EPIDEMIOLOGY AND KEY CLINICAL AND THERAPEUTIC INDICATORS OF DIABETES MELLITUS IN RUSSIAN FEDERATION ACCORDING TO THE WORLD HEALTH ORGANIZATION'S STRATEGY GOALS

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BACKGROUND: Diabetes mellitus (DM) is a dangerous challenge to society and high-priority goals for health systems worldwide due to the severity of diabetic complications leading to disability and premature mortality in this category of patients.
AIM: To carry out an analysis of epidemiological, clinical and therapeutic characteristics of DM control in the Russian Federation (RF) according to the strategy goals of the World Health Organization (WHO) by 2030 (diagnosis of DM; control of glycemia, blood pressure in DM patients; assignment of statins to DM patients; ensuring the availability of insulin and means for self-monitoring of the level of glycemia) based on the «Database of clinical and epidemiological monitoring of DM in the territory of the Russian Federation (RF)».
MATERIALS AND METHODS. The research performed on the basis of the de-personalized "Database of clinical and epidemiological monitoring of DM in the territory of the RF", certificate of state registration database №2020622447 (http://diaregistry.ru, register of DM), which included 87 regions of the RF. Data are presented as cross-sectional study in 01.07.2024.
RESULTS: According to the Database of clinical and epidemiological monitoring of DM in the territory of the RF, the target HbA_{1c}<7% is achieved in 29% of patients with type 1 DM (T1DM) and 42% of patients with T2DM. Effective blood pressure control in people with diagnosed DM is achieved in 84% of patients with T1DM and 60% of patients with T2DM. The proportion of patients receiving statins aged 40 and over is 14.1% for T1DM, 15.9% for T2DM. All patients with T1DM (100%) and T2DM on insulin therapy are provided with insulin under the program of state guarantee of drug provision, of them insulin analogues in T1DM — 84,8%, in T2DM — 60,9%, the rest — recombinant human insulins. Self-monitoring devices (glucometers and test strips for them) are provided to 100% of patients with DM. Since 2023, patients with T1DM under 18 years old are provided by continuous glucose monitoring systems.
CONCLUSION: Common diabetes monitoring system based on "Database of clinical and epidemiological monitoring of DM in the territory of the RF" at the national level allows to assess the effectiveness of programs to achieve the WHO targets. The data analysis identifies priority areas for the most effective and achievable interventions to strengthen and monitor diabetes control. Providing timely, reliable and sustainable national information on risk factors, epidemiology and clinical data of DM, access to medical drugs and modern technologies of control requires coordinated work by health professionals.

KEYWORDS: diabetes mellitus (DM); Database of clinical and epidemiological monitoring of DM in the territory of the Russian Federation; strategic goals of the World Health Organization (WHO).

ЭПИДЕМИОЛОГИЯ И КЛЮЧЕВЫЕ КЛИНИКО-ТЕРАПЕВТИЧЕСКИЕ ПОКАЗАТЕЛИ САХАРНОГО ДИАБЕТА В РОССИЙСКОЙ ФЕДЕРАЦИИ В РАЗРЕЗЕ СТРАТЕГИЧЕСКИХ ЦЕЛЕЙ ВСЕМИРНОЙ ОРГАНИЗАЦИИ ЗДРАВООХРАНЕНИЯ

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ОБОСНОВАНИЕ. Сахарный диабет (СД) является опасным вызовом обществу и приоритетом первого порядка для систем здравоохранения во всем мире ввиду тяжести диабетических осложнений, приводящих к инвалидизации и преждевременной смертности данной категории пациентов.
ЦЕЛЬ. Провести анализ эпидемиологических и клинико-терапевтических характеристик контроля СД в Российской Федерации (РФ) в соответствии со стратегическими задачами Всемирной организации здравоохранения (ВОЗ) к 2030 г. (диагностика СД; контроль гликемии; контроль артериального давления (АД), терапия статинами у пациентов с СД; обеспечение доступности инсулинов и средств самостоятельного мониторинга уровня гликемии) на основе «Базы данных клинико-эпидемиологического мониторинга СД на территории РФ».
МАТЕРИАЛЫ И МЕТОДЫ. Объект исследования: деперсонифицированная выгрузка «Базы данных клинико-эпидемиологического мониторинга СД на территории РФ», свидетельство о государственной регистрации базы данных №2020622447 (http://diaregistry.ru, регистр СД), включающая 87 регионов РФ. Данные представлены в формате одномоментного среза на 01.07.2024 г.

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РЕЗУЛЬТАТЫ. По данным клинико-эпидемиологического мониторинга СД на территории РФ целевой показатель гликированного гемоглобина (HbA_{1c}<7%) достигается у 29% пациентов с СД 1 типа (СД1) и 42% пациентов с СД 2 типа (СД2). Эффективный контроль АД у лиц с диагностированным СД достигается у 84% пациентов с СД1 и 60% пациентов с СД2. Доля пациентов с СД в возрасте ≥40 лет, получающих статины, составила при СД1 14,1%, при СД2 — 15,9% пациентов. Все пациенты с СД1 (100%) и с СД2 на инсулинотерапии обеспечиваются инсулинами в рамках программы государственных гарантий лекарственного обеспечения, из них аналогами инсулина при СД1 — 84,8%, при СД2 — 60,9%, остальные — рекомбинантными инсулинами человека. Средствами самоконтроля (глюкометрами и тест-полосками к ним) обеспечиваются 100% пациентов с СД. С 2023 г. пациенты с СД1 в возрасте до 18 лет обеспечиваются системами непрерывного мониторирования гликемии.

ЗАКЛЮЧЕНИЕ. Единая система мониторинга СД на основе «Базы данных клинико-эпидемиологического мониторинга СД на территории РФ» позволяет на национальном уровне оценить эффективность реализации программ достижения поставленных целей ВОЗ. Анализ выделяет направления приоритетного внимания для проведения наиболее эффективных мероприятий по усилению и отслеживанию мер борьбы с СД. Обеспечение своевременных, надежных и устойчивых национальных данных о факторах риска, эпидемиологической и клинической картине СД, оценке использования лекарственных средств и современных технологий контроля требует скоординированной работы всех звеньев здравоохранения.

КЛЮЧЕВЫЕ СЛОВА: сахарный диабет; База данных клинико-эпидемиологического мониторинга СД на территории РФ; стратегические задачи Всемирной организации здравоохранения.

RATIONALE

Diabetes mellitus (DM) is a non-communicable socially significant disease that challenges global health due to epidemic rates of increase in prevalence and the global medical and social burden associated with the severity of diabetic complications, the risk of disability and premature death of patients. According to the data of the International Diabetes Federation (IDF), the number of diabetic patients aged 20–79 years has reached 537 million worldwide (IDF Atlas 2021), which exceeds the previously predicted growth rates by 10–12 years. By 2045, this number is expected to be almost twice as high and reach 783 million people (a 46% increase) [1].

Due to its high social significance, DM rates are monitored by the leading international organizations, including the United Nations (UN) and the World Health Organization (WHO). On December 20, 2006, the 61st General Assembly adopted the UN Resolution on the need for all countries of the world to unite in the fight against the catastrophically growing DM epidemic. In the history of the UN, this was the fourth resolution and the first one dedicated to the combating a non-communicable disease; the resolution for the first time called for the development and initiation of government programs to reduce global risks associated with DM in all countries of the world. Later in 2015, the UN General Assembly approved a strategy for the development of healthcare and medicine until 2030. Among the global goals, this very essential document included measures to control the growing non-communicable epidemics, namely DM and obesity, as well as the cardiovascular risks associated with these diseases and the prevention of cardiovascular events and mortality.

In 2023, WHO, together with the International Diabetes Federation, as part of the implementation of this development strategy, named the key targets to be achieved by 2030 [2]:

- at least 80% of people with diabetes are diagnosed;
- at least 80% of people with diagnosed diabetes have good control of glycemia;
- at least 80% of people with diagnosed diabetes have good control of blood pressure;
- at least 60% of people with diabetes of 40 years or older receive statins;
- 100% of people with type 1 diabetes have access to affordable insulin and blood glucose self-monitoring.

The list of these tasks once again emphasizes the importance of a comprehensive multifactorial approach to DM aimed at early diagnosis of carbohydrate metabolism disorders and control of all pathogenetic mechanisms associated with the development of diabetic complications.

In the Russian Federation, as in other countries, an epidemic increase in the prevalence of DM is also observed: since 2000, the number of DM patients has increased by more than 2 times [3]. According to the Federal State Statistics Service (Rosstat) and Russian Research Institute of Health, the increase in the number of patients with DM for the period 2009–2023 amounted to 74.5%; the total number of diabetes in the Russian Federation as of 01.01.2024 is 5,547,879 people, of which the vast majority are adults with T2DM — 5,168,374; 349,338 people are patients with T1DM, of which 288,020 adults and 61,318 children (under 18 years old) [4, 5].

Since 1996, for three decades, the State Research Center "National Medical Research Center of Endocrinology" of the Ministry of Health of Russia has been carrying out continuous clinical and epidemiological monitoring of DM in the Russian Federation through the Federal Diabetes Mellitus Register (formerly State Diabetes Mellitus Register), which was founded on the initiative of Academician I.I. Dedov in the process of implementation of the Federal Target Program (FTP) "Diabetes Mellitus" [6]. In the 2000s, FTP "Diabetes Mellitus" became a unique state program in the medical industry, the implementation of which allowed for the creation of create a modern structure of the diabetic service of Russia: establishment of more than 70 regional diabetic centers, about 200 diabetic foot rooms, more than 120 specialized ophthalmological rooms for the treatment of diabetic retinopathy, more than 1,100 schools of therapeutic education for DM patients (adults and children), first ever Diabetes and Pregnancy rooms in Russia [6].

In the diabetic service system, the Database of Clinical and Epidemiological Monitoring of Diabetes Mellitus in the Russian Federation has become a key clinical and

analytical tool for controlling DM, through which comprehensive ongoing monitoring of the disease was initiated, with the possibility of personalized assessment of a specific patient and aggregated assessment of big data. Over the years, the register has gone a long way from filling out paper maps to a unique information and analytical platform with regional centers of the register in all constituent entities of the Russian Federation. Since 2014, the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation has been transformed into a system with a unified online data entry format, access authorization, and a standardized remote analytics function. Since 2022, the database has integrated a medical decision support system (MDSS), which provides control of the diagnostic and therapeutic algorithm of DM in accordance with clinical guidelines (CG). Since 2024, the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation has used only domestic software (https://www.diaregistry.ru/).

The Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation is used not only for standard statistical analysis of prevalence and incidence rates. Thanks to the state-of-the-art analytical platform, it has become a unique tool for analyzing epidemiological, demographic, clinical and therapeutic indicators of DM, which allows targeted assessment of information characterizing the quality of diabetic care in a particular region and throughout the country [7–12].

This makes it possible to position the Database of Clinical and Epidemiological Monitoring of DM not only as a powerful statistical system, but precisely as a clinical tool for monitoring, assessing the long-term prognosis and controlling the quality of the management of patients with DM in accordance with international targets and current domestic clinical guidelines [13–16], which determined the purpose and objective of our study.

PURPOSE OF THE STUDY

To carry out an analysis of epidemiological, clinical and therapeutic characteristics of DM control in the Russian Federation (RF) for the period 2009-2023 according to the strategic objectives adopted by the World Health Organization at the 75th Assembly in 2022.

WHO strategic objectives for achieving DM targets by 2030 [2]:

- at least 80% of people with diabetes are diagnosed;
- at least 80% of people with diagnosed diabetes have good control of glycemia;
- at least 80% of people with diagnosed diabetes have good control of blood pressure;
- at least 60% of people with diabetes aged 40 years or older receive statins;
- 100% of people with type 1 diabetes have access to affordable insulin and blood glucose self-monitoring.

MATERIALS AND METHODS

The study was performed on the basis of the de-personalized Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation, database registration certificate No. 2020622447 (http://diaregistry.ru).

To assess the quality of DM detection and diagnosis, we used data obtained during the national epidemiological study NATION conducted in 2016 and including 27,252 people from 63 regions of Russia [17]. This study evaluated the criteria for diagnosed and undiagnosed DM by HbA_{1c} level in the age groups 20–79 years. If $HbA_{1c} \geq 6.5\%$ (≥48 mmol/mol) was detected in a person without a previous history of DM, this person was given a diagnosis of newly diagnosed T2DM.

To assess the remaining WHO's strategic objectives, was analyzed the depersonalized Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation, which includes T1DM and T2DM patients from 87 regions of the Russian Federation who are under routine follow-up at the primary health care institutions (n=5,062,511 at the time data retrieval on 01.07.2024).

1. Quality of glycemic control in DM patients:
   - this indicator was evaluated if patient's data were available in the "HbA_{1c}" field of the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation; the target for glycemia control was defined as the achievement of $HbA_{1c}<7\%$, according to the Russian clinical guidelines [13–16];
   - estimated proportion of patients achieving target glycemic control:

$$N\,(\%) = \frac{\text{Number of DM patients with } HbA_{1c}<7\%}{\text{Number of DM patients with specified } HbA_{1c}} \times 100\%.$$

2. Quality of blood pressure control in DM patients:
   - this indicator was evaluated if patient's data were available in the "Blood pressure" field of the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation; the target for blood pressure control was defined as the achievement of systolic blood pressure (SBP)of ≤130 mmHg and ≥120 mmHg and diastolic blood pressure (DBP) of ≤80 mmHg and ≥70 mmHg according to the Russian clinical guidelines [18];
   - estimated proportion of patients achieving target BP control:

$$N\,(\%) = \frac{\text{Number of DM patients who acieved SBP} \leq 130 \text{ mmHg and DBP} \leq 80 \text{ mmHg}}{\text{Number of DM patients with specified BP}} \times 100\%.$$

Statin therapy in patients with DM:

- the indicator was evaluated if two criteria were met: 1) DM patient age ≥40 years, 2) statin therapy is indicated in the "lipid-lowering drugs" field of the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation;
- estimated proportion of patients on statin therapy:

$$N\,(\%) = \frac{\text{Number of DM patients aged 40+ with information about prescription of statins}}{\text{Number of DM patients}} \times 100\%.$$

3. Insulin use:
   - the indicator was evaluated if insulin therapy was indicated in the "Diabetes mellitus therapy" section of the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation;
   - calculation of the indicator:

$$N\,(\%) = \frac{\text{Number of DM patients on insulin therapy}}{\text{Number of DM patients who need insulin therapy}} \times 100\%;$$

   - taking into account that in the Russian Federation insulin is provided for 100% of DM patients, we assessed the structure of prescribed insulin therapy and calculated the proportion of prescriptions of insulin analogs, recombinant human insulin (RHI), and analog + RHI for T1DM and T2DM patients on insulin therapy.
4. Use of glycemic self-monitoring in T1DM:
   - taking into account that in the Russian Federation glucometers and test strips are provided for 100% of T1DM patients, we calculated the proportion of T1DM patients using continuous glucose monitoring (CGM) devices:

$$N\,(\%) = \frac{\text{Number of T1DM patients using CGM}}{\text{Number of T1DM patients}} \times 100\%.$$

Ethical review

Analytical studies based on the Database of Clinical and Epidemiological Monitoring of Diabetes Mellitus in the Russian Federation have been approved by the local ethical committee of the State Research Center of the Russian Federation of the Federal State Budgetary Institution "National Medical Research Center of Endocrinology" of the Ministry of Health of Russia, the approval is contained in the protocol No. 20 of December 14, 2016.

RESULTS

The results obtained in terms of the targets stated by WHO are presented in Table 1.

The current Russian clinical guidelines for the diagnosis and treatment of T1DM and T2DM in children and adults [13–16] have been approved by the Scientific and Practical Council of the Ministry of Health of Russia and published in the Clinical Guidelines Rubricator (https://cr.minzdrav.gov.ru/) in June 2022.

Table 1. Targets according to the requirements of the World Health Organization according to clinical and epidemiological monitoring of diabetes mellitus in the Russian Federation

No.	Target set by WHO	Results of assessment of WHO targets based on data of clinical and epidemiological monitoring of DM in the Russian Federation
1	Diagnosis of DM in 80% of affected individuals	Currently, the Russian Federation actively implements programs to conduct preventive medical examinations and identify disorders of carbohydrate metabolism. According to the large-scale national epidemiological study (NATION), which included more than 26 thousand people from 63 regions of the Russian Federation, the percentage of patients with undiagnosed T2DM in the Russian Federation averaged 54%, that is, every second patient with DM was not aware about his/her disease [17]
2	Good control of glycemia in 80% people with diagnosed diabetes	Target glycated hemoglobin (HbA_{1c}<7%) is achieved in 29% of patients with T1DM and 42% of patients with T2DM, for a total of 41% of patients with DM
3	Good control of blood pressure in 80% people with diagnosed diabetes	SBP ≤130 mmHg and DBP ≤80 mmHg are achieved in 84% of patients with T1DM and 60% of patients with T2DM, for a total of 61% of patients with DM
4	Statin therapy 60% in people with DM aged 40 years and older	* The proportion of patients receiving statins aged 40 years and older is 14.1% of patients with T1DM, 15.9% of patients with T2DM, for a total of 15.9% of patients with DM
5a	Ensuring access to insulins	100% of patients with T1DM and T2DM are provided with insulin free of charge under the Program on State Guarantees for the Free Provision of Medical Care, of which insulin analogs are 84.8% for T1DM patients and 60.9% for T2DM patients, the rest are recombinant human insulins
5b	Making self-monitoring glycemic tools affordable for 100% individuals with T1DM	Self-monitoring tools (glucometers and test strips) are provided for 100% of patients with DM, in addition, patients with T1DM under the age of 18 are provided with continuous glycemia monitoring (CGM) systems and consumables for them

* filling the field on prescription of statins is not mandatory in the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation, and therefore this indicator may be underestimated.

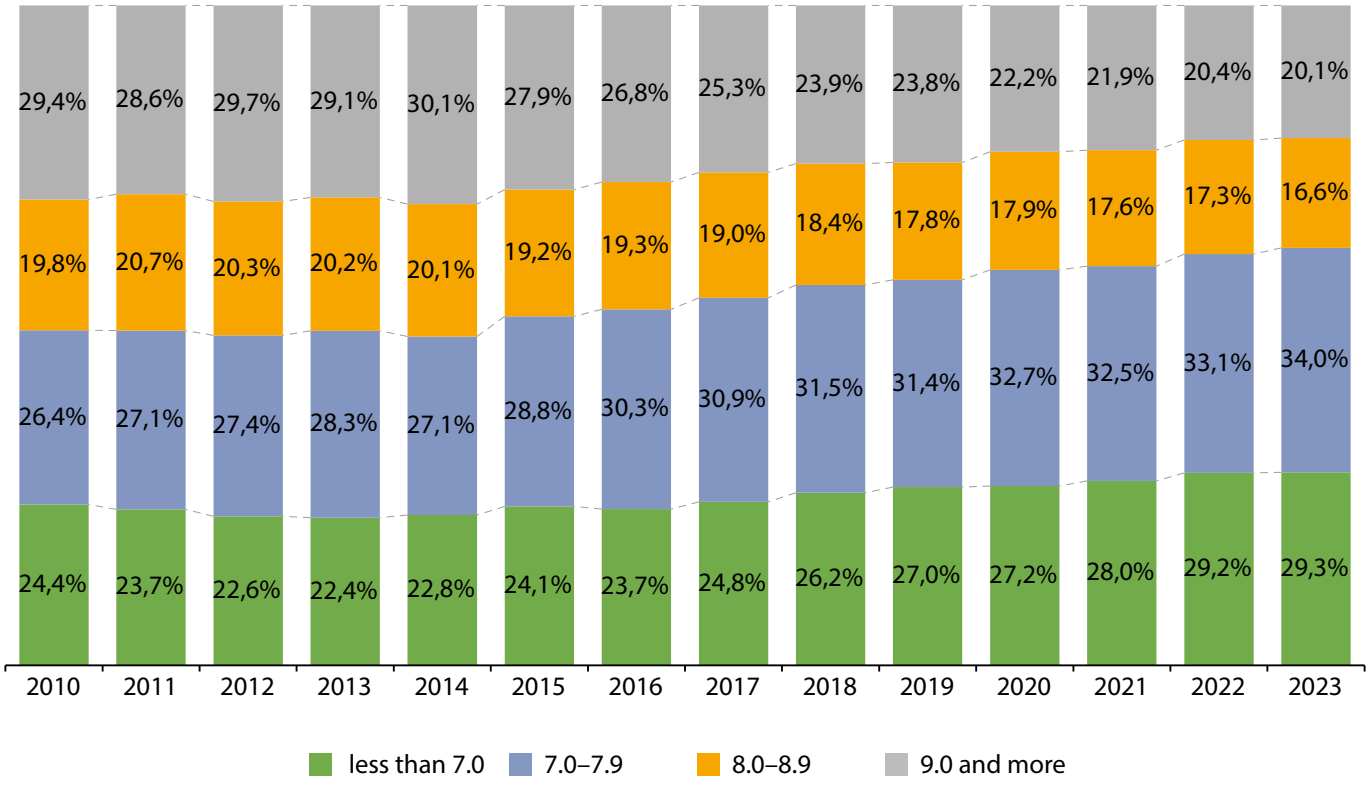

Figure 1a. Distribution ranges of HbA_{1c} levels (laboratory-measured indicator) in patients with type 1 diabetes mellitus across all age groups from 2010 to 2023, based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation (87 regions).

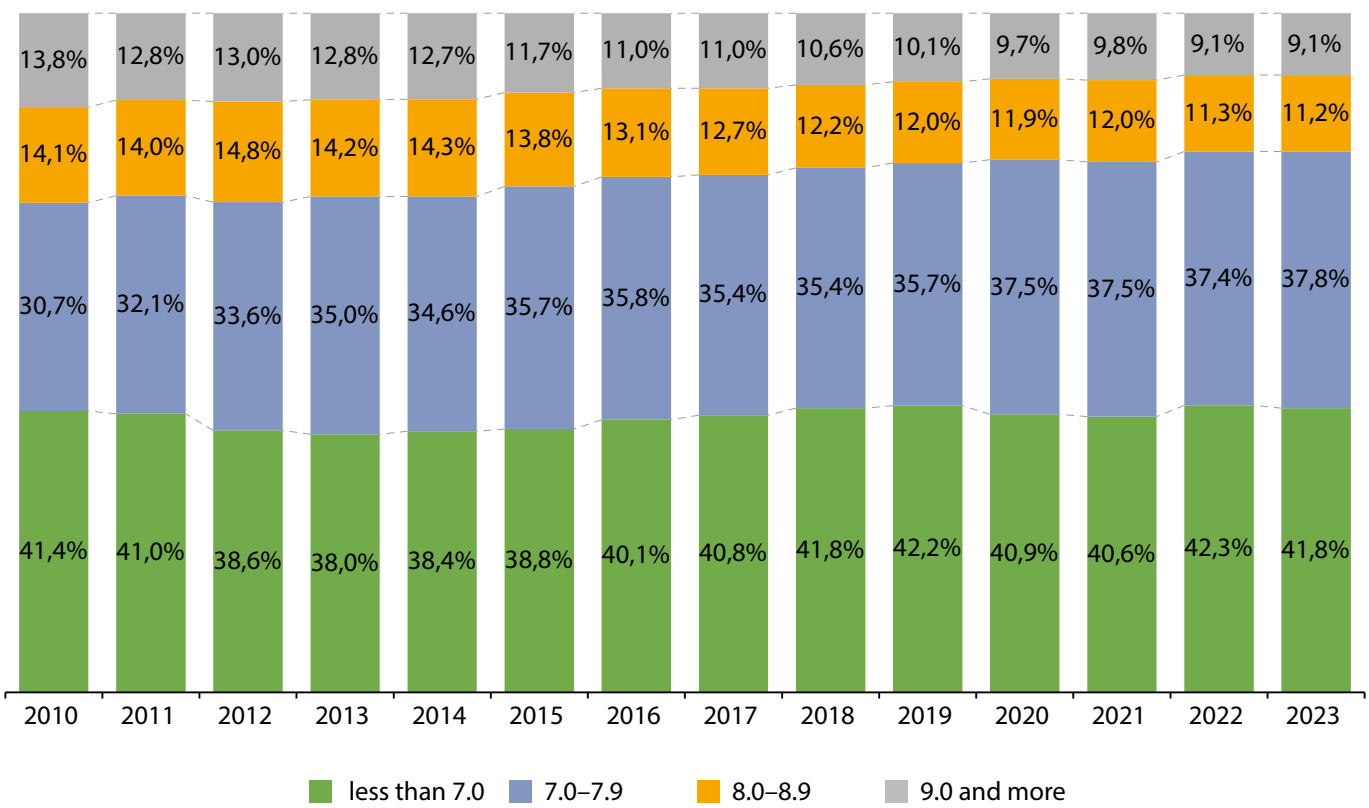

Figure 1b. Distribution ranges of HbA_{1c} levels (laboratory-measured indicator) in patients with type 2 diabetes mellitus across all age groups from 2010 to 2023, based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation" (87 regions).

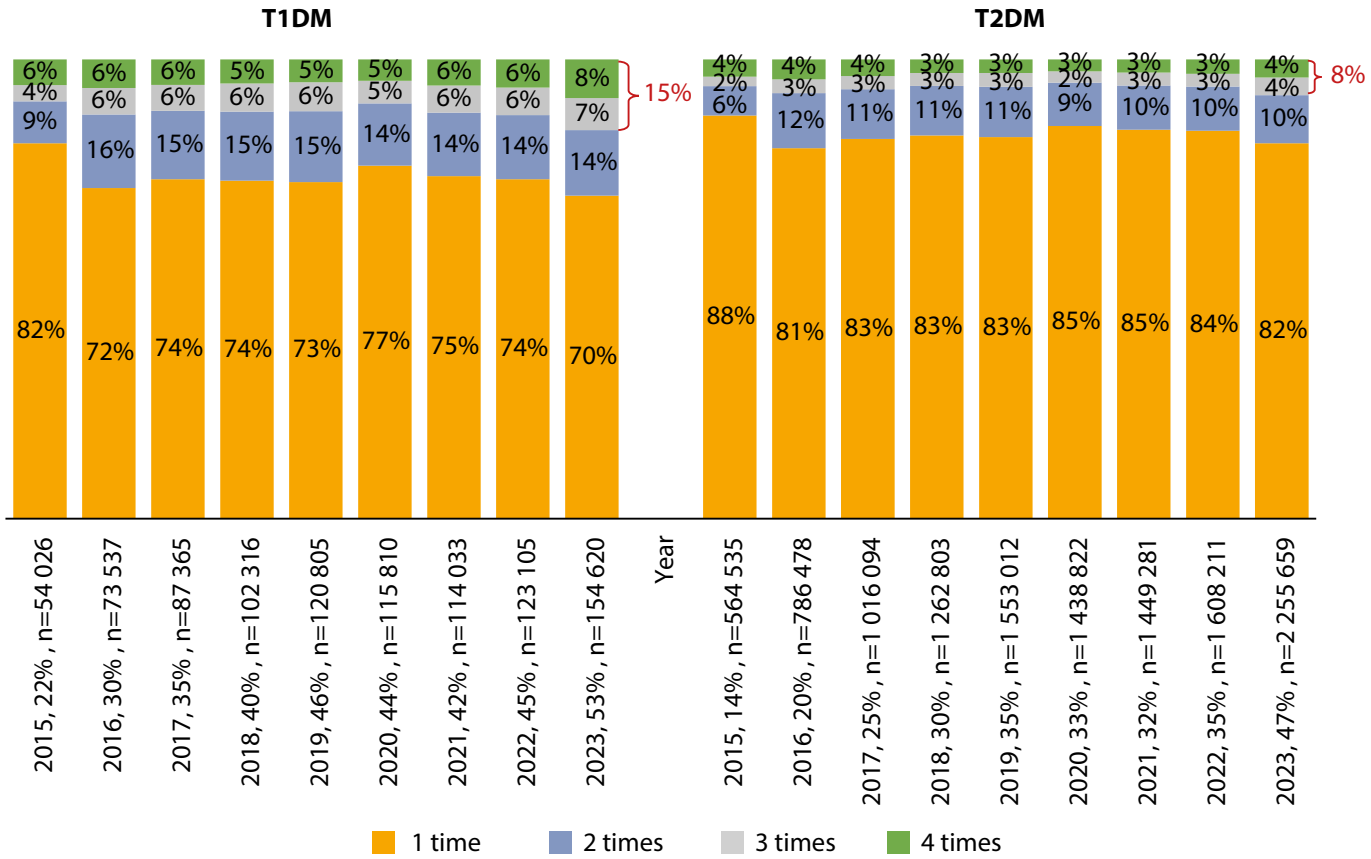

Figure 2. Frequency of laboratory tests for glycated hemoglobin (HbA_{1c}) in patients with type 1 and type 2 diabetes mellitus from 2015 to 2023, based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation (87 regions).

The key indicators of the WHO 2030 strategy were adopted as measures aimed at increasing the number of people covered by the diagnostic measures to detect carbohydrate metabolism disorders to have DM timely diagnosed in at least 80% of people who have to be able to correct cardiovascular risk factors early. Achieving the target glycemic control is seen as a basic strategy for preventing the risk of diabetic complications and associated cardiovascular diseases. In turn, the correction of arterial hypertension (AH) and dyslipidemia are the leading measures of the multifactorial approach in the protection of target organs in DM patients, along with glycemic control. The social and economic aspects of DM, namely the availability of modern glucose-lowering therapy, first of all the elimination of insulin deficiency and self-monitoring of glycemia by patients, are integral factors in achieving targeted control of DM and preventing the risks of complications.

According to the 2021 IDF Atlas, the number of DM patients in the world has reached 537 million adults and 1.2 million children and adolescents, which corresponds to 10.5% of the total population; in the countries of the European Region, the prevalence of the disease varies from 4.0% (Ireland) to 15.9% (Turkey) [1]. According to the data of clinical and epidemiological monitoring in the register, DM prevalence in the Russian Federation is 3.3% in the total population [20].

Comparison with the results of NATION epidemiological study where active screening detected T2DM in 5.4% of people [17] clearly demonstrates the problem of insufficient diagnosis and verification of carbohydrate metabolism disorders. The solution of this problem is one of the key tasks for the near future as part of the implementation of the Russian Federal Project "Combating diabetes mellitus".

The analysis of the clinical and demographic parameters of DM in the NATION study showed an increase in T2DM prevalence with patient age: for age over 45 years, it reaches 9.5% [19], with the highest proportion of undiagnosed DM in the age group 65-69, accounting for 61% of the examined persons of this age [17]. The observed trends correspond to global trends of higher prevalence of T2DM in older people [1, 4, 5].

Regarding the gender distribution of DM patients in the Russian Federation, there is a significantly higher proportion of women — two-thirds of the total number of patients with T2DM — 70.0% in 2021 [12] and 65.5% in 2023 [20].

Assessment of the carbohydrate metabolism compensation showed that the target HbA_{1c} (<7.0%) is achieved in 29% of T1DM patients and 42% of T2DM patients from the total number of patients with available laboratory values of HbA_{1c} (Figures 1a and 1b).

Among patients with available data on HbA_{1c}, the overwhelming majority have this indicator measured only once a year — 71% of T1DM and 82% T2DM patients; in only 15 and 8% of patients, respectively, the recommended test frequency of 3–4 times a year is achieved (Fig. 2).

According to the clinical and epidemiological monitoring of DM, 100% of T1DM patients in the Russian Federation are provided with insulin, among them 84.8% of patients use modern human insulin analogs (Fig. 3). In the pediatric

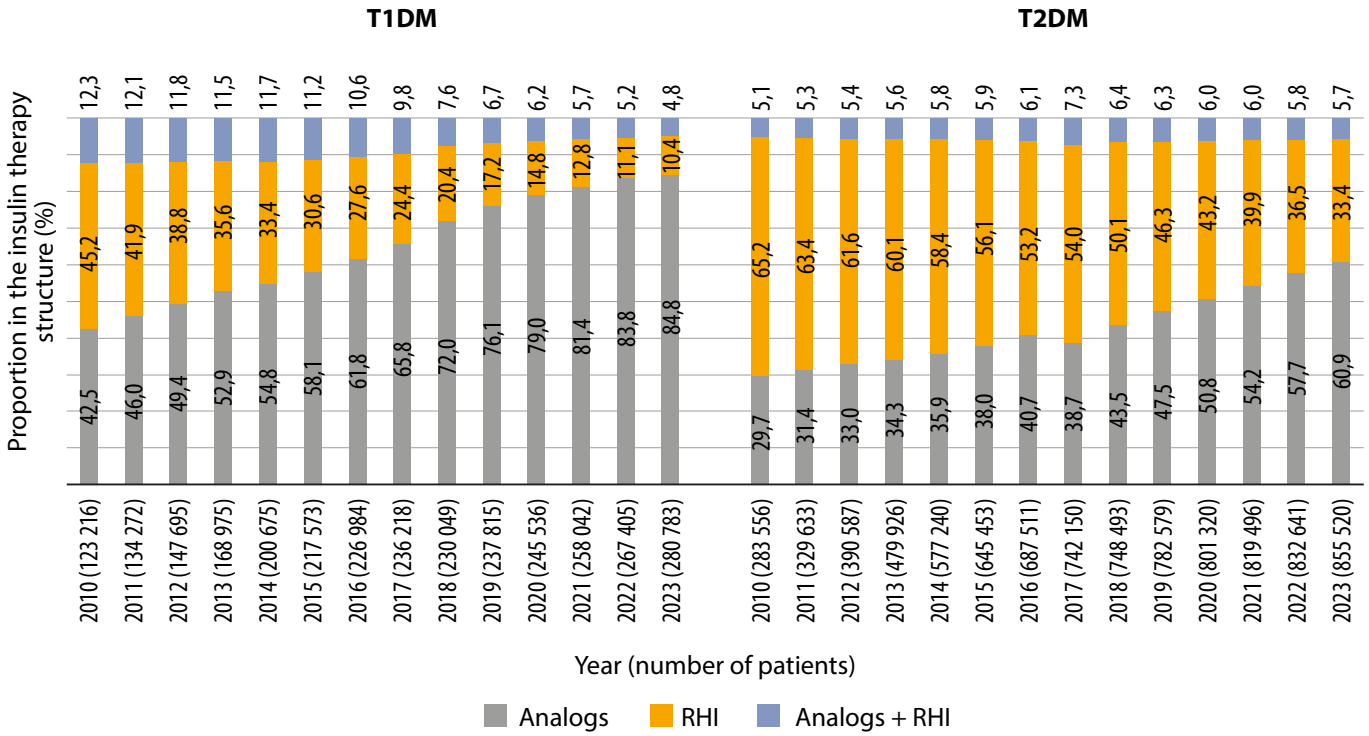

Figure 3. Dynamics of insulin therapy structure in patients with type 1 and type 2 diabetes mellitus (insulin analogues, recombinant human insulin, their combination) from 2010 to 2023, based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation" (87 regions).

cohort of T1DM patients (under 18 years of age), insulin analogs are prescribed in almost 100% of cases (Fig. 4), 24% of children and adolescents use insulin pump therapy (Fig. 4).

All patients with T2DM are also provided with insulin products, over the past decade there has been an increase in the prescriptions of insulin analogs for T2DM from 29.7 to 60.9% (Fig. 3).

DISCUSSION

WHO Target 1: Diagnosis of DM

DM is a disease with epidemic rates of increase in prevalence in all countries. In the Russian Federation the number of DM patients has more than doubled over the past 20 years: from 2 million to more than 5 million patients, including by more than 1 million over the past 5 years [3, 5]. But even these alarming statistical data do not reflect the depth of the problem, since the statistics takes into account only patients who have a diagnosis and are followed-up.

According to estimates of epidemiological studies with active screening in the world and in the Russian Federation, the quality of DM diagnosis is about 50%, i.e. for each detected case there is one undiagnosed patient. Insufficient detection of DM is consistent with data from the International Diabetes Federation stating 46% of undiagnosed DM worldwide in the latest issue of IDF Diabetes Atlas. Extrapolating the percentage of undetected DM according to the NATION results to the general population of Russia, we can say that the actual number of DM is 2 times higher than the registered one, i.e. 10–12 million patients.

According to IDF estimates, 537 million patients in the world have a diagnosis of DM, which corresponds to a prevalence of 10.5% among adults aged 20 to 79 years [1, 21, 22], although these figures vary from 1% to 15% in different countries [21]. This variability in prevalence is largely due to the quality of T2DM detection, which accounts for about 98% of all DM diagnoses in the world. When analyzing data from the National Health Interview Survey in 2016 and 2017, the prevalence of diagnosed T2DM among the adult population in the United States was 8.5% [23]. Other US national databases, such as the Center for Disease Control and Prevention Diabetes Surveillance System, provided data on the total prevalence of DM in 2024: 11.6% in the population — 38.4 million people, of which 29.7 million were diagnosed DM and 8.7 million — undiagnosed DM, which is T2DM in 95% of cases [24]. Given the significant increase in obesity, including in childhood and adolescence, there are concerns that the global prevalence of T2DM will continue to grow. Global data confirm this negative trend. For example, the incidence rate of T2DM among adolescents and young adults (aged 15 to 39 years) in the period from 1990 to 2019 increased from 117 to 183 per 100 thousand population, i.e. more than 1.5 times [25]. Outside the United States, T2DM is most common on the islands of Polynesia (~25%) with similarly high rates in the Middle East and South Asia (in particular, Kuwait and Pakistan) [1, 26]. In China, the most populous country in the world, 13% of the adult population is diagnosed with diabetes, while there is a general problem of insufficient diagnosis of diabetes, when half of the patients (51.7%) are unaware of their diagnosis [1, 27].

The epidemic increase in the prevalence of DM is caused by many factors, including the aging of the population. With a general desire to increase life expectancy, society should be ready for the accumulation of age-associated diseases: T2DM, CVD, cancer, degenerative diseases, etc. Age is one of the most significant and non-modifiable risk factors;

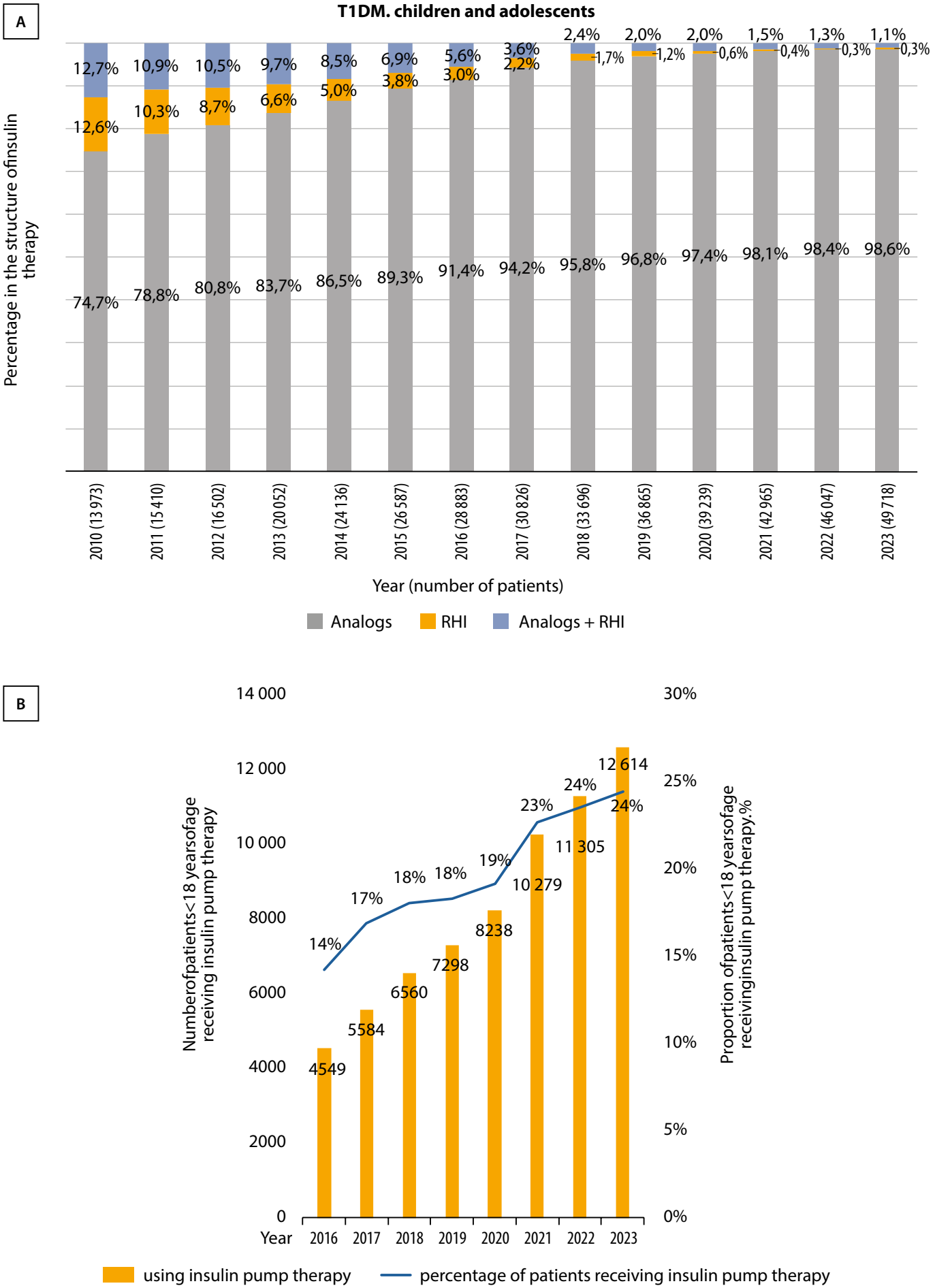

Figure 4. Dynamics of insulin therapy structure (analogues, recombinant human insulin (RHI), their combination), and insulin pump therapy in patients under 18 years old with type 1 diabetes mellitus from 2010 to 2023 and 2016 to 2023, based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation (87 regions).

in these conditions, attention should be focused on the possibility of correcting other factors associated with the development of DM — a "diabetogenic" lifestyle. Excessive caloric nutrition, physical inactivity, stress — all this leads to weight gain and obesity, increasing the risk of T2DM.

T1DM has a fundamentally different mechanism of development: it is characterized by chronic, immune-mediated destruction of beta cells, which leads to absolute insulin deficiency. T1DM is an autoimmune multifactorial disease; however, the exact mechanisms of interaction of genetic predisposition, environmental factors, and the state of the immune system underlying the pathogenesis of T1DM are still under study [15].

With regard to gender, the risk of developing T2DM in men and women is the same, since lifestyle factors that are independent of gender are predominant. However, there are more women in the total number of T2DM patients in some countries, which is associated with gender redistribution of the general population, especially in older age groups.

To prevent global risks associated with the epidemic of chronic non-communicable diseases (CNCDs), the National Guidelines for the Prevention of CNCDs, which include T2DM, have been adopted in the Russian Federation. This document establishes at the national level the need for an integrated approach to the mitigation of consequences associated with these diseases, including not only healthcare, but also education, culture, media, finance and trade systems. Key priorities include preventive measures aimed at early detection of diseases, timely treatment measures, and control of trends. To this end, in primary health care, a doctor of any specialty, not only an endocrinologist, should be focused on identifying high-risk groups for carbohydrate metabolism disorders and should strictly follow the diagnostic algorithm. Expert assessments show that preventive measures are a promising economic investment that reduces the need for more expensive treatment [28].

WHO Target 2: HbA_{1c}

The level of glycated hemoglobin (HbA_{1c}) is the main indicator of the degree of carbohydrate metabolism compensation in DM patients [29].

According to international and Russian guidelines, the choice of glycemic control targets should be personalized depending on many parameters of clinical status (patient age, life expectancy, functional dependence, and the presence of atherosclerotic CV diseases and the risk of severe hypoglycemia). For most DM patients, HbA_{1c} less than 7.0% is necessary and sufficient to achieve the primary goal of reducing the risk and progression of diabetic complications. According to the clinical and epidemiological monitoring of DM, in the Russian Federation, the target HbA_{1c} is achieved in 29% of T1DM patients and 42% of T2DM patients.

It should be noted that in different regions of the world, the proportion of patients who achieve target HbA_{1c} remains insufficient and varies depending on the type of DM, the source of data and the method used for continuous or selective assessment of HbA_{1c} in the study cohort. For example, in the study based on the registry of England, with the HbA_{1c} target of <7.5%, the proportion of patients in the target range was 36.3% for T1DM and 63.1% for T2DM; the study covered 79% patients with T1DM and 90% patients with T2DM [30].

Regular monitoring of HbA_{1c} should be carried out in order to assess the effectiveness of glucose-lowering therapy and make a timely decision on the need for its intensification. However, the frequency of HbA_{1c} assessment is currently far from the provisions of the clinical guidelines. According to the data of clinical and epidemiological monitoring of DM in the Russian Federation, among patients with available information about HbA_{1c} the recommended test frequency of 3–4 times a year is achieved only in 15% of T1DM cases and 8% of T2DM cases.

Currently, various digital assistants are being actively introduced into healthcare, including medical decision support systems (MDSS) designed to support medical specialists in real clinical practice. In 2022, the MDSS was introduced into the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation, which allows monitoring the appropriate diagnostic and therapeutic algorithm for DM in accordance with the current clinical guidelines [20].

HbA_{1c} is a universal predictor of the risk of DM development and diabetic complications. Large international clinical studies in T1DM and T2DM (UKPDS, ADVANCE, VADT, ACCORD, DCCT/EDIC, etc.) provided convincing data on the key value of strict glycemic control for the prevention of the risk of diabetic complications [29, 31–35].

Considering the priority of HbA_{1c} for clinical monitoring of DM patients, the Federal Project "Combating diabetes mellitus" sets the coverage at least 98% of patients by testing as one of the key indicators. To this end, the provision of regions with HbA_{1c} analyzers has been increased, which will make it possible to increase the testing frequency in a sufficient amount in the near future.

WHO Target 3: Good control of blood pressure in 80% people with diagnosed diabetes

The frequency of hypertension in T2DM reaches 80-90%; in T2DM patients [37] hypertension is often a condition preceding the development of carbohydrate metabolism disorder. In an additional sub-analysis of CV risk factors in the NATION study, the proportion of patients reporting a diagnosis of AH was 23.2%, of which 13.3% of patients were diagnosed with T2DM; among people who received antihypertensive therapy as a criterion for the presence of hypertension, the proportion of patients with T2DM and prediabetes was higher and amounted to 14.7% and 38.2% respectively [18].

The blood pressure control targets significantly changed over the past 10 years. The leading international cardiology and diabetes associations have reached a consensus on the need to follow the strict therapeutic range of the target BP in DM, given the highest risks of progression of CV complications [13, 14, 18].

Since 2018, the mandatory SCORE2 CV risk assessment for DM patients has been canceled, since these patients are automatically classified as having very high and high CV risk (with the exception of T1DM patients younger than 35 years and T2DM younger than 50 years without target organ damage and duration of DM <10 years classified as having moderate CV risk) [23].

According to international and Russian recommendations — European Society of Cardiology (ESC), European Society of Hypertension (ESH) [37], Russian Association of cardiologists [18], and clinical guidelines for T1DM and T2DM [13, 14] the uniform BP targets for adult DM patients receiving antihypertension therapy are as follows: target SBP <130 and ≥120 mmHg for age group 18–65 years and <140 and ≥130 mmHg for age over 65 years; DBP <80 and ≥70 mmHg regardless of age.

When analyzing the achievement of WHO targets for blood pressure, it was found that according to the data of clinical and epidemiological monitoring of DM in the Russian Federation, the target BP level in DM patients receiving antihypertensive therapy is achieved in 84% and 60% of T1DM and T2DM patients, respectively (Table 1). ESSE-RF and ESSE-RF2 studies in the Russian population of persons with CV risk factors, including hypertension and obesity, do not, unfortunately, present data on achieving the proportion of patients with target BP, however, it is indicated that 24.9% of people with hypertension control BP with the help of drug therapy and only 49.7% of patients with hypertension are treated effectively [38]; while the proportion of patients who do not control their BP was shown to decrease from 78.5 to 73.0% [39].

The advantages of combined antihypertensive therapy are explained by multifactorial genesis of AH. According to ESSE-RF studies, the most common combination of antihypertensive therapy in the general population was a combination of ACE inhibitors and a diuretic (ESSE-RF: 49.1%; ESSE-RF2: 45.9%). The second place in ESSE-RF belongs to combination of diuretic + angiotensin II receptor blockers (25.8%); in ESSE-RF 2 — calcium antagonist + ACE inhibitor (22.4%). The combination of ACE inhibitor and calcium antagonist was found only in 8.7% cases in ESSE-RF, while in ESSE-RF2 the proportion of this combination increased by 2.5 times [38].

Drug therapy of hypertension in DM also involves a focus on combination therapy, the recommended first-line therapy includes drugs with angio-, cardio- and nephro-protection properties — this is a group of renin angiotensin system inhibitors (ACE and ARB inhibitors).

Thus, BP control, along with glycemic control, is one of the key factors in preventing the development and progression of diabetic complications and is an integral part of the algorithm for monitoring DM patients.

WHO Target 4: Lipid-lowering therapy

Along with hyperglycemia and hypertension, lipid spectrum disorders have a significant impact on the development of diabetic vascular complications. Dyslipidemia in DM is characterized by an increase in the formation rate and concentration of very low density lipoprotein (VLDL), a decrease in high density lipoprotein (HDL), hypertriglyceridemia, and an increased concentration of free (non-esterified) fatty acids (NEFA). At the same time, the total cholesterol (TC) level may be within the reference values or only moderately increased. A key indicator for monitoring of lipid disorders in DM is LDL. Impaired lipid metabolism leads to the progression of vascular complications of DM, which emphasizes the importance of achieving personalized lipid targets.

According to the 2023 Clinical Guidelines for lipid metabolism disorders and 2022 Clinical Guidelines for DM, the target levels of LDL, as well as glycemic targets, should be personalized depending on the patient's CV risk [13, 16, 40].

Data from our analysis of the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation to achieve the targets set by WHO showed that the proportion of DM patients over the age of 40 receiving statins is only 14.1% of T1DM patients and 15.9% of T2DM patients (Table 1). Of course, when interpreting this indicator, one should take into account the limitations associated with the method of reporting data on concomitant therapy to the register, since this field of the online map is not mandatory. On the other hand, for comparison, the data for Russian general population with CC risk factors in the ESSE-RF study are indicative and demonstrate that among high and very high risk individuals who made up 31.3% of the surveyed cohort, only 13.6% of men and 18.2% of women were aware that they have elevated level of total cholesterol, while only ~7.0% of patients were taking statins, of whom the LDL cholesterol target was reached in 14.4% of men and 4.8% of women [41].

Thus, the data obtained emphasize the relevance of the problem of prescribing lipid-lowering therapy and achieving lipid spectrum targets in risk populations — in DM patients and in persons with CV risk factors in equal measure, which requires an increase in the activity of preventive examinations in the general population and improvement of programs for DM patients monitoring.

WHO Target 5: Access to affordable insulin and blood glucose self-monitoring

In the original version of the WHO document, this target is worded as follows: "100% of people with type 1 diabetes have access to affordable insulin and blood glucose self-monitoring" (without specification of insulin type and type of glucose monitoring tool). Thus, the priority of provision of insulins and glucose self-monitoring tools for T1DM patients is emphasized, because for them insulin is a vital drug. Nevertheless, in terms of modern approaches to the management of DM patients, in order to reduce the risks of complications and mortality, this target can be extrapolated to the entire cohort of DM patients, including T2DM patients.

Insulin replacement therapy is the only treatment for T1DM patients. For T2DM patients, there should be awareness of the insulin therapy option if targeted control of carbohydrate metabolism cannot be achieved using non-insulin strategies, given the significant role of beta cell dysfunction in T2DM progression.

According to our analysis, the achievement of this WHO target is 100%. Patients with T1DM are provided with insulins under the program of state guarantees, while in the Russian Federation there is an unprecedented high use of insulin analogs, which have the advantages of a lower risk of hypoglycemic conditions and/or glycemic variability, for example, insulin analogs are provided for 84.8% of T1DM patients [13]. In the pediatric cohort of T1DM patients (under 18 years of age), insulin analogs are prescribed in almost 100% of cases; 24% of children and adolescents use insulin pump therapy. If insulin therapy is prescribed to patients with T2DM, they are also fully provided with insulin and there is an increase over the past decade in the prescriptions of insulin analogs in T2DM from 29.7% to 60.9%.

Randomized clinical trials and meta-analyses confirm that modern glycemic monitoring tools are the most important option for improving glycemic control parameters. For example, according to a large meta-analysis of 15 studies from 12 to 36 weeks with a total of 2,461 patients, the use of CGM was associated with a moderate decrease in HbA_{1c} and an increase of the "time in range" (TIR) [42]. In addition, CGM provided additional benefits of reducing the risk of hypoglycemia, including a significant reduction of the "time below range" (TBR) and glycemic variability (CV) compared to the use of glucometers and test strips [13, 14, 21]. Under the Federal Project "Combating diabetes mellitus" CGM systems are provided for children and adolescents since 2023 and for pregnant women with DM since 2024.

CONCLUSION

DM is a CNCD, which global social significance is associated with the risks of early disability and high mortality from vascular catastrophes and diabetic complications. More than 80% of premature deaths due to CNCDs depend on manageable/modifiable risk factors.

This position seems to be extremely important in terms of the possibilities of influencing the prognosis and outcomes for DM patients, provided that disorders are detected early and appropriate therapy is started in a timely manner. In order to implement this concept, WHO has set specific clinical targets for diabetes control. Success in achieving these targets depends on public policy at the level of legislative and administratively regulated measures aimed at optimizing the health care system and improving the quality of care provided for DM patients.

The unified DM control system based on the Database of Clinical and Epidemiological Monitoring of DM in the Russian Federation allocates priority areas at the national level to achieve the set targets. A key part of this strategy is a comprehensive approach to the problem of DM, including the development and implementation of prevention and health promotion programs at the population level; proactive preventive measures for high-risk groups; ensuring maximum coverage of the population with effective therapeutic and preventive measures. Under these conditions, the Federal Project "Combating diabetes mellitus" started in 2023 should become a priority project for consolidating the efforts of various health professionals in implementing measures to mitigate medical and social costs of diabetes in the Russian Federation.

ADDITIONAL INFORMATION

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