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REVIEW

From global experience to the Russian future: strategic vectors for the development of pediatric hematology and oncology

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ABSTRACT

The article focuses on the analysis of current issues and challenges facing pediatric oncology and hematology. Data on cancer incidence in children at the level of economic development of the state, relative to the healthcare model are provided. The main characteristics of oncological care systems in economically developed countries and in developing countries around the world are identified, and the features of the Russian model are emphasized. Particular attention is paid to recent technologies and development vectors of molecular-targeted, cell therapy, precision surgery. The role of information technology and digital transformations in increasing the efficiency of healthcare models for providing oncological care to children in Russia is shown. National and foreign experience convincingly proves that a breakthrough in pediatric oncology is possible only with a systematic approach combining scientific innovations with access to medical care. Russia, being at a unique stage of development, demonstrates both significant successes in the field of high technologies and persistent structural problems. Thus, the key vector of development is not only the introduction of individual innovations but also solving

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fundamental tasks of standardization, overcoming regional inequality, and developing personnel potential, which will allow fully realizing the accumulated scientific and clinical potential.

Key Words: pediatric oncology; oncohematology; healthcare system; model challenges; medical technologies; molecular and cellular treatment methods; oncosurgery; prospects

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Introduction

Pediatric oncology and hematology remain one of the most rapidly developing fields in modern medicine. Despite the achievements of recent decades, malignant neoplasms (MN) in children continue to be a leading cause of mortality from non-communicable diseases. A key challenge is the pronounced inequality in survival rates: in high-income countries (HICs), the 5-year survival rate exceeds 80%, while in resource-limited countries it does not reach 30%.

Modern systems of care for children with oncohematological diseases are directly dependent on the level of infrastructure, availability of highly qualified personnel, and innovative technologies. In the modern world, progress is driven by the standardization of therapy protocols, initiation and participation in multicenter studies, and the implementation of precision and personalized medicine. Persistent barriers, found almost everywhere, are primarily related to late diagnosis and a shortage of qualified specialists. Russia currently occupies a unique position: on one hand, major federal centers have accumulated extensive experience in hematopoietic stem cell transplantation (HSCT), gradual digitalization is occurring, and new treatment methods are being introduced; on the other hand, disparities in the quality of care between federal centers and regions have not yet been fully overcome, and charitable organizations continue to play a significant role in financing medical care. Prospects for development in this area are associated with accelerating the pace of technological transformation of the industry, digitalization, the establishment of national registries, the development of genomic technologies, and expanding access to targeted and cellular therapies.

The international landscape of pediatric hematology and oncology: achievements and challenges

Modern pediatric oncology and hematology represent a field of medicine where scientific achievements stand in sharp contrast to global inequality in access to healthcare. On one hand, it is a story of triumph: thanks to decades of international collaboration and systematic clinical research, in HICs, the 5-year survival rate for children with cancer has exceeded 80%, especially for acute lymphoblastic leukemia (ALL) (Table 1) [1, 2]. On the other hand, these successes remain virtually inaccessible to the vast majority of the world's children living in low- and middle-income countries (LMICs). This disparity is due not so much to tumor biology

Table 1. Evolution of overall survival in children with acute lymphoblastic leukemia [1, 2, 4]

Protocol	Number of patients	5-year survival, %
BFM-90	469	68%±3%
MB-91	460	72%±2%
MB-2002	1544	76%±1%
MB-2008	3466	86%±1%

Note: 5-year survival is represented as mean ± standard deviation. BFM – international clinical protocol of treatment patients with acute lymphoblastic leukemia The Berlin–Frankfurt–Münster consortium; MB – International clinical protocol of treatment patients with acute lymphoblastic leukemia Moscow–Berlin.

as to fundamental differences in the organization, funding, and functioning of national healthcare systems [3].

The high-income countries model

Healthcare delivery systems in HICs (North America, Western Europe, Australia) are characterized by several key principles that have enabled therapeutic breakthroughs:

- Large research groups and standardization of therapy protocols. The foundation of success has been the creation of cooperative groups (e.g., Children's Oncology Group in the United States of America, the Berlin–Frankfurt–Münster consortium in Europe, the Moscow–Berlin protocol in Russia), which has allowed for large-scale randomized clinical trials, rapid data accumulation, protocol standardization, and finding effective solutions even for rare tumors [5, 6].
- Patient risk stratification. Modern treatment is based on the principle of therapy individualization depending on various clinical and molecular-genetic parameters. Using high-precision methods, including genetic techniques and minimal residual disease assessment, patients are stratified into risk groups. This allows for reducing therapy intensity and subsequent toxicity for patients with a favorable prognosis and, conversely, applying more aggressive approaches for high-risk patients, thereby increasing the chances of cure [7].
- Reduction of therapy toxicity. As overall survival has increased, the system has faced a new challenge – the "cost of cure." Aggressive therapy in the 1970s–80s led to a high frequency of severe adverse reactions (secondary tumors, cardiomyopathies), resulting in reduced quality of life and increased mortality among survivors. Analysis of these long-term consequences within studies such as the Childhood Cancer Survivor Study became the basis for revising protocols and modifying therapy. Targeted reduction of doses, the volume of radiation therapy, and cumulative doses of anthracyclines led to a statistically significant reduction in mortality among patients treated in the 1990s compared to the 1970s [7].
- Funding. Treatment is typically covered by national or private health insurance systems, ensuring a high level of access to expensive drugs and technologies [3].

The main challenge for systems in HICs today, and Russia is no exception, is the treatment of complex cases (early relapses, as well as refractory tumors) and further personalization of therapy (Table 2).

The low- and middle-income countries model

In most countries of Asia, Africa, and Latin America, the care system is fragmented and faces barriers at every stage of the "treatment cascade."

Table 2. Key characteristics of medical care models for children with malignant neoplasms worldwide

Parameter	HICs (USA, Europe, Canada), incl. Russia	LMICs (Asia, Africa, Latin America)	"Hybrids" (India, Latin America, Africa)
System organization	Integrated, multicenter networks (cooperative groups), standardized protocols	Fragmented systems, weak routing, infrastructure deficit	Centers of "excellence hubs," public-private partnerships, twinning programs
Diagnostics	Access to modern molecular and genetic diagnostics, minimal residual disease assessment	Access to molecular-genetic diagnostics is limited	Modern diagnostics available in major centers
Funding	Government or insurance coverage, access to expensive therapy	Lack of universal insurance, out-of-pocket expenses (up to 60%)	Mixed: government programs + NGOs + international grants (St. Jude, GFAOP, foundations)
Quality of therapy	Risk-stratified therapy, access to transplantation, CAR-T	Lack of standard protocols, personnel shortage, high mortality	Some protocols adapted, staff training, improving quality in pilot centers
5-year overall survival	>80–90% (for ALL in leading centers)	<30-40% on average, with wide variation (<25% in Africa)	In successful centers, approaches HIC levels
Main challenges	Complex cases, integration of costly innovations, minimizing late complications	Late diagnosis, treatment abandonment, drug shortages, personnel deficit	Scaling up experience, expanding coverage, sustainable government funding
Successful examples	COG (USA), BFM (Europe), CCSS, MB (Russia)	Tata Memorial (India), hospitals in Africa with limited support	Renaci Foundation (Paraguay), Fundación Ayúdame a Vivir (El Salvador), PhilHealth (Philippines), GFAOP (Africa)

Note: HICs – high-income countries; LMICs – low- and middle-income countries; NGOs – non-governmental organizations; GFAOP – Franco-African Pediatric Oncology Group; CAR-T – chimeric antigen receptor T-cells; ALL – acute lymphoblastic leukemia; COG – Children's Oncology Group; BFM – international clinical protocol of treatment patients with acute lymphoblastic leukemia The Berlin–Frankfurt–Münster consortium; CCSS – Childhood Cancer Survivor Study; MB – international clinical protocol of treatment patients with ALL Moscow–Berlin.

Problems and challenges:

- Large-scale of "under-diagnosis". According to models presented in the Lancet Oncology Commission report, up to 44% of all childhood MN cases worldwide remain undiagnosed. In low-income countries, this figure can exceed 55%. This means that for every child diagnosed, there is another who dies without a correct diagnosis and adequate care [3].
- Funding and treatment abandonment. Funding systems in LMICs are extremely heterogeneous. In most, government insurance is absent or covers a small portion of costs. This forces patient families to bear catastrophic out-of-pocket expenditures, which are the main reason for the high rate of treatment abandonment. In some regions, treatment abandonment is the leading cause of death, affecting up to 60% of patients [3, 8, 9].
- Resource deficits and low quality of care. Even if a child reaches a specialized center, they face problems such as: a) a shortage of highly qualified personnel, especially nurses, pathologists, and pediatric oncologists; b) a lack of supportive therapy in the form of safe blood components and drugs, basic antibiotics; and c) a high prevalence of nutritional deficiency (up to 50–70% of patients), which collectively leads to high mortality from toxicity and infections [3, 8].
- Limited access to high technologies: Many countries experience shortages of basic chemotherapy drugs. Access to radiation therapy and qualified surgery is extremely limited; for example, 80% of the African population lacks access to radiation therapy [8, 9].

International experience shows that successful strategies are built on the adaptation and creation of hybrid models based on interaction between major centers and international partners.

The model of "centers of excellence" and the role of partnerships can be illustrated by the examples of African and South Asian countries (India). In countries with huge populations and a deficit of government funding, care has historically developed around individual large centers (e.g., Tata Memorial Hospital in India). These centers, often with the support of international partners (twinning programs), achieve good and quality results. The experience of the "My Child Matters" program showed that even local projects focused on training medical personnel, improving diagnostic methods, or organizing palliative care can serve as catalysts for larger-scale changes. Thus, the creation of the African School of Pediatric Oncology was a good and quality response to the personnel deficit; the implementation of this program has trained many highly qualified specialists in pediatric oncology.

Latin American countries: the model of public-private partnership and "network" interaction

The experience of this region demonstrates the high effectiveness of public-private partnerships. In El Salvador and Guatemala, services were created through the cooperation of public hospitals, local foundations, and international partners. A unique example of a solution is the national care network in Paraguay (Renaci Foundation), which united the country's three disparate healthcare systems. The creation of satellite clinics allowed for the decentralization of care and reduced the rate of treatment abandonment for ALL from 17.5% to 0%[1] [3, 9].

Analysis of international experience, summarized in the Lancet Oncology Commission report, showed that modifying the oncology care system could not only prevent over 6 million childhood deaths by 2050 but also bring colossal benefits to the global economy: every dollar invested returns three dollars through the future contribution of surviving patients.

The care system in the Russian Federation: current state and main challenges

Currently, the healthcare system of the Russian Federation faces both traditional, historically established tasks and new ones dictated by modernity. According to expert assessment, the issue of developing and expanding primary medical care remains relevant [10, 11]. A comparative 20-year analysis of the healthcare system in the European Union and the Russian Federation showed that inpatient care still predominates in our country, and the expansion of primary care occurs through hiring new staff rather than expanding their authority. At the same time, researchers note significant growth in preventive measures and successes in early disease diagnosis, as well as a reduction in hospital bed capacity and a decrease in the average length of patient hospital stay. Forming a unified preventive environment requires active state participation, additional funding, and the development of regional programs to combat MN, taking into account local characteristics.

Funding for medical care for children with oncological and onco-hematological diseases in the Russian Federation today is a complex, multi-level ecosystem based on the principle of segmented financial responsibility. This model is not monolithic but consists of four key, complementary elements:

(1) the compulsory medical insurance (CMI) system, covering basic and specialized medical care;
(2) direct budgetary funding from the federal and regional budgets for providing high-tech medical care (HTMC);
(3) the state fund "Krug Dobra" (Circle of Kindness), ensuring access to innovative and orphan drugs, unique medical care technologies;

[1] Gupta S, Howard SC, Hunger SP, et al. Treating childhood cancer in low- and middle-income countries. In: Gelband H, Jha P, Sankaranarayanan R, Horton S, eds. Cancer: Disease Control Priorities, Third Edition (Volume 3). The International Bank for Reconstruction and Development / The World Bank; 2015. Accessed 20.11.2025. https://openknowledge.worldbank.org/server/api/core/bitstreams/62c36567-a0c0-52c4-9720-85b1dfcbbd69/content

(4) the non-governmental sector represented by charitable foundations, compensating for systemic gaps and providing non-medical support.

The foundational document securing citizens' right to free medical care is the Constitution of the Russian Federation. Federal Law No. 323-FZ of November 21, 2011, "On the Fundamentals of Protecting the Health of Citizens in the Russian Federation," establishes constitutional guarantees in the field of healthcare and serves as the legal basis for all subsequent programs and funding mechanisms. The relevance of the regulatory framework is maintained by regular amendments; the latest changes, clarifying, in particular, the concept of clinical recommendations, were introduced into the law in July 2025. It is this act that defines the state's guarantee of medical care for neoplasms, creating a legal obligation realized through specific financial instruments discussed below.

An analysis of the four main elements of funding shows that they function not as isolated structures but as elements of a single, albeit complex, integrated ecosystem.

To illustrate their interaction, consider a hypothetical patient pathway:

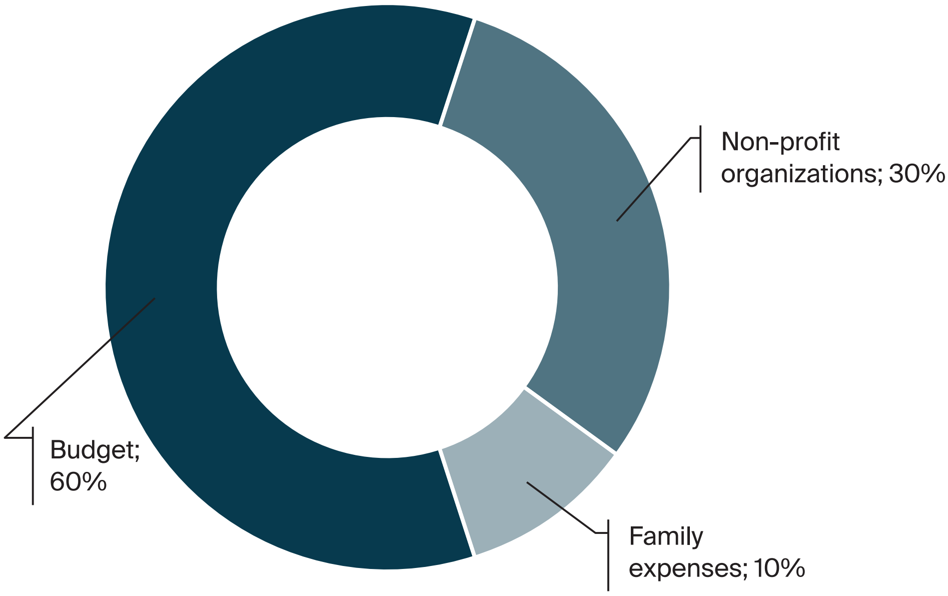
(1) CMI: Primary diagnosis, standard chemotherapy courses, hospitalization, and stay of a legal representative in the ward are paid for from CMI funds according to relevant clinical-statistical groups.
(2) "Krug Dobra": During treatment, it is determined that standard therapy is ineffective, and a medical council prescribes an innovative targeted drug not registered in Russia. An application is sent to the "Krug Dobra" fund, which organizes the purchase and delivery of the drug.
(3) HTMC (Budget): Treatment leads to remission, but its consolidation requires a bone marrow transplant from an unrelated donor. This type of care falls under HTMC, not included in the basic CMI program, and is funded directly from the federal budget.
(4) Charitable Foundations: The family lives in a remote region. A charitable foundation pays for air tickets to the federal center where the transplant will be performed and provides accommodation outside the hospital for the period of post-transplant outpatient observation.

This example demonstrates that all four funding channels may be involved for the successful treatment of one child. The strength of this model is its multi-level nature and ability to provide a comprehensive approach, from basic care to the most advanced technologies and social support. Figure and Table 3 present the structure and volumes of funding for medical care for children with MN.

According to external assessments, our country has noted a necessary focus on the performance indicators of the World Health Organization, which helps identify weaknesses and adjust management decisions. A deficit of motivation and knowledge among pediatricians, as well as their insufficient awareness of MN prevention and early diagnosis, has been identified [12]. This is confirmed by the fact that over 30% of physicians participating in surveys had an insufficient level of knowledge about MN. Also, to reduce mortality and improve treatment outcomes, it is necessary to improve the material and technical base and introduce modern standards of diagnosis and treatment into the regions [13].

Order No. 55n of the Russian Ministry of Health dated 05.02.2021 establishes a three-level system of medical care. It regulates that medical care must be provided in accordance with clinical recommendations and standards. To date, unified standards and professional standards for physicians have been developed and are being implemented, allowing for the unification of approaches to diagnosis and treatment. This is the result of the joint work of the Russian Society of Pediatric Oncologists and Hematologists, Dmitry Rogachev National Medical Research Center

FIG. Structure and volumes of funding for medical care for children with malignant neoplasms



of Pediatric Hematology, Oncology and Immunology, and other federal centers with the support of the National Medical Chamber [14]. The start time for specialized care for oncological diseases should not exceed 14 calendar days, which is an important step in combating the problem of late diagnosis [15].

In modern Russian pediatric oncology and hematology, there is a clear trend towards the formation of multidisciplinary teams, which is essential for treating complex cases. This approach is one of the key components of success through the exchange of accumulated experience, along with the interaction of national centers with leading professional societies both within our country and abroad.

According to the standardized incidence rate of MN among children (0–14 years), the Russian Federation ranks 42nd in the world, with this indicator being 44.7% higher than the global average [16]. Using the Northwestern Federal District as an example, a decrease in mortality and an increase in survival rates are noted [17]. In the period 2005–2010, the 5-year survival rate of adolescents with MN (15–17 years) was 68.1%, and in 2011–2020 it was already 73.4%. This demonstrates a positive trend in the system of pediatric oncology care. Nevertheless, despite improvements in diagnostics, the problem of late detection of MN remains;

Table 3. Funding sources and volumes for pediatric oncology care in the Russian Federation (estimated)

Funding source	Funding volume	Note
Compulsory medical insurance (oncology part)	389.9 billion rubles	Targeted budget within CMI for all oncology care (adult and pediatric)
"Krug Dobra" fund	218.9 billion rubles	Total fund budget for 106 severe and orphan diseases, including oncological
High technology medical care (HTMC, oncology part)	~32.7+ billion rubles (estimated)	Estimation is based on 2024 data (32.7 billion rubles) considering general HTMC budget increase in 2025
Non-governmental funds	> 2.2 billion rubles (estimated)	Estimation is based on annual expenses of the largest specialized fund "Podari Zhizn" (Give Life) in 2024

Note: CMI – compulsory medical insurance; HTMC – high-tech medical care.

the rate of active detection is 4.7–7.9% (compared to over 20% in the adult population). This dictates the need to make efforts to improve the system of early screening and increase oncological alertness among physicians.

The current agenda in pediatric oncology and hematology in Russia is closely linked to the implementation of the National Project "Healthcare," specifically the federal project "Combating Oncological Diseases" [18]. Initially, pediatric oncology was not explicitly highlighted in this project, but a decision was later made to include it, which allowed for significant funding from 2021. From 2025, new federal projects are taking over, particularly "Family" and "Long and Active Life," which, within the framework of the "Protection of Motherhood and Childhood" program, are designed to ensure the further development of high-tech medical care for children. Thus, national projects serve as a key tool for the systemic development of pediatric oncology and hematology in Russia, providing its funding and infrastructure renewal.

Having analyzed the models, from integrated systems in HICs to fragmented approaches in LMICs, it is important to determine Russia's place in this global landscape. The domestic healthcare system combines features of both models: the presence of powerful federal "centers of excellence" comparable to the best world centers, and systemic challenges characteristic of resource-limited countries, especially at the regional level. Let's examine these features in detail.

Vectors of transformation in pediatric oncology and hematology: from innovative therapy to digitalization

Innovative approaches in therapy

Russia is actively introducing new, as well as modernizing and improving existing approaches to therapy in pediatric oncology and hematology. Among the main therapeutic directions, targeted drugs, immunotherapeutic and transplantation approaches stand out, allowing for a significant improvement in prognosis even for the most complex patient categories.

Targeted and immunotherapy

Among cases of malignant diseases, there are frequent instances where standard therapy approaches based solely on chemotherapy are powerless, which necessitates the search for new methods. Thus, following foreign experience, the inclusion of rituximab in the standard protocol for the treatment of relapsed B-cell non-Hodgkin lymphomas in our country has increased the 10-year event-free survival to 93.8% [19]. Similarly, blinatumomab is actively used for the treatment of relapsed acute lymphoblastic leukemia (ALL), serving as a "bridge" to HSCT and allowing the achievement of remission in the majority of patients. Early inclusion of blinatumomab in the ALL-REZ 2016 protocol showed an increase in event-free survival by more than 2 times compared to the ALL-REZ 2014 protocol.

Modern, highly effective approaches to the treatment of relapsed and refractory forms of Hodgkin's lymphoma (HL) are also successfully applied. The use of the GVD (gemcitabine, vinorelbine, pegylated liposomal doxorubicin) protocol in combination with pembrolizumab showed high efficacy, allowing more than 2/3 of patients with HL relapse to achieve a complete metabolic response [20]. The possibility of applying personalized therapy is based on the rapid development of molecular-genetic and cytogenetic research methods, thanks to which “targets” characteristic of the tumor in a particular patient become clear to physicians. Thanks to this, a system for early prediction of Ewing sarcoma progression, based on clinical, laboratory, and molecular-genetic indicators, has been developed and successfully tested in Russia. This system allows for dividing patients into groups with different risks of progression, enabling treatment personalization [21].

Transplantation technologies

Hematopoietic stem cell transplantation, where healthy, fully functional hematopoietic cells from a donor are transplanted to a recipient, replacing “pathological” hematopoiesis, remains the main method of treating many onco-hematological diseases. In Russia, this method is being actively modernized to achieve a balance between the graft-versus-leukemia effect and graft-versus-host disease. At Dmitry Rogachev National Medical Research Center of Pediatric Hematology, Oncology and Immunology, a platform for HSCT with $\alpha\beta$-T-lymphocyte depletion has been developed and successfully tested, allowing for significant time savings and the use of haploidentical parents as donors. This approach reduced transplant mortality to 2% (compared to 13% in a historical cohort) and accelerated immune reconstitution (recovery of the immune system) [22]. A reduced-toxicity conditioning regimen based on thiotepa and treosulfan for patients with primary immunodeficiencies has also been developed and successfully tested, thanks to which the period after HSCT proceeds with fewer side effects [23].

In the treatment of resistant neuroblastoma at Raisa Gorbacheva Memorial Research Institute for Pediatric Oncology, Hematology and Transplantation (Saint Petersburg), combined RIST (rapamycin, irinotecan, sunitinib, temozolomide) therapy followed by haploidentical HSCT is successfully used, achieving a long-term response in 20% of patients [24]. For consolidation of remission in patients with high-risk solid MNs, tandem HSCT is used. The two-year overall survival in this group is 53.8%, and event-free survival is 46.2%, which is comparable to world data [25].

Cellular technologies

Chimeric antigen receptor T-cells (CAR-T) therapy continues to be actively introduced into clinical practice. This method of cellular therapy is aimed at producing special lymphocytes that recognize and eliminate malignant cells from the patient’s body. Experts emphasize its high efficacy in the treatment of relapsed and refractory forms of B-cell ALL.

An important step in solving organizational problems related to the legal aspects of the production and implementation of biomedical cellular products (BMCP) and high-tech medicinal products (HTMP) was the Decree of the Government of the Russian Federation dated December 13, 2024, No. 3736-r [26]. This document approves the list of medical organizations that receive the right to manufacture and apply biomedical cellular products for individual medical use. The list includes 11 institutions, demonstrating strategic support for the development of a local “academic” model of CAR-T production.

The list includes leading research centers located not only in Moscow and St. Petersburg but also in the regions (Novosibirsk, Tomsk, Kazan, Vladivostok). This fact indicates a targeted creation of regional biotechnological clusters. This is a practical response to the need for local production capacities and may become the basis for the further development and expansion of access to cellular therapy in the country.

In the Russian Federation, research and development of CAR-T therapy are conducted in several large scientific and clinical centers.

A distributed network of research and clinical centers working on the implementation and improvement of CAR-T therapy is being formed in Russia, reflecting the strategic importance of this technology for healthcare.

Russia is conducting its own clinical trials of CAR-T (Table 4) [27, 28].

These examples show that pediatric onco-hematology is one of the priority areas in the development of CAR-T therapy in the Russian Federation. The focus on a comprehensive safety assessment demonstrates the responsible approach of Russian scientists to translating CAR-T technologies into clinical practice, which is critically important for patient protection.

High-tech and reconstructive surgery

Surgery in pediatric oncology in Russia goes beyond simple tumor removal, turning into a high-tech direction focused on preserving quality of life. A number of the most dynamically developing oncological surgical vectors can be identified:

- Complex oncological surgery. Russian centers successfully perform the most complex operations for rare tumors, such as calcifying nested stromal-epithelial tumor of the liver. Radical tumor removal through mesohepatectomy and anatomical liver resection is the only effective treatment method, and its successful performance without complications demonstrates the high level of qualification of surgeons [29].
- Minimally invasive methods. Minimally invasive surgical methods, such as laparoscopy and thoracoscopy, are being actively introduced. They allow reducing the trauma of operations, shortening the postoperative period, and ensuring rapid patient rehabilitation. For example, minimally invasive nephrectomies for kidney tumors comply with all principles of oncological surgery and have a number of advantages over open operations.
- Organ-sparing operations. In the treatment of renal cell carcinoma, the possibility of performing organ-sparing operations without worsening the prognosis is indicated, which allows preserving kidney function, especially in patients with bilateral tumors or a single kidney.
- Reconstructive surgery. Separate attention is paid to reconstructive surgery, including the use of additive technologies, which allows restoring aesthetic and functional characteristics after radical tumor removal, optimizing the organizational model of medical care for this category of patients. The successful application of precision prosthetics technologies based on individual prototyping, "growing" prostheses, and new materials has opened a new chapter in pediatric oncological orthopedics and maxillofacial oncological surgery [30].

Table 4. Clinical trials of CAR-T conducted in the Russian Federation

Study / drug	Organization	Description	Patient groups
MB-CAR-T 19.1	Dmitry Rogachev National Medical Research Center of Pediatric Hematology, Oncology and Immunology	Academic production of anti-CD19 CAR-T lymphocytes	Pediatric patients with relapsed or refractory B-cell ALL
In-house production and therapy	FSBI "NMRCO named after N.N. Blokhin" of the Ministry of Health of Russia	Academic production of CAR-T lymphocytes	Planned application in pediatric cohort
Utzhefra drug development	FSBI "NMRCH" of the Ministry of Health of Russia	Production of HTMP	Adult patients with B-cell ALL

Note: CD – cluster of differentiation; CAR-T – chimeric antigen receptor T-cells; ALL – acute lymphoblastic leukemia; HTMP – high-tech medicinal products.

Improvement of supportive therapy and rehabilitation

Improvement of supportive therapy and rehabilitation is an integral part of clinical success in the treatment of MN in children. According to modern concepts, it is often properly conducted supportive therapy and the fight against complications that can guarantee a positive outcome of therapy. Here it is also important to highlight a number of areas:

- Nutritional Support. A particularly important subject of observation is the full enteral nutrition of the patient; not always do children retain their previous appetite after such aggressive treatment, and the placement of a nasogastric tube in some cases can represent serious psychological discomfort. Percutaneous endoscopic gastrostomy is successfully used as a minimally invasive and effective method of long-term nutritional support in children with oncological diseases, improving their quality of life and reducing risks associated with other feeding methods.
- Complication Management. Russian centers are developing and implementing methods for treating rare and severe therapy complications: for example, the use of daratumumab has shown high efficacy in the treatment of partial red cell aplasia after HSCT. The drug romiplostim is successfully used to treat severe resistant immune thrombocytopenia in children, allowing to avoid long-term immunosuppressive therapy. The course of infectious complications during periods after chemo- and immunotherapy are frequent but no less dangerous complications that pose a mortal danger to oncological and hematological patients. An important achievement is the introduction of strict protocols for infection control and prevention of infectious complications, which is crucial for the safety and survival of immunocompromised children.
- Psychological Support. For the first time in Russia, a prospective study of the quality of life and subjective well-being of families of patients receiving HSCT was conducted. The results show that the most psychologically difficult stage is the preparation for transplantation, which justifies the need for early and active psychological support. It is noted that a family approach in support is key to successful rehabilitation [31].

Digital transformation

The digital transformation of the healthcare system is one of the strategic priorities of the state policy of the Russian Federation. Unlike the market-oriented model of the United States of America or the decentralized European one, the domestic approach is characterized by the construction of a unified, vertically integrated system with a leading role of the state. A key tool for these changes has been the federal project “Creating a Unified Digital Circuit in healthcare based on the Unified State Information System in Healthcare (EGISZ).” Its goal is to form a holistic digital environment to improve management efficiency, as well as the quality and accessibility of medical care, which is of particular importance for such a complex and high-tech field as pediatric oncology and hematology.

“Unified digital circuit” and telemedicine

The basis of digitalization is the Unified State Information System in Healthcare platform, designed to unite medical organizations of all levels. For pediatric oncology, where treatment lasts for years and often requires the participation of both regional clinics and federal centers, creating a unified information space based on electronic medical records is critically important for ensuring continuity of therapy. However, a key barrier on this path is the lack of a single standard for medical information systems. The historically established diversity of regional and hospital medical information systems, often incompatible with each other, creates significant difficulties for data aggregation and exchange. For a child with acute leukemia, this may mean that detailed information about conducted chemotherapy courses, results of minimal residual disease monitoring, or arising complications will not be "seamlessly" transferred from the regional dispensary to the federal center, complicating decision-making and increasing risks. The situation is exacerbated by the different levels of technical equipment in the regions.

Against this background, telemedicine consultations in the "doctor–doctor" format are developing most successfully. Leading federal institutions, such as the Dmitry Rogachev National Medical Research Center of Pediatric Hematology, Oncology and Immunology, actively use this tool to maintain communication with regional clinics. Through telemedicine, consultations on complex clinical cases are conducted to correct diagnostic and therapeutic tactics. The potential of "doctor-patient" consultations can be used for discussing control examinations after the main stages of therapy, for dynamic monitoring of children with orphan hematological diseases.

Application of artificial intelligence

Russia demonstrates continuity in mastering technologies based on artificial intelligence, primarily in the analysis of medical images. The Moscow experiment on the use of artificial intelligence for the analysis of radiological studies showed high diagnostic efficacy [32]. In perspective, such technologies can be adapted for the needs of pediatric hematology/oncology, for example, for the primary diagnosis of onco-hematological diseases through the analysis of bone marrow or peripheral blood smears, using computer vision for the analysis of magnetic resonance and computed tomography images.

However, scaling up such programs is limited by two main problems:

(1) Quantitative and qualitative data deficit: Hematological and oncological diseases in children are rare, which makes it difficult to collect sufficient data for training artificial intelligence models. It is also appropriate to mention registry filling; mainly, the attending physician is responsible for filling out registries, but given the high workload on physicians in federal centers, registry filling does not always occur with quality and regularity. In this regard, the creation of representative national datasets requires centralized efforts to collect information.

(2) Lack of specialists in related fields: There is an acute shortage of specialists with competencies at the intersection of pediatric hematology, oncology, and data science, which are necessary for the development and clinical validation of such complex systems.

National registries: potential and risks

The next stage in the development of the patient accounting system was the creation of vertically integrated medical information systems (VIMIS), in particular, for the "Oncology" profile, which includes pediatric patients. VIMIS are complex analytical tools for collecting clinical data in real-time.

The potential of VIMIS for pediatric oncology is enormous; the accumulated anonymized data ("Big Data") can become the basis for conducting quality multicenter research, allowing for the assessment of protocol effectiveness, analysis of various outcomes, and the formation of patient cohorts for studying the long-term consequences of therapy, by analogy with international studies.

However, the main challenge for the effectiveness of VIMIS is ensuring the completeness and quality of primary data. The high administrative burden on physicians combined with their different levels of digital literacy creates a risk of entering incomplete or heterogeneous information. In pediatric hematology/oncology, where treatment protocols are multi-stage, poor-quality registry filling can completely devalue the record for subsequent analysis, posing risks of distorting conclusions both in the managerial and scientific spheres.

Conclusion

National and foreign experience convincingly proves that a breakthrough in pediatric oncology is possible only with a systematic approach combining scientific innovations with access to medical care. Russia, being at a unique stage of development, demonstrates both significant successes in the field of high technologies (HSCT, CAR-T) and persistent structural problems. Thus, the key vector of development is not only the introduction of individual innovations but also solving fundamental tasks of standardization, overcoming regional inequality, and developing personnel potential, which will allow fully realizing the accumulated scientific and clinical potential.

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