary drugs for the treatment of patients with acute myocardial infarction in some cases is close to the same amount.

Thus, patients with myocardial infarction do not always receive the necessary treatment and even in the hospital, these patients receive only medications that are in the approved list. After discharge from hospital patients do not get free treatment.

The problems of drug provision of patients with CVD in the Republic of Dagestan

The most important quantitative indicator to analyze the completeness and quality of implementation by the authorities of the Republic of Dagestan of their authority on drug provision of the population of the region is the dynamics of the number of citizens appeal. In 2014 THE healthcare in the Republic of Dagestan has received 49 complaints on the topics of drug supply (51% of total).

The vast majority of complaints come on issues of failures in the prescriptions of preferential recipes (38,8%), lack of necessary medicines in pharmacies (24,5%), long-deferred maintenance (22.4 percent).

The systemic problems of drug supply of the population with circulatory system diseases in the Republic of Dagestan include the following:

The deficit of financial support of the regional program of state guarantees

Republic of Dagestan is a region with an endowment regions: the fiscal capacity of the region

to the distribution of subsidies is one of the lowest in the country, and is 0,264¹⁸.

The total amount of funds spent on medicinal maintenance of citizens, was formed based on the capabilities of the Republican budget, and not depending on the cost of the necessary medicinal treatment of a particular disease. By the end of 2014, the deficit of financial support of the territorial programs of state guarantees (TPSG) reached for 78.4% of the budgetary requirements of the budget of the Republic of Dagestan, calculated in accordance with established standards. This is the highest indicator among all subjects of the Russian Federation.

At the same time, the Republic of Dagestan entered the TOP 20 regions with the most high cost of drug coverage, planned in 2015. The total cost of drug coverage in 2015 will amount of 7.58 billion rubles, their share in the volume TPSG planned at the level of 29,9%¹⁹.

Low effectiveness of the system of public procurement of medicines

Procurement of medicines for state needs is focused primarily on the price of medicines, and not on their quality and efficiency. As the main method of placing such orders was applied to an open auction in the electronic form, the criterion for selecting the winner which was the lowest price of the medicinal product, proposed by the party placing the order. The purchase was made for international nonproprietary names.

Despite some improvement with the procurement of vital drugs in 2013-2014, the authority of the organization of providing the population with drugs, that were passed to the subjects of the Russian Federation in the Republic of Dagestan are executed not in full.

The majority of violations are typical and are systemic in nature, is:

- The lack of institutional control on the part of health authorities of the Republic for organization of preferential drug provision for certain categories of citizens;
- The documentation of approved procurement was taken with the violations

of the law on the contract system in the procurement field, the application forms were allowed to participate in the procurement unreasonably. In addition, unreasonably concluded contracts with suppliers who have not made the enforcement of contracts and registered with the inflated prices for vital and essential medicinal preparations without the use of competitive methods of determination of suppliers.

- Insufficient control over the execution of provisions of the concluded state contracts, resulting in systematic failure of terms of deliveries of drugs.
- Delays in the preparation of technical documentation for procurement of medicines by the Ministry of health of the Russian Federation. This leads to the absence in the pharmacy network of vital medicines. This fact is confirmed by the analysis of the previous years, which shows that the flow of drugs is delayed until the middle of the year, and leads to the threat to public health.

Low availability of medications for patients with CVD living in rural areas

Inadequate infrastructure system of medicinal maintenance of population due to the lack of economic feasibility of opening of pharmacies; a reduction of pharmacies providing a full range of services (night mode of operation, the production of medicines under individual prescription, the release of oxygen, etc.) – all these factors have a negative impact on the availability of medicinal maintenance of the population.

Ways of improving drug provision of patients with CVD in the Republic of Dagestan

Two years ago the Department adopted the Strategy of medicinal maintenance of the population of Russia till 2025 – global document that defines the policy of the state concerning the production, control, sale and use of drugs. Among other things, were proposed and alternatives to public procurement: drug insurance, co-payments and partial reimbursement of expenses for the purchased medicines.

The model of medical insurance is one of common world models, when all the people make

monthly payments, and the drugs patients receive in case of illness. Medicinal insurance can be organized in a special sequence: first to be part of the MMI system to provide ambulatory patients, and then in the hospital.

As one of the main measures of improving drug provision of population of the Republic of Dagestan is the introduction of the Law on contract system procurement planning through preparation of procurement plan for a period of three years and annual schedule, combined time and options with planning of Federal and regional budgets²⁰.

The regional authorities recommended to pay attention to the volumes generated and the adequacy of inventory of medicines purchased for the implementation of benefits programmes in the current year.

It is necessary to carry out the overall planning of drug procurement through creation of a consolidated register of medicines, which is updated regularly, and contains information about the types, amount, and characteristics of procured medicines with the distribution of the regions. This registry will avoid procurement of obsolete and ineffective drugs that will provide patients in the region in the necessary drugs.

The highest authorities of the Republic of Dagestan it is advisable to consider the possibility of organizing centralized procurement of hospital needs. This will reduce the cost of purchased medicines for the hospital segment.

Effective measure of improving drug provision of patients with CVD is the introduction of new effective mechanisms of price control on the pharmaceutical market. Urgent task of the state is to combat unjustified price growth for medicines in the regulated segment, ie are included in the list of vital and essential drugs. This will allow to avoid unreasonable budgetary expenditures of the region associated with these purchases²¹.

One of the most progressive measures to improve drug supply is the introduction of a system of reference prices. In such a system is installed the cost of the medications, which would reimburse the

cost patients by the state. At desire of the patient to purchase a more expensive drug, it pays the difference between the market value of the drug and its reference price. This practice exists abroad and has fully justified itself: having come with the prescription to the pharmacy, the patient decides to choose a generic, the cost of which covers the amount of compensation, or the original drug. In this way he will simply pay extra on top.

New rules for the regulation of prices of vital drugs aims to implement the import substitution policy and supporting Russian pharmaceutical companies²². So, imposed a maximum threshold of price of generic drug to the original drug. For generics - 80%, for biosimilars - 90%. Appeared the transparent mechanism of increase of drug prices. The domestic companies were allowed to re-register prices on vital drugs above the projected level of inflation, if they can prove the cost of components and excipients that comprise a medicament. Foreign companies are also given the opportunity to index rates, but within the level of inflation. The basis for the calculation are prices of medicines in reference countries.

In General, it should be noted that in Russia there are favorable conditions for the development of a strong pharmaceutical industry based on high quality medicines and affordable prices. It is a reliable platform to support the population of the Republic of Dagestan and the population of country with safe, effective and affordable medicines.

CONCLUSION

In conclusion, it should be noted that identified in the Republic of Dagestan problems of drug provision of patients with CVD preclude access to full medical assistance and create conditions for violations of human rights in the sphere of health protection. One can judge about the effectiveness of the response by the Republican leadership measures on those facts that the most of the violations are systemic in nature and are repeated from year to year.

In recent years, the government is taking certain measures to remedy the situation. Were developed and approved a number of Federal laws,

improved legal framework in the field of drug supply and procurement of medicines.

You can believe that the adoption of new legislation and activity of regional authorities of the

Republic of Dagestan on the implementation of its powers will be a major impetus in improving the availability of drug supply patients with CVD and quality of the medicinal help to the population, which directly affects the sustainable development of the social sphere of the Republic of Dagestan.

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