

WAYS OF IMPROVING THE LEGAL REGULATION OF HUMAN ORGAN AND TISSUE TRANSPLANTATION IN THE RUSSIAN FEDERATION

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Over the past 10 years, significant breakthroughs have been achieved in Russian transplantology in the field of regulatory legal framework. During this period, the powers of government authorities in the field of health-care on organization of transplant care and organ donation have been defined, and sources and mechanisms for target financing of medical activities related to organ donation for transplantation purposes have been identified. The procedure for providing medical care under surgery (human organ and/or tissue transplantation) has been adopted, and a state registry system for donor organs, donors and recipients has been created. Measures on organ donation and transplantation in the Russian Federation have been approved within the "Healthcare Development", a framework of the state program of the Russian Federation. The Shumakov National Medical Research Center of Transplantology and Artificial Organs (Shumakov Center) has also been identified as the core institution that coordinates the activities of the entire transplant industry in the Russian Federation. Transplant medical care is currently being provided by specialist physicians trained in human organ and tissue transplantation, in collaboration with other specialist physicians. The Nomenclature of Specialties of Specialists with Higher Medical and Pharmaceutical Education, approved by the Russian Ministry of Health via Order No. 700n of October 7, 2015, does not contain a separate specialty related to human organ and tissue transplantation activities, and this is quite justified. However, in order to improve the legal regulation of transplantation activities, it is necessary to unify the requirements for specialists providing medical care in human organ/tissue transplantation. This can be achieved by developing uniform approaches to the definition of labor functions in the professional standards of specialist doctors involved in transplantation.

Keywords: organ donation, organ transplantation, tissue transplantation, donation and transplantation law, donation and transplantation procedure, donation and transplantation licensing, medical personnel, nomenclature of medical specialties, nomenclature of medical services, professional standards of specialist physicians, organ and tissue transplantation, surgery, transplant team.

According to the Constitution of the Russian Federation, a person, their rights and freedoms are the supreme value, and the recognition, observance and protection of human and civil rights and freedoms are the duties of the state; everyone has the right to life and the right to health protection and medical care. Among the inalienable human rights is also the right to physical integrity, enshrined in Article 22 of the Constitution of the Russian Federation, which excludes unlawful influence on a person in both physical and mental sense [1], and the concept of "physical integrity" covers not only the lifetime existence of the human body, but also creates the necessary prerequisites for the legal protection of the body of a deceased person. This applies equally to

the right to state protection of personal dignity, as well as to the human right, derived from these constitutional rights to a dignified handling of the human body after death.

When performing organ and/or tissue transplantation, the task is to achieve a balance of constitutionally significant values and protected rights that do not violate the rights of any of them, which are determined by the legal regulation in this sphere, taking into account, among other things, moral, social and other aspects.

In the Soviet Union, organ transplantation started developing in the 1960s. However, until 1985, only kidney transplantations were performed in the Soviet Union; the possibility of transplantation of other organs arose after the government allowed the leading, most trained

institutions to diagnose brain death. For the subsequent 20 years (until 2006), development of various types of organ transplantation was not systemic, but was a priority for individual clinics.

In modern Russia, Law No. 4180-1 dated December 22, 1992 “On Transplantation of Human Organs and Tissues” (hereinafter referred to as “Transplantation Law”) was adopted in 1992 [2].

According to the Transplantation Law, human organ and tissue transplantation (hOTT) is a means of saving life and restoring the health of citizens and may be carried out under compliance with the laws of the Russian Federation and human rights in accordance with humane principles proclaimed by the international community, with the interests of the individual prevailing over the interests of society or science. On this basis, Article 1 of the Transplantation Law stipulates that hOTT from a living donor or a dead person is used only if other medical means cannot guarantee preservation of life of the patient (recipient) or restoration of their health. Removal of organs and tissues from a living donor is permitted only if their health, according to a Concilium of physicians, will not cause significant harm and may only take place with the consent of a living donor; human organs and tissues may not be bought or sold; the purchase and sale of such organs and tissues, as well as advertising of these actions carry criminal liability in accordance with the laws of the Russian Federation.

The task of saving lives and restoring the health of citizens through transplantation remains an extremely urgent problem and is addressed taking into account not only scientific achievements in this sphere but also by improving legal regulation.

In the period from 2006 to 2021, there has been a long-term positive trend in the development of transplantology in the Russian Federation. It has been characterized by an annual increase in the number of organ and tissue transplants from 662 to 2,348, an expansion in the geography of transplantation care and organ donation from 20 to 35 federal subjects of the Russian Federation, an increase from 31 to 63 in the number of medical organizations performing organ transplants and an increase in the number of patients with transplanted organs under observation and receiving lifelong drug therapy with immunosuppressants increased from 4,007 to 21,012. In Russia, post-transplant survival rates are comparable (not worse) than in Europe and the USA.

From 2019 to 2021, medical care accessibility through human organ transplantation was improved within the framework of the departmental target program “Organ Donation and Transplantation in the Russian Federation” [3], and from January 2022 – in accordance with the Complex of process measures “Organization of Organ Donation and Transplantation in the Russian Federation”, approved by the Russian Ministry of Health on December 28, 2021, which is part of “Healthcare Development”, a state program of the Russian Federation.

Within the framework of the mentioned Complex, tasks on improving the regulation of medical activities related to human organ donation for transplantation, increasing the number of human organ transplants performed, increasing the volume of medical activity associated with human organ donation for transplantation, and raising public awareness of the social significance of human organ donation are all being solved. For instance, by 2024 there are plans to increase to 73 the number of medical institutions allowed to harvest, procure and transplant human organs and tissues and which have submitted information about donor organs, organ donors, patients (recipients) to the information system of the Russian Ministry of Health. The number of donor organs for transplantation in regional medical organizations should be 1,520.

In accordance with Article 4 of the Transplantation Law, the Russian Ministry of Health, together with the Russian Academy of Sciences, approves the current list of health care institutions allowed to harvest and procure human organs and tissues and the list of health care institutions allowed to carry out human organ and tissue transplant surgeries. At present, the list of health care institutions is approved by order No. 515n/1, a joint order of the Russian Ministry of Health and Russian Academy of Sciences dated May 25, 2021 [4].

The Russian Ministry of Health has created a state registry for donor organs, donors and recipients [5]. On its basis, a personalized transplantation register, *Transplantology*, a federal state information system, has been developed and implemented at regional transplantation centers since 2018, which includes, in addition to the System of registration of donor organs, donors and recipients, a register of non-consent for organ removal after death for transplantation and the Unified Waiting List for organ transplantation.

According to Federal Law No. 323-FZ of November 21, 2011 “On the Fundamentals of Protecting the Health of Citizens in the Russian Federation” (hereinafter referred to as “Federal Law No. 323-FZ”), the basic principles of health protection include the priority of patient interests in the provision of medical care, accessibility and quality of medical care, as well as unacceptability of refusal of medical care [6]. According to Federal Law No. 323-FZ, transplantation is a type of medical professional activity and that the implementation of measures to organize hOTT medical activities, including organ and tissue donation for transplantation is under the powers of the federal executive body responsible for developing and implementing state policy and legal regulation in the field of healthcare.

The content of Article 47 of Federal Law No. 323-FZ providing for registration of donor organs and tissues, as well as persons in need of hOTT is significantly expanded and clarified by Federal Law No. 271-FZ of 13 July 2015, which established legal grounds for registering donor human organs and tissues, organ and tissue

donors, patients (recipients) and procedures for financing relevant activities [7].

For the first time, a list of human organs – objects of transplantation – and the list of health care institutions that are allowed to perform organ transplantation were established by the Russian Ministry of Health via Order No. 448 and by the Russian Academy of Medical Sciences via Order No. 106 of December 13, 2001 [8].

Pursuant to Article 2 of the Transplantation Law, the Russian Ministry of Health and the Russian Academy of Medical Sciences approved the list of transplantation objects, including 25 names of transplantation objects, via joint order No. 306n/3 of June 4, 2015 [9].

The concept of medical activity enshrines that it is a professional activity on the provision of medical care, medical evaluation, medical examinations and medical check-up, sanitary and anti-epidemic (preventive) measures and professional activities associated with hOTT, handling of donor blood and (or) its components for medical purposes (Article 2 of Federal Law No. 323-FZ).

According to Article 12 of the Federal Law No. 99-FZ of May 4, 2011 “On Licensing of Certain Types of Activities”, medical activity is subject to licensing [10].

In order to obtain a medical activity license, the applicant must meet the established license requirements.

The specified licensing requirements are contained in the Medical Activity Licensing Regulation (except for the specified activities carried out by medical institutions and other organizations that are part of the private healthcare system, on the territory of the Skolkovo Innovation Center, approved by Resolution No. 852 of the Government of the Russian Federation dated June 1, 2021 (hereinafter referred to as “Licensing Regulation”) [11].

Apart from the general requirements for all applicants for a medical activity license, for entities intending to provide hOTT services, there is a requirement for organizational and legal status – hOTT is performed exclusively at state and municipal healthcare institutions. This correlates with the provisions enshrined in Article 4 of the Transplantation Law.

Separately, it should be noted that the list of services constituting medical activity provided for in the Annex to the Licensing Regulation contains several types of human organ and tissue transplantation services: removal and storage of human organs and tissues for transplantation; bone marrow and hematopoietic stem cell transplantation; hematopoietic stem cell and bone marrow transportation; human organ and tissue transportation for transplantation; surgery (organ and tissue transplantation).

So, in order for a state/municipal institution to be allowed to provide medical care for organ transplantation and to perform medical activities related to organ donation for transplantation, the institution must meet the following requirements: obtain a license for the relevant services, be included in the lists of healthcare institutions that perform organ and tissue harvesting, procurement

and transplantation, which are approved by the Russian Ministry of Health together with the Russian Academy of Medical Sciences [4].

In addition, one of the main requirements when applying for a medical activity license is compliance with the Medical Care Procedure approved by the authorized federal executive body and mandatory for all medical organizations on the territory of the Russian Federation (Article 37 of Federal Law No. 323-FZ).

The Medical Care Procedure for Surgery (human organ and tissue transplantation) was approved by Order No. 567n of October 31, 2012 of the Russian Ministry of Health (hereinafter referred to as “Procedure”) [12]. The Procedure stipulates that medical care for hOTT shall be provided in the form of specialized, including high-tech, medical care, under inpatient settings.

Transplant medical care is provided depending on the type and object of transplantation at surgical wards, including pediatric surgical wards, cardiac surgical wards, surgical (thoracic) wards, and urological wards.

The Procedure also establishes rules for activities of a surgical ward performing hOTT, recommended staffing standards for such surgical ward and standard of additional equipment for a medical institution where there is such a surgical ward.

At the same time, the imperfections of the Procedure are conspicuous, for example, lack of specification of the scope of regulation of the procedure (with indication of transplantation objects to which the Procedure applies).

The Procedure also does not contain provisions regulating human donor organ and (or) tissue transportation for transplantation. It should be noted that human organ and tissue transportation services for transplantation are independent, separately licensed services included into the list of services constituting medical activity envisaged by the Annex to the Licensing Regulation, and they contain several types of services.

In this regard, work is currently underway to update the Procedure to ensure its compliance with developing transplantation technologies.

The recommended staffing standards for a surgical hOTT ward contain subsections depending on the type and object of transplantation.

For example, a surgical (urological) ward that performs kidney and pancreas transplantation includes the following positions: a surgeon (urologist); a nephrologist (general practitioner); a pediatrician (in the case of provision of kidney transplant medical care for minors); an endocrinologist (in the case of provision of medical care for kidney and pancreas transplantation for patients suffering from diabetes).

A pediatric surgical (urological) ward that performs kidney transplantation shall include the following positions: pediatric surgeon (pediatric urologist and andrologist); surgeon (urologist); pediatrician (pediatric nephrologist); general practitioner.

A surgical ward that performs liver transplantation must be staffed with the following positions: a surgeon; a gastroenterologist (a general practitioner); a pediatrician (in the case of provision of medical care for liver transplantation for minors).

A pediatric surgical ward that performs liver transplantation must be staffed with the following positions: a pediatric surgeon; a surgeon; a pediatrician (a gastroenterologist); a general practitioner.

A cardiac surgical ward that performs heart transplantation must be staffed with the following positions: a cardiovascular surgeon, a cardiologist, a thoracic surgeon (in the case of provision of heart-lung transplant medical care), a pulmonologist, a pediatrician (in the case of provision of heart transplant medical care for minors).

A thoracic surgical ward that performs lung transplantation must be staffed with the following positions: a thoracic surgeon; a pulmonologist; a pediatrician (in the case of provision of lung transplant medical care for minors).

Analytical activities and organizational and methodological management of regional and district medical institutions at federal subjects of the Russian Federation in the field of surgery (organ transplantation) are performed by the Shumakov Center. It is included in the network of national medical research centers and is classified as the highest (fourth) level of medical organizations [13, 14].

In the course of the analytical activities of the Shumakov Center, the following activities are carried out: analysis of implementation of clinical guidelines at medical institutions of the federal subjects of the Russian Federation; collection and analysis of information on the state of organization of medical care at the federal subjects of the Russian Federation; assessment of the uniqueness of drugs included in the list of vital and essential drugs within the framework of the existing clinical practice on their use and the possibility of replacing these drugs; analysis of the availability in federal subjects of the Russian Federation of drugs most in demand in practice and used in basic treatment regimens, the presence of defects and their causes; analysis and assessment, taking into account medical care standards and clinical guidelines of the needs of federal subjects of the Russian Federation for drugs included in the list of vital and essential drugs for medical use; formation and updating of the list of priority research areas in the field of health care, including the development of personalized approaches in medicine; development of methodological guidelines on creation of conditions for provision of paid medical services to foreign citizens; analysis of staffing of medical institutions at federal subjects of the Russian Federation and the need for training (retraining) of medical workers; analysis of professional standards in health care and training programs of medical and pharmaceutical education.

In addition, the Shumakov Center provides organizational and methodological support for the following

activities: introduction and development of medical information systems that ensure the implementation of quality management and quality control of medical care in surgery (organ transplantation) at medical institutions participating in the territorial program of state guarantees of free medical care for citizens, including through information interaction between medical information systems; analysis and evaluation of organization of medical care at the federal subjects of the Russian Federation through field visits to these federal subjects and remotely using medical information systems with the development of guidelines for improving the provision of medical care in surgery (organ transplantation) at the federal subjects of the Russian Federation and quarterly monitoring of the implementation of these guidelines; holding consultations (telemedicine Concilium) among medical institutions at federal subjects of the Russian Federation; development of interactive electronic educational modules for medical workers.

At present, the Russian Transplant Society has developed and is under expert review seven draft clinical guidelines: liver fragment living donation (Z52.6, adults); heart transplantation, presence of a transplanted heart, heart transplant death and rejection (Z94.1, T86.2, I42, I25.3, I25.5, I50, children/adults); kidney living donation (Z52.4, adults); pancreas transplantation, presence of transplanted pancreas, pancreas graft death and rejection (Z94.8, T86.8, E10, E10.2, N18.5, adults); lung transplantation, heart-lung transplantation, presence of a transplanted lung, presence of a transplanted heart-lung complex, lung graft death and rejection, heart-lung graft death and rejection (J43.9, J44.9, J47, J84, J98, J98.4, J99.1, E84.0, E84.9, I27.0, I27.8, I27.9, I28, Z94.2, Z94.3, T86.3, T86.8, children/adults); liver transplantation, transplanted liver, liver transplant death and rejection (Z94.4, T86.4, children/adults); kidney transplantation, presence of a transplanted kidney, kidney transplant death and rejection (Z94.0; T86.1, children/adults).

After approval of these clinical guidelines in accordance with the established procedure, appropriate medical care standards will be developed and approved on their basis. This would contribute to the creation of uniform conditions and requirements in the provision of medical care throughout the Russian Federation.

In turn, medical care standards are developed on the basis of the Nomenclature of Medical Services [15]. The current Nomenclature contains only 15 medical services related to hOTT. At the same time, there are differences in the terms used in the names of medical services and there are no medical services for some transplantation objects.

Thus, work is being done to further detail the Nomenclature of Medical Services, including medical services specifying the anatomical area of transplantation, clarifying the technology of transplantation operations.

The Nomenclature of Specialties of Specialists with Higher Medical and Pharmaceutical Education, approved

by the Russian Ministry of Health via Order No. 700n of October 7, 2015, does not contain a separate specialty related to hOTT activities [16]. Transplant medical care is provided by medical specialists trained in hOTT, in collaboration with other medical specialists. Transplantology specialists (surgeons, nephrologists, cardiovascular surgeons, urologists, therapists, pediatricians, gastroenterologists, cardiologists, doctors of laboratory, functional and radiology diagnostics, health organizers and others) are united by a professional community – the Russian Transplant Society.

The various requirements contained in the professional standards for the above-mentioned medical specialists come under notice.

For example, in professional standard “Surgeon” (Order No. 743n of the Russian Ministry of Labor dated November 26, 2018), the following labor functions are specified: “transplantation of the musculoskeletal complex”, “ simultaneous transplantation of the musculoskeletal complex”, and “autotransplantation of the musculoskeletal complex” [17]. Professional standard “Nephrologist” (Order No. 712n of the Russian Ministry of Labor dated November 20, 2018) presents a generalized labor function “providing medical care to patients in the field of nephrology, including kidney transplant recipients” [18].

At the same time, professional standards “Pediatric surgeon” (Order No. 134n of the Russian Ministry of Labor dated March 14, 2018), “Urologist” (Order No. 137n of the Russian Ministry of Labor dated March 14, 2018), “Pediatric urologist/andrologist” (Order No. 4n of the Russian Ministry of Labor dated January 13, 2021), “General practitioner (district physician)” (Order No. 293n of the Russian Ministry of Labor dated March 21, 2017), “District pediatrician” (Order No. 306n of the Russian Ministry of Labor dated March 27, 2017), “Endocrinologist” (Order of the Russian Ministry of Labor of March 14, 2018 No. 132n), “Gastroenterologist” (Order No. 139n of the Russian Ministry of Labor dated March 11, 2019), “Cardiovascular surgeon” (Order No. 143n of the Russian Ministry of Labor dated March 14, 2018), “Cardiologist” (Order No. 140n of the Russian Ministry of Labor dated March 14, 2018), “Thoracic surgeon” (Order No. 140n of the Russian Ministry of Labor dated March 11, 2019), and “Pulmonologist” (Order No. 154n of the Russian Ministry of Labor dated March 19, 2019), have no labor functions that contain references to “transplants,” “organ and tissue transplantation” [19–29].

When providing medical care under the program of state guarantees of free medical assistance to citizens and territorial programs of state guarantees of free medical care to citizens, medical activities associated with human organ and tissue donation for transplantation, including measures for medical examination of the donor, ensuring the safety of donor organs and tissues until they are harvested from the donor, harvest of donor organs and

tissues, storage and transportation of donor organs and tissues (Article 80 of Federal Law No. 323-FZ). At the same time, financial support for medical activities related to human organ donation for the purpose of transplantation comes from allocations from the national budget and from the budgets of federal subjects of the Russian Federation (Article 83 of Federal Law No. 323-FZ).

In order to develop the transplant service in the Russian Federation, it would be advisable to introduce a differentiated approach to the rules of allocation of federal budget funds for transplant medical care, including the use of financial incentives, for example, introduction of a factor that increases the amount of subsidy provided to the budget of a federal subject of the Russian Federation that provides high-tech transplant medical care.

The limited number of institutions (Shumakov Center, Evdokimov Moscow State University of Medicine and Dentistry and Moscow Regional Clinical Research Institute (Moscow Oblast) that provide postgraduate training for specialists in organ donation and transplantation is conspicuous.

In order to increase the number of hOTT medical care specialists, additional study is required on the introduction of teaching the basics of transplantology in the secondary and higher medical and pharmaceutical educational institutions in order to identify the interest of future specialists in this field.

Given the multidisciplinary approach, it is necessary to note the importance of forming a register of transplantation teams – specialized structural units of medical institutions that perform organ and/or tissue transplantation, including specialist physicians. The composition of such teams should depend on the object of transplantation, the individual characteristics of the organ recipient, and include medical specialists who have received postgraduate training in organ donation and transplantation, an anesthesiologist/resuscitator, medical specialists who provide medical care to recipients with a transplanted organ (nephrologist, gastroenterologist).

Based on the analysis carried out, we can conclude that it is necessary to continuously improve not only the legal regulation of transplantation activities, but also practical implementation of existing transplantology regulations and programs.

As priority measures for improving the organization of transplantology today, it is expedient to:

- Expand the network of medical institutions that perform hOTT;
- Promote further development of interregional collaboration between these medical institutions for the exchange of unclaimed donor organs that are suitable for transplantation;
- Intensify sharing of information on the possibilities of personalized transplantation *Transplantology* with regional transplant centers;

- Form unified approaches to the definition of labor functions in the professional standards of specialist physicians providing hOTT medical care;
- Harmonize the Nomenclature of Medical Services taking into account the list of transplant objects;
- Update the Medical Care Procedure for Surgery (human organ and tissue transplantation) taking into account the developing trends in the field of transplantation.

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