





Analysis of preferential drug provision for patients with diabetes mellitus in the Stavropol Region

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The aim. To study the quantitative characteristics of the implementation of drug provision for beneficiaries with diabetes mellitus (DM) in the Stavropol Region in the period from 2020 to 2024.

Materials and methods. The regulatory legal basis of the study was made up of legislative acts of the federal and regional levels on the organization of preferential drug provision (PDP). Clinical and epidemiological monitoring of DM was carried out according to the data of the State Register of DM for the Stavropol Region, data from the Regional Endocrinological Dispensary (Stavropol Region, Russia), as well as reports from executive authorities.

Results. According to the clinical and epidemiological monitoring of DM in the Russian Federation in 2024, the prevalence of DM in the Stavropol Region did not exceed the average Russian indicators (rating 36). A decrease in the number of federal beneficiaries and an increase in the number of regional beneficiaries (with a predominance of DM type II) was noted. 10 municipalities where about 60% of patients with DM live were identified. Therapy for patients with DM type I is based on insulin therapy for 100% of patients. Therapy for patients with DM type II includes the use of insulin for 14,140 (20.63%) patients, oral hypoglycemic agents for 53,404 (77.88%) patients, and dietary adjustments for 1,025 (1.49%) people. Since 2024, in accordance with changes in the legislation of the Stavropol Region, all patients with DM are provided from general funds of the regional budget, with the exception of federal beneficiaries in Lermontov, who are provided at the expense of the program for the provision of necessary medicines (PNMs). The structure of expenditures from the federal and regional budgets for the purchase of funds for the treatment of DM is presented. The dynamics of the growth of expenses per one beneficiary with DM is shown. It should be noted that in 2024 there was an equalization of the amount of expenses per one federal and regional beneficiary.

Conclusion. The results obtained can be used by other researchers to take solutions to improve the availability of drug provision for beneficiaries with DM both in the Stavropol Region and in other subjects of the Russian Federation.

Keywords: diabetes mellitus; regional drug provision; provision of necessary medicines; Stavropol Region

Abbreviations: DM — diabetes mellitus; SSDs — socially significant diseases; PDP — preferential drug provision; RDP — regional drug provision; VED — list of vital and essential drugs; PNMs — provision of necessary medicines; SLDs — sugar-lowering drugs; CGM — continuous glucose monitoring.

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Анализ льготного лекарственного обеспечения больных сахарным диабетом в Ставропольском крае

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Цель. Изучение количественных характеристик реализации лекарственного обеспечения льготополучателей с сахарным диабетом (СД) в Ставропольском крае в период с 2020 по 2024 г.

Материалы и методы. Нормативную правовую основу исследования составили законодательные акты федерального и регионального уровней по организации льготного лекарственного обеспечения (ЛЛО). Клинико-эпидемиологический мониторинг СД проведён по данным Государственного регистра СД по Ставропольскому краю, данных ГБУЗ СК «Краевой эндокринологический диспансер», а также отчётов органов исполнительной власти.

Результаты. По данным клинико-эпидемиологического мониторинга СД РФ в 2024 году распространённость СД в Ставропольском крае не превышала среднероссийских показателей (рейтинг 36). Отмечено снижение федеральных и увеличение численности региональных льготополучателей (с преобладанием СД ІІ типа). Выявлены 10 муниципальных образований, в которых проживает около 60% пациентов с СД. Терапия больных СД І типа основана на инсулинотерапии для 100% пациентов. Терапия больных СД ІІ типа включает применение инсулинов для 14140 (20,63%) пациентов, таблетированных сахароснижающих средств для 53404 (77,88%) пациентов и корректировки питания для 1025 (1,49%) человек. С 2024 года в соответствии с изменениями в законодательстве Ставропольского края все больные СД обеспечиваются из единого источника средств краевого бюджета, за исключением федеральных льготополучателей г. Лермонтова, обеспечиваемых за счёт средств программы обеспечения необходимыми лекарственными средствами (ОНЛС). Представлена структура затрат федерального и регионального бюджетов на закупку средств для терапии СД. Показана динамика роста затрат на одного льготополучателя с СД. Следует отметить, что в 2024 году произошло выравнивание сумм затрат на одного федерального и регионального льготополучателя.

Заключение. Полученные результаты могут быть использованы другими исследователями для выработки организационных решений по повышению доступности лекарственного обеспечения для льготополучателей с СД как в Ставропольском крае, так и в других субъектах Российской Федерации.

Ключевые слова: сахарный диабет; региональное лекарственное обеспечение; обеспечение необходимыми лекарственными средствами; Ставропольский край

Список сокращений: СД — сахарный диабет; СЗЗ — социально значимые заболевания; ЛЛО — льготное лекарственное обеспечение; РЛО — региональное лекарственное обеспечение; ЛП — лекарственные препараты; ЖНВЛП — жизненно необходимые и важнейшие лекарственные препараты; ОНЛС — обеспечение необходимыми лекарственными средствами; ССП — сахароснижающие препараты; СНМГ — система непрерывного мониторинга глюкозы.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease characterized by a high prevalence [1–3] and leading to a significant deterioration of the condition and physical abilities of a person, disability, as well as high treatment costs [4, 5]. DM (according to ICD-10 code of diseases E10–E14), by Decree of the Government of the Russian Federation No. 715 of

December 01, 2004, is classified as a socially significant disease (SSD)¹. SSDs affect the population of working age, lead to a deterioration in the patient's condition,

¹ Decree of the Government of the Russian Federation No. 715 dated December 01, 2004 "On approval of the list of socially significant diseases and the list of diseases that pose a danger to others" (revised on January 31, 2020; effective from February 11, 2020). Available from: https://normativ.kontur.ru/document?moduleId=1&documentId=356130. Russian



limitation of his physical capabilities and to the loss of temporary disability [6–8]. All this causes significant socioeconomic damage to the country [9, 10].

In accordance with Federal Law No. 323-FZ², for a citizen suffering from SSD, including DM, social support measures are established when receiving all types of medical care: patient has the right to free diagnosis of the disease, specialist monitoring of his health throughout the entire period of the disease. At the outpatient treatment stage, patients with DM have the right to receive medicines under the federal and regional preferential drug provision (PDP) [11–13].

Currently, the categories of citizens entitled to PDP at the expense of the federal budget (federal beneficiaries) are defined by Federal Law No. 178-FZ of 17.07.1999 "On State Social Assistance"³. In case of persistent disorders of body functions associated with the duration of DM or severe conditions due to hypoglycemia, ketoacidosis, neuropathies, etc., disability may be established for both a child under 18 years of age and a citizen aged 18 years and older^{4,5}. Such persons have the right to a set of social services, receiving the necessary medicines included in the list of vital and essential drugs (VED), formed by order of the Government of the Russian Federation No. 2406-r dated October 12, 2019 (as amended on January 15, 2025)^{6,7,8}.

A citizen with DM, in accordance with the Decree of the Government of the Russian Federation No. 890 of 30.07.1994, has the right to drug provision at the

expense of the regional budget⁹, the provision of MPs is also carried out in the amount of the VED list.

At the same time, if a citizen refuses a set of social services, he retains the right to drug provision at the expense of the regional budget. There is some legal conflict regarding the duplication of rights to PDP for patients with DM who have the right to receive medicines at the expense of the federal and regional budgets. This imposes responsibility on healthcare authorities in organizing the provision of MPs to this category of patients, and the rational use of the allocated budget in order to predetermine the availability of drug provision [14–16].

The increase in the number of patients with DM who take medicines for life increases the costs of the federal and regional budgets for PDP for this category of beneficiaries, contributes to the formation of regional characteristics in the PDP for this category of patients and the consolidation of provisions in regional regulatory documents on drug provision for patients with DM [17–19]. At the same time, the rational use of allocated budget funds contributes to ensuring the availability of medicines for this category of patients [20–22].

Content analysis of regulatory documentation, which became the basis for organizing drug provision for citizens with DM in the Stavropol Territory, showed that along with federal regulations and the territorial program of state guarantees¹⁰, the subject adopted and operates regional regulations on social support measures for persons with SSDs¹¹, as well as the regional program "Fighting against Diabetes Mellitus on the Stavropol Territory", approved by the Decree of the Government of the Stavropol Territory¹².

n order to rationally allocate financial resources and optimize PDP for patients with DM, changes were

² Federal Law of the Russian Federation dated November 21, 2011 No. 323-FZ "On the Basics of Public Health Protection in the Russian Federation (with Amendments and Additions): (as amended on September 26, 2024. Available from: https://www.consultant. ru/document/cons_doc_LAW_121895/. Russian

³ Federal Law No. 178-FZ of 07/17/1999 "On State Social Assistance" (as amended on May 29, 2024; effective from July 01, 2024). Available from: https://normativ.kontur.ru/document?moduleld=1&document

⁴ Federal Law No. 181-FZ of November 24, 1995 (as amended on October 29, 2024) "On Social Protection of Persons with Disabilities in the Russian Federation". Available from: https://normativ.kontur.ru/document?moduleId=1&documentId=475963. Russian

⁵ Letter of the Ministry of Labor and Social Protection of the Russian Federation dated February 22, 2020 No. 7222.FB77/2020 "On sending clarifications on the issue of conducting a medical and social examination upon reaching the age of 18 to citizens with insulindependent diabetes mellitus who were assigned the category of "disabled child". Available from: https://www.garant.ru/products/ipo/prime/doc/73564214/. Russian

⁶ Decree of the Government of the Russian Federation No. 10-r dated January 15, 2025 "On Amendments to Decree of the Government of the Russian Federation No. 2406-r dated October 12, 2019". Available from: https://lglv.ru/#/document/97/527333/. Russian

⁷ Federal Law No. 206-FZ dated July 13, 2020 "On Amendments to Certain Legislative Acts of the Russian Federation on the Provision of Medicines, Medical Devices and Specialized Medical Nutrition Products to Citizens" (as amended on July 10, 2023; effective from January 01, 2024). Available from: https://normativ.kontur.ru/document?moduleId=1&documentId=457204. Russian

⁸ Letter of the Ministry of Health of the Russian Federation dated July 05, 2024 No. 25-1/3081600-7932 "On the provision of medicines". Available from: https://www.garant.ru/products/ipo/prime/doc/409230040/

⁹ Decree of the Government of the Russian Federation dated July 30, 1994 No. 890 "On State Support for the Development of the medical industry and improving the provision of medicines and medical products to the Population and Healthcare Institutions" (with Amendments and additions). Available from: https://normativ.kontur.ru/document?moduleId=1&document Id=61472. Russian

¹⁰ Resolution of the Government of the Stavropol Territory dated December 27, 2024 No. 784-p "On approval of the Territorial Program of State guarantees of free medical care to Citizens in the Stavropol Territory for 2025 and the planning period of 2026 and 2027". Available from: http://publication.pravo.gov.ru/document/2600202412280005. Russian

¹¹ Resolution of the Government of the Stavropol Territory dated December 02, 2021 No. 625-p "On Amendments to the Resolution of the Government of the Stavropol Territory dated April 19, 2006 No. 49-p "On the organization of social support measures for citizens suffering from socially significant diseases and citizens suffering from diseases that pose a danger to others". Available from: https://mz26.ru/activity/sub-52/. Russian

¹² Resolution of the Government of the Stavropol Territory dated April 26, 2024 No. 230-p "On approval of the regional program "Fighting against Diabetes Mellitus on the Stavropol Territory". Available from: https://stav-pravo.ru/postanovlenie/2024/04/26/n-230-p/. Russian



made to regional legislation regarding the assignment of certain state powers to local governments. Thus, the law of the Stavropol Territory dated February 15, 2013 No. 10-kz "On assigning to local governments of the Stavropol Territory urban district of Lermontov certain state powers of the Stavropol Territory in the field of protecting the health of citizens" assigned to local governments state powers in the field of protecting the health of citizens to provide social support measures¹³. In this regard, according to the current regional legislation, there has been a redistribution of funding for drug provision for beneficiaries with DM. Since 2024, the provision of benefits to beneficiaries with DM is carried out from a single source — all regional beneficiaries with DM and patients who have refused a set of social services are provided with medicines from the regional budget, and patients with a disability group living in Lermontov are provided with all necessary medicines at the expense of the federal budget under the program of provision of essential medicines (PEMs).

The regional program approves target indicators, the achievement of which contributes to improving medical and drug care for patients with DM, reducing the level of complications of the disease and improving the quality of life of patients. The study of the epidemiological situation of DM in the Stavropol Territory indicates the relevance of organizing drug provision for patients with DM as part of state social assistance in the Stavropol Territory, both at the expense of federal and regional budgets. In this regard, monitoring the organization of drug provision for patients with DM allows us to assess the implementation of the tasks set.

THE AIM was to study the consumption of hypoglycemic drugs in the implementation of preferential drug provision for patients suffering from diabetes mellitus in the Stavropol Territory.

The following tasks were identified and solved:

- 1. Analyze data on the prevalence of DM in the Stavropol Territory;
- 2. Assess the dynamics of the number of federal and regional beneficiaries with DM, identify

- municipalities, urban districts with the largest number of beneficiaries with DM;
- To study the structure of budget spending aimed at purchasing funds for the treatment of DM in the Stavropol Territory;
- Determine the structure of consumption of hypoglycemic agents by beneficiaries with DM.

MATERIALS AND METHODS

The regulatory framework of the study consisted of legislative acts of the Russian Federation and the Stavropol Territory on PDP (Preferential Drug Provision) for patients with DM, which were obtained using the Consultant Plus legal reference system, ¹⁴ the official website of the Ministry of Health of the Stavropol Territory ¹⁵, providing current regulatory documentation. To structure and systematize the data obtained, content analysis was used, which allows determining the principles and parameters of PDP in the Stavropol Territory.

The source of information on the number of patients with DM was the State Register of Diabetes Mellitus in the Stavropol Territory¹⁶, as an interactive report on the number of patients with DM types I and II, materials of annual reports of the State Budgetary Healthcare Institution of the Stavropol Territory "Regional Endocrinological Dispensary" on the implementation of the Federal Project "Fighting against Diabetes Mellitus" and reporting materials on the implementation of preferential drug provision, as well as the State Register of Medicines¹⁷.

Retrospective analysis methods were used to study the dynamics and changes in indicators of the number of patients with DM, including federal and regional beneficiaries; spending budget funds on the purchase of medicines for PDP for the period 2020–2024; ranking quantitative indicators of the number of beneficiaries by municipal and urban districts and identifying districts with the largest number of beneficiaries; comparative analysis of individual group and intragroup indicators; graphical analysis to visualize changes in

¹³ The Law of the Stavropol Territory dated February 15, 2013 No. 10-kz "On Granting local self-government bodies of the Stavropol Territory of the city of Lermontov separate State Powers of the Stavropol Territory in the field of public health protection" (as amended on April 28, 2023) (as amended by Laws of the Stavropol Territory dated November 15, 2013 No. 100-kz, dated April 28, 2023 No. 39-kz). Available from: https://base.garant.ru/27130578/?ysclid=m7su9nr93980718211. Russian

¹⁴ ConsultantPlus Legal Reference System. Available from: https://www.consultant.ru/. Russian

¹⁵ Ministry of Health of the Stavropol Territory. Available from: https://www.mz26.ru/. Russian

¹⁶ Databases of clinical and epidemiological monitoring of endocrinopathies in the Russian Federation. Endocrinology Research Centre of the Russian Federation. Available from: https://diaregistry.ru/. Russian

 $^{^{\}rm 17}$ The State Register of Medicines of the Russian Federation. Available from: https://grls.rosminzdrav.ru/GRLS.aspx. Russian



indicators in the analyzed period. The study of the dynamics of changes in the number of beneficiaries, the costs of the regional and federal budgets for PDP, the costs per beneficiary was carried out on the basis of calculating the rates of change. The study of the structure of consumption of sugar-lowering drugs (SLDs) by type of therapy and depending on the type of DM was carried out according to the State Register of DM in the Stavropol Region for 2024. MS Excel 2021 spreadsheets (Microsoft Corp., USA) were used to work with digital data.

RESULTS

Clinical and epidemiological monitoring of diabetes mellitus (DM) in the Russian Federation is carried out through the State Register of DM, the methodological and organizational center of which is the Endocrinological Research Centre, which contributes to medical and statistical observations. A unified system for monitoring DM based on the "Database of clinical and epidemiological monitoring of DM in the Russian Federation" allows, at the national level, to obtain information on risk factors, the epidemiological and clinical picture of DM, the use of drugs and modern technologies for monitoring glycemia levels, to assess the effectiveness of program implementation, and to coordinate the work of all levels of healthcare at the level of any subject of the Russian Federation [23–25].

As of January 01, 2024, data on the number of patients with DM in the Russian Federation and the Stavropol Territory were extracted (Table 1).

The presented data show that the prevalence of DM in the Stavropol Territory per 100 thousand people is lower than the average Russian indicators, but, nevertheless, the number of patients with DM is large. The published final ranking of regions by DM showed that the Stavropol Region in 2024 ranked 36th among all subjects of the Russian Federation, in 2023 this figure was 41, which indicates an increase in morbidity¹⁸

Based on the data from the State Register of DM for the Stavropol Territory and the data from the SBIH of the Stavropol Region "Regional Endocrinological Dispensary", an analysis was made of the number of patients with DM, with the allocation of groups of citizens entitled to drug provision (Table 2).

The data presented in Table 2 indicate a slight decrease in the number of patients with an established diagnosis of DM (a decrease of 2 990 people — -3.52 %), while the number of such patients reached 81 827 by 2024. In the analyzed period, the number of federal beneficiaries decreased by 4 246 people (29.72 %), and regional beneficiaries, on the contrary, increased by 13 992 people. At the same time, their slight decrease by 2022 was replaced by an increase — from 61 670 people in 2022 to 77856 in 2024. Beneficiaries under 14 years of age accounted for about 1.5 % of the total number — their number increased from 929 people in 2020 to 1 172 people in 2024.

When studying the structure of DM morbidity among beneficiaries, it was found that patients with type 2 DM predominated, the proportion of which exceeded 90.0 % (93.95% in 2024).

In the Stavropol Territory, 33 municipal and urban districts are identified¹⁹, in which a different number of beneficiaries are registered, based on data on their number, a ranking of municipalities was carried out from the position of decreasing number of resident beneficiaries (Fig. 1).

Grouping of municipalities by the number of beneficiaries made it possible to identify territories with the largest number of beneficiaries, in 10 (30.3 %) municipal and urban districts, almost about 60 % of beneficiaries are registered. The largest number is registered in Stavropol, Shpakovsky district, Nevinnomyssk, Georgievsky urban district, etc. The identified municipalities are a priority for further study of the organization of drug provision, which will allow building a more effective drug routing for this group of patients. At the same time, in the territories with the smallest number of beneficiaries with DM (Turkmensky, Arzgirsky, Stepnovsky and Novoselitsky municipal districts), the formation of the most acceptable ways of drug routing for patients is an important task for the healthcare authorities of the region.

Drug provision for patients with DM is carried out from the federal and regional budgets. The study of the dynamics of financing drug provision made it possible to determine the trend of changes in indicators (Table 3).

¹⁸ Databases of clinical and epidemiological monitoring of endocrinopathies in the Russian Federation. Endocrinology Research Centre of the Russian Federation.

¹⁹ Resolution of the Government of the Stavropol Territory dated May 04, 2006 No. 63-p "On Approval of the Register of Administrative-territorial Units and Territorial Units of the Stavropol Territory (as amended on July 31, 2024)". Available from: https://docs.cntd.ru/document/461505266. Russian



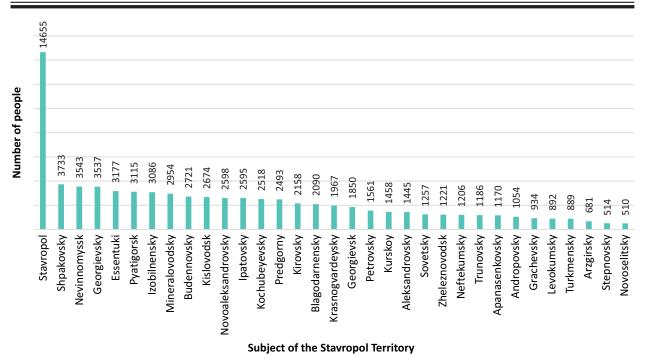


Figure 1 – Ranking of the number of beneficiaries by municipal and urban districts of the Stavropol Territory as of 2024.

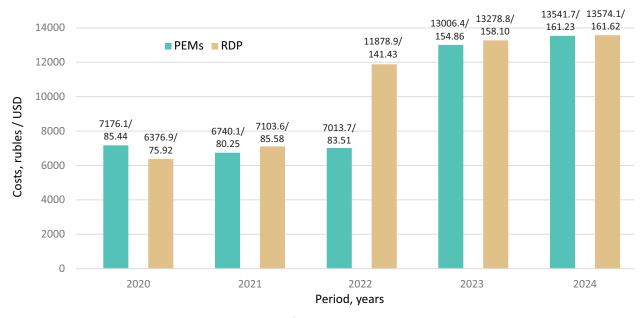


Figure 2 — Costs per beneficiary with Diabetes Mellitus, rubles. Note: RDP — regional drug provision; PEMs — provision of essential medicines.

Table 1 – Number of patients with DM as of January 01, 2024 according to the State Register of Diabetes Mellitus in the Stavropol Territory

Region	Number of people	Prevalence per 100 thousand people		
	Type 1 Diabetes Mell	litus		
Russian Federation	290 700	194.2		
Stavropol Territory	4 391	152.2		
	Type 2 Diabetes Mell	itus		
Russian Federation	4 805 659	3 211.2		
Stavropol Territory	73 124	2 533.9		



Table 2 - Dynamics of the number of patients with Diabetes Mellitus in the Stavropol Territory

Indicator		Comparison result,				
indicator	2020	2021	2022	2023	2024	2020 / 2024
Total number of patients with DM, people	84 817	84 711	82 224	81 182	81 827	-2990
Rate of change, %	-	99.88	97.06	98.73	100.79	96.47 (-3.52)
Federal beneficiaries with DM, people	14 287	13981	13 450	13 312	10 041	-4246
Rate of change, %	-	97.86	96.20	98.97	75.43	70.28 (-29.72)
Regional beneficiaries with DM, people	63864	63485	61670	62173	77856	+13992
Rate of change, %		99.41	97.14	100.82	122.25	121.91 (+21.91)
Beneficiaries "children category", people	929	1 109	1 111	1 095	1 172	+243
Specific weight in the total number of beneficiaries, %	1.19	1.43	1.49	1.45	1.43	+0.24

Note: ${\sf DM}-{\sf diabetes}$ mellitus.

Table 3 – Costs of federal and regional budgets for drug provision to beneficiaries with Diabetes Mellitus

	Analyzed period	Comparison				
Indicator	2020	2021	2022	2023	2024	results, 2024 / 2020
Federal budget funds, million rubles / USD	102.525 / 1.220	94.232 / 1.122	94.334 / 1.123	173.141 / 2.061	53.774 / 0.640	-48.751
Rate of change, %	-	91.91	100.11	183.54	31.06	-47.55
Federal budget funds for PDP of beneficiaries in Lermontov, million rubles / USD	-	5.3 / 0.063	4.07 / 0.048	6.24 / 0.074	7.37 / 0.088	2.07
Rate of change, %	-	-	76.79	153.32	118.11	139.06
Regional budget funds allocated for PDF of patients with DM, million rubles / USD	407.26 / 4.85	450.97 / 5.37	732.54 / 8.72	825.58 / 9.83	1 056.82 / 12.58	649.56
Rate of change, %	_	110.73	162.44	112.70	128.01	259.50

Note: PDF-Preferential Drug Provision; DM - diabetes mellitus.

Table 4 – Structure of budget expenditures for the therapy of Diabetes Mellitus in the Stavropol Territory

	"Insulins"	Tablets	Test strips	Syringes + needles	CGM system	Pump
Years	million rubles / % USD	million rubles / % USD	million rubles / % USD	million rubles % / USD	million rubles / % USD	million rubles / % USD
2020	305.52 / 3.64 62.00	103.77 / 1.24 21.06	40.29 / 0.48 8.18	13.05 / 0.16 2.65		
2021	345.58 / 4.11 59.47	95.79 / 1.16 16.48	88.08 / 1.05 15.16	21.54 / 0.26 3.71		
2022	402.53 / 4.79 54.95	107.88 / 1.28 14.73	70.49 / 0.84 9.62	28.66 / 0.34 3.91	89.39 / 1.06 12.20	
2023	392.67 / 4.68 47.56	135.02 / 1.61 16.35	82.07 / 0.98 9.94	32.14 / 0.38 3.89	140.43 / 1.67 17.01	
2024	457.53 / 5.48 43.29	264.28 / 3.15 25.01	130.45 / 1.55 12.34	38.55 / 0.45 3.65	39.16 / 0.47 3.71	61.96 / 0.74 5.86
Comparison 2024/2020	+152.01 -18.71	+160.51 +3.95	+90.16 +4.16	+25.50 +1.0		

Note: CGM system — continuous glucose monitoring system.



Table 5 – Structure of expenditure of federal budget funds for the therapy of diabetes mellitus according to the program of providing necessary medicines

Years	"Insulins" million rubles / USD	%	Tablets million rubles / USD	%	Test strips million rubles / USD	%	Syringes + r million rubles / USD	needles %	Pump million rubles / USD	%
2020	70.23 / 0.84	68.11	6.01 / 0.07	5.83	4.97 / 0.06	4.82	4.31 /	4.18	17.59 / 0.21	17.06
2021	104.01 / 1.24	67.82	11.41 / 0.13	7.44	14.75 / 0.18	9.62	_	_	23.19 / 0.28	15.12
2022	107.83 / 1.28	55.45	10.48 / 0.12	5.39	12.04 / 0.14	6.19	_	_	64.12 / 0.76	32.97
2023	77.28 / 0.92	44.86	14.66 / 0.17	8.51	4.92 / 0.06	2.86	_	_	75.41 / 0.90	43.77
2024	0.32 / 0.004	0.85	0.06 / 0.0007	0.16	1.56 / 0.019	4.16	_	_	35.59 / 0.42	94.83

Table 6 — Structure of expenditure of the regional budget on the purchase of funds for the therapy of diabetes mellitus

Years	"Insulins" million rubles / % USD	Tablets million rubles / % USD	Test strips million rubles / % USD	Syringes + needles million rubles / % USD	CGM system million rubles / % USD	Pump million rubles / % USD
2020	235.29 / 2.80 62.39	97.75 / 1.16 25.92	35.32 / 0.42 9.37	8.74 / 0.1 2.32		
2021	241.57 / 2.88 57.41	84.38 / 1.00 20.05	73.33 / 0,87 17.43	21.54 / 0.26 5.12		
2022	294.70 / 3.51 51.83	97.40 / 1.16 17.13	58.45 / 0,69 10.28	28.66 / 0.34 5.04	89.39 / 1.06 15.72	
2023	315.39 / 3.76 46.01	120.36 / 1.43 17.56	77.14 / 0,92 11.25	32.14 / 0.38 4.69	140.43 / 1.67 20.49	
2024	452.14 / 5.38 45.57	260.63 / 3.10 26.27	141.07 / 1,68 14.22	38.55 / 0.46 3.89	38.54 / 0.46 3.88	61.18 / 0.73 6.17
Comparison 2024 / 2020	+216.85 -16.82	+162.88 -0.35	+105.75 +4.85	+29.81 +1.57		

The presented data indicate an annual increase in regional budget funds for PDF of patients with DM: for the period from 2020 to 2024, regional budget expenditures increased 2.5 times - from 407.26 / 4.85 to 1056.82 million rubles / 12.58 million dollars, the growth rate was 259.50 %. It should be noted that federal funds allocated for the treatment of DM in the period from 2020 to 2023 tended to increase, while in 2024 there was a decrease in the amount of federal funds by 47.55 %. Federal budget funds were allocated for PNMs (provision of necessary medicines) of beneficiaries with a disability group living in Lermontov, in the analyzed period the funds were increased by 2.07 million rubles / 0.088 million dollars (139.06 %) and in 2024 amounted to 7.37 million rubles.

For the therapy of DM, "insulins" are used in the form of injectable drugs, hypoglycemic tablets and dietary adjustments using developed diets. The study of the data of the state register of DM in the Stavropol Territory for 2024 made it possible to identify the structure of consumption of hypoglycemic tablets by type of therapy and depending on the type of DM. Therapy for patients with DM type I is based only on insulin therapy, which is received by 100 % of patients (4 375 people). Therapy for patients with DM type II includes the use of insulins for 20.63 % (14 140 patients), hypoglycemic tablets for 53 404 people (77.88 %) and for 1.49 % (1 025 people) dietary adjustment is sufficient. It should be noted that the use of oral drugs is based on the combined use of several hypoglycemic tablets. Further study showed that in 2024, for 38.50 % of patients (20 563 people), the treatment regimen includes monotherapy, for 45.76 % (24 436 people) a combination of two drugs is used, and a combination of three hypoglycemic tablets is used in the therapy of 15.74 % of patients (8 405 people).

The results of our analysis of the expenditures of the allocated budget for the purchase of funds for



drug provision to beneficiaries with DM allowed us to establish its structure. Budget funds are allocated for the purchase of hypoglycemic tablets, injectable forms of insulins depending on the duration of action, necessary means of monitoring blood glucose levels (test strips) and continuous glucose monitoring (CGM) systems, consumables for an insulin pump for children under 18 years. (Table 4).

The presented data demonstrate the predominant expenditure of budget funds on injectable drugs "insulins". The costs of purchasing these drugs increased by 152.01 million rubles / 1.81 million dollars, but at the same time, the proportion of this group in the analyzed period tends to decrease from 62. 0% in 2020 to 43.29 % in 2024, which indicates the preservation of leading positions. In our opinion, this may be due to a decrease in the number of federal beneficiaries with type I DM, who are prescribed "insulins". The costs of oral drugs increased by almost 4.0 % by 2024 — from 103.77 million rubles / 1.24 million dollars in 2020 to 264.28 million rubles / 3.15 million dollars in 2024. It should be noted that CGM system have been purchased for the therapy of patients with DM since 2022: in 2024, 67.96 million rubles / 0.74 million dollars were spent on the purchase of an insulin pump (a device that promotes continuous subcutaneous administration of insulin).

Table 5 presents the structure of expenditures of federal budget funds for drug provision to beneficiaries with DM in the PNMs (provision of necessary medicines).

The analysis of the structure of purchases of funds for beneficiaries with DM in the PEMs in the period from 2020 to 2023 indicates the predominance of "insulins" in the structure, the proportion of which in the analyzed period tends to decrease — from 68.11 % to 44.86 %. During this time, the volume of expenditures on the purchase of hypoglycemic tablets almost doubled - from 6.01 million rubles / 0.07 million dollars in 2020 to 14.66 million rubles / 0.17 million dollars in 2023, the proportion of this group of funds in 2023 amounted to 8.51 %. The volume of expenditures on the purchase of insulin pumps increased from 17.59 million rubles / 0.21 million dollars to 75.41 million rubles / 0.90 million dollars, while there was also an increase in the proportion of expenditures on this group of funds — up to 43.77 % in 2023.

In accordance with the adopted regional regulatory documents on the redistribution of the budget for the

purchase of funds for the therapy of DM, since 2024, the subject has decided to provide all citizens with DM, regardless of the presence/absence of a disability group (with the exception of beneficiaries from Lermontov), at the expense of the budget of the Stavropol Region, purchases of drugs at the expense of the federal budget separately for federal beneficiaries in the region have been discontinued. Such a redistribution of funds is a regional feature in the legislation of the Stavropol Region.

The results of the analysis of the distribution of regional budget funds allocated for PDP of beneficiaries with DM are presented in Table 6.

In the analyzed period, funds for the purchase of "insulins" increased by 216.85 million rubles / 2.58 million dollars. In the structure of purchases for regional beneficiaries, "insulins" have a significant downward trend from 62.39 % in 2020 to 45.57 % in 2024, while maintaining a leading position. The costs of hypoglycemic tablets were increased by 162.66 million rubles / 1.94 million dollars, the proportion in the structure of purchases was increased slightly and reached 26.27 % in 2024. An increase in the cost of test strips for beneficiaries was recorded from 35.32 million rubles / 0.42 million dollars in 2020 to 141.07 million rubles / 1.68 million dollars in 2024, the proportion of this group increased by 4.85 % and amounted to slightly more than 14 % in 2024.

It should be noted that since 2022, consumable materials (syringes + needles) have been purchased at the expense of the regional budget, the proportion in the consumption structure is about 4.0%, CGM system in the consumption structure tends to decrease — from 15.72 % in 2022 to 3.88 % in 2024, slightly more than 6.0 % of the funds were allocated for the purchase of insulin pumps and consumable materials for them.

Figure 2 shows changes in the costs per beneficiary, which tend to increase. Thus, the costs per beneficiary with DM in the analyzed period almost doubled, in the PEMs the increase in costs occurred by 88.7 % from 7 176.1 rubles / 85.44 dollars in 2020 to 13 541.7 rubles / 161.23 dollars in 2024, the increase in costs per beneficiary in the regional drug provision (RDP) was 212.9%, and the amount reached 13 574.1 rubles / 161.62 dollars. The presented results indicate an increase in consumption and increased availability of funds for the therapy of DM for beneficiaries.

Furthermore, the redistribution of budgetary funds and the provision of benefits to beneficiaries from a single source made it possible to equalize the costs



per beneficiary in the PEMs and RDP. In 2024, the costs practically corresponded to the same amount, which indicates equal opportunities for both federal and regional beneficiaries.

Traditional insulin therapy is based on the parenteral use of various insulin preparations. Currently, the main devices for insulin administration are syringes, pen injectors, cartridge systems, and insulin pumps. The study determined the proportion of beneficiaries in diabetes therapy who use various devices for insulin administration.

The results of the study indicate the predominant use of insulin in cartridges for patients with type 1 diabetes, both for adults (90.91 %) and for children (81.32%). Insulin therapy for type 2 diabetes is based on the use of insulin preparations in cartridges (87.19 %) and in vials (12.81 %). At the same time, insulin pumps are predominantly provided to children with type 1 DM (18.49 %), which exceeds their use in adults (6.3 %).

DISCUSSION

DM is recognized as one of the main factors of disability and mortality worldwide. According to data published in foreign scientific literature, from 1990 to 2022, the prevalence of DM in the world increased: in 131 countries among women and in 155 countries among men. The healthcare resources of all countries are aimed at optimizing the work of primary health care and healthcare resources for the early detection and effective treatment of DM [26, 27].

In the constituent entities of the Russian Federation, DM is an important medical and social problem an increase in the incidence among the adult population [28–30] and among patients under 14 years of age [31], as well as with the assessment of the loss of working capacity of patients [32] and the organization of drug provision, which has variable regional options.

According to the results of the study, the dynamics of changes in the number of patients with DM in the Stavropol Territory has an upward trend, while there is a decrease in the number of federal beneficiaries and an increase in regional ones. At the same time, state guarantees in the field of drug provision are aimed at ensuring access to drugs for patients with DM, regardless of the category of beneficiary. The implementation of accessibility in drug provision also has regional options. A regional feature of drug provision for beneficiaries with DM in the Stavropol Territory is the redistribution of funding

for drug provision for patients with DM, and since 2024, beneficiaries have been provided with drugs from a single source — the regional budget, with the exception of federal beneficiaries in Lermontov (Stavropol Territory, Russia), who are provided at the expense of the PEMs program. In this regard, amendments were made to the regional legislation regarding the delegation of certain state powers to local governments.

From a practical point of view, this made it possible to increase the funds of the regional budget and ensure equal opportunities in drug provision for federal and regional beneficiaries confirmed by the dynamics of costs per beneficiary with DM, which almost doubled in the analyzed period and in 2024 correspond to the same amount — over 13.5 thousand rubles / 0.16 thousand dollars for both federal and regional beneficiaries.

Study Limitations

This study examines certain quantitative indicators of the implementation of drug provision for beneficiaries with DM in the Stavropol Territory. The analysis of the range of self-monitoring devices used in terms of trade names of drugs and nosological forms of DM was not carried out, and the qualitative indicators of the implementation of the drug provision program related to the redistribution of funding for drug provision for beneficiaries with DM since 2024 were not evaluated. All this is a promising area for further scientific research.

CONCLUSION

This study examined the quantitative characteristics of drug provision for beneficiaries with DM in the Stavropol Territory: the dynamics of the number of beneficiaries with DM is presented, municipal and urban districts with the largest number of them are identified, the structure of spending federal and regional budget funds on self-monitoring devices is presented, as well as the dynamics of costs per beneficiary. The results obtained can be used to develop organizational solutions to improve the accessibility of drug provision for beneficiaries with DM both in the Stavropol Territory and in other constituent entities of the Russian Federation. In the future, the authors plan to continue the study of the organization of drug provision for patients with DM in the Stavropol Territory from the point of view of analyzing the range of drugs in the public procurement sector and their possible impact on treatment outcomes.



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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Rosa I. Yagudina — idea, conceptualization, methodology, data curation, writing—review & editing. Olga L. Listova — data collection and curation, processing and interpretation of results, writing—original draft. All authors confirm that their authorship meets the international ICMJE criteria (all authors made a significant contribution to the development of the concept, conduct of the study and preparation of the article, read and approved of the final version before the publication).

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