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GUIDELINES ON IMPROVING HEALTH CARE QUALITY IN TRANSPLANTATION SERVICES IN THE FEDERAL SUBJECTS OF RUSSIA

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Objective: to provide guidelines on how to improve the quality of health care in transplantation services for Russian regions; the recommendations were prepared by the Shumakov National Medical Research Center of Transplantology and Artificial Organs (Shumakov Center) based on field trips made by Shumakov Center from 2018 to 2019 in order to assess the status and development prospects of organ donation and organ transplantation in various regions of the Russian Federation. **Materials and methods.** Based on the over 40 field trips made by the Center, analytical reports, as well as recommendations were prepared by the Ministry of Health of Russia for regional health authorities and transplant centers. Guidelines were selected from these recommendations to address the most significant and common gaps and errors inherent in organ donation and organ transplantation in the regions. On the basis of the analytical reports, guidelines for the roadmap (plan) for organ donation and transplantation in the region were prepared. **Results.** A methodological framework for solving a wide range of managerial challenges on organ donation and organ transplantation is proposed for heads and experts at health-care institutions and medical organizations. **Conclusion.** Organ donation and organ transplantation should be developed for the regions using the roadmap (plan) prepared and approved by the regional health authority. This approach brings stability and consistency to the development process, creates a resource base for development, and provides coordination and oversight.

Keywords: organ donation, organ transplantation, Shumakov center of transplantology, transplant register, transplant recommendations.

INTRODUCTION

In 2018–2019, Shumakov National Medical Research Center of Transplantology and Artificial Organs, Moscow, Russia (the Center), guided by the order of the Ministry of Health of Russia of September 11, 2017 No. 622, by the order of the Ministry of Health of Russia of March 13, 2019 No. 125, within the framework of its authority as the national medical research center for transplantation, carried out field trips to the subjects of the Russian Federation to assess the organization of medical care for transplantation and organization of medical activities related to organ donation. In total, the specialists of the Center made over 40 visits in this period.

At this, the workshops were held with participating top managers of health administration, chief doctors of hospitals, chief external expert, where topical regional problems and tasks for the development of transplantation were discussed. In medical institutions of the 3rd level providing or planning to provide medical care for organ transplantation, scientific and practical conferences, joint visits to structural units were held, medical documentation was reviewed, and discussions with medical staff

were held. By the results of each field trip, the Center prepared an analytical report for the Russian Ministry of Health.

Analyzes of the material collected in the regions showed certain resemblance of the problems and tasks facing the regional medical institutions as well as common faults in the development of organ donation and transplantation.

Based on this, the Center prepared recommendations for improving the organization of medical care for transplantation in the subjects of the Russian Federation which are presented in this article.

The recommendations were prepared using long-term data from the register of the Russian Transplant Society [1–10].

This material has been prepared for managers and experts of health authorities and medical institutions as a methodological basis for solving a wide range of management tasks in the field of organizing organ donation and transplantation. The recommendations are planned to be regularly updated and supplemented; the study of the methodological aspects of organizing medical care

for organ transplantation and medical activities related to organ donation for transplantation is planned to continue in the regions of the Russian Federation.

RECOMMENDATIONS FOR ROADMAP (PLAN) CONTENT FOR DEVELOPMENT OF ORGAN DONATION AND TRANSPLANTATION IN THE REGION

A common drawback in organizing organ donation and transplantation in the subjects of the Russian Federation revealed during the field trips of the Center experts is the lack of the subjects' coherent strategy for the development of this field of high-tech medical care which is confirmed by the absence of an appropriate methodological or regulatory legal act.

In this regard, the Center, within the framework of the organizational and methodological guidelines, recommends that regional health authorities guided by Federal Law No. 323-ФЗ of November 21, 2011 (Article 16), should obligatorily prepare and approve such a document.

As a methodological support, the Center proposed recommendations for the content of the road map, a plan for the development of organ donation and transplantation in the region (hereinafter, the road map).

Such a roadmap should include an assessment of the current state of organization of medical care for organ transplantation, medical activities related to organ donation for transplantation. As a general rule, such an analytical report is prepared by the chief external transplant expert of the regional health authority.

The satisfaction of the region's population with the availability and quality of medical care for organ transplantation must be necessarily assessed.

The costs of the regional budgetary and non-budgetary funds for renal replacement therapy by dialysis and kidney transplantation must be compared. It is known that kidney transplantation as a method of renal replacement therapy is significantly more cost effective than hemodialysis. Savings on medical support for the kidney transplant patients, including drug therapy in comparison with those on dialysis averages RUR 1.2 million per year, starting from the 2nd year after kidney transplantation.

It is necessary to describe the planned (desired) state of the organization of medical care for organ transplantation, medical activities related to organ donation for transplantation purposes. The number of kidney transplants in the region should be such as to effectively use the existing and unique donor resource, and most importantly, contain the growth of the number of patients on dialysis as much as possible.

The road map should provide for measures to form a network of medical institutions involved in the provision of medical care for organ transplantation, in medical

activities related to organ donation for transplantation (licensing, listing, charter).

It is necessary to legally consolidate, distribute the rights and responsibilities between medical institutions in the organization and provision of medical care for organ transplantation, medical activities related to organ donation for transplantation. The same applies to the rights and responsibilities of the experts of medical institutions in the organization and provision of medical care for organ transplantation, medical activities related to organ donation for transplantation.

It is necessary to distribute the rights and responsibilities between the chief external experts of the region in the organization and provision of medical care for organ transplantation, medical activities related to organ donation for transplantation.

The road map should include measures for the material and technical support of medical institutions involved in the provision of medical care for organ transplantation; in medical activities related to organ donation for transplantation in accordance with regulatory requirements. This should be guided by the procedures for the provision of medical care, and consideration of the standards, clinical and methodological recommendations for transplantation.

Mandatory for development are measures for staffing medical institutions involved in the provision of medical care for organ transplantation, in medical activities related to organ donation for transplantation in accordance with regulatory requirements. In compliance with the requirements of the Procedure for the "surgery (transplantation of human organs and (or) human tissues)" profile of October 31, 2012 No. 567H, experts involved in the provision of medical care for organ transplantation must undergo advanced training on relevant issues.

The road map should provide measures for the technological support of medical institutions involved in the provision of medical care for organ transplantation, in medical activities related to organ donation for transplantation. For example, kidney removal from live relative donors at the present stage is advisable to be performed laparoscopically; accordingly, this technique should be introduced in transplant centers where related kidney transplantations are performed.

Medical institutions involved in the provision of medical care for organ transplantation, in medical activities related to organ donation for transplantation, must be methodically provided. For this, in particular, it is necessary to work out measures for the implementation of clinical guidelines and protocols for transplantation.

The road map should include measures for drug provision of medical institutions involved in the provision of medical care for organ transplantation, in medical activities related to organ donation for transplantation, for patients before and after organ transplantation.

It is necessary to provide grounds for the timely identification and follow-up of patients in need of organ transplantation (waiting list) in accordance with clinical guidelines.

It is necessary to work out measures to ensure dynamic monitoring of patients with transplanted organs in accordance with clinical guidelines.

It is necessary to provide conditions for registering donor organs, donors and recipients in accordance with regulatory requirements.

The roadmap should include measures to ensure the timely identification of potential organ donors, to introduce the diagnosis of brain death in accordance with the methodological recommendations.

Mandatory for development are measures to ensure the quality and safety of medical care for organ transplantation and medical activities related to organ donation for transplantation.

The basic condition for the development of organ donation and transplantation in the region is the proper legal support for the organization of medical care for organ transplantation, medical activities related to organ donation for transplantation in the region. In this regard, measures to improve legal support are also mandatory for the road map.

The roadmap should include activities to inform and educate the population, including the medical community, on organ donation and transplantation, and work with the media.

It is also advisable that the road map includes measures for interaction with the national medical centers for transplantation profile including remote consultation of patients using telemedicine technologies.

The road map should Obviously provide for measures of the financial support for the organization of medical care for organ transplantation and medical activities related to organ donation for transplantation in the region.

Considering the judicial practice in cases in the field of health care in a number of regions, it may be useful to include in the road map measures for interaction with law enforcement agencies to inform about organ donation and transplantation and prevent offenses.

The layout template of the roadmap is presented in the Table.

STANDARD SOLUTIONS FOR IMPROVING THE ORGANIZATION OF MEDICAL CARE FOR TRANSPLANTATION

The Center has prepared standard solutions for regional health authorities and medical institutions to improve the organization of medical care for transplantation in the subjects of the Russian Federation. It is advisable to work out these recommendations, specificate and include them in the road map (plan) for the development of organ donation and transplantation in the region.

At all levels of regional health care, the persons responsible for the development of organ donation and transplantation should be appointed; in the regional health authority, it is the head or one of the deputy heads and the deputy of the profile unit; at the transplantation center, the chief physician or one of the deputy chief physicians, the head or deputy of the profile department (responsible for the transplantation program), the head or deputy of the profile department (responsible for the donor program); at the donation center, the chief physician or one of the deputy chief physicians, the head or deputy of the profile department (responsible for the donor program).

The regional health authority's chief external transplant expert should be appointed. The chief external transplant expert should ensure that an annual analysis of the state and prospects for the development of medical care for organ transplantation in the region is performed.

It is advisable to form a coordination council under the regional health authority for the development of organ donation and transplantation, to approve its rules and regulations, composition and working plan.

It is recommended that the regional health authority approve a road map (plan) for the development of organ donation and transplantation in the region; in the state regional program on the development of regional health care, include measures for the development of organ donation and transplantation in compliance with the order of the Ministry of Health of Russia of June 4, 2019 No. 365; develop and/or update the regulatory legal act of the regional health authority regulating the organization of medical care for organ transplantation, organization of medical activities related to organ do-

Table

Road map (plan) for the development of organ donation and transplantation in the region

Nos.	List of activities from recommendations of the Center	Content (essence) of events	Target indicator	Target indicator value	Deadlines	Responsible person	Legal support	Financing
1	2	3	4	5	6	7	8	9

nation for transplantation in the region; plan and assist medical institutions providing medical care for organ transplantation, carrying out medical activities related to organ donation for transplantation, in their licensing and inclusion in the Lists (Order of the Ministry of Health of Russia and the Russian Academy of Sciences of February 20, 2019 No. 73H/2); conduct an audit and, if necessary, equip these medical institutions in accordance with the requirements of the Procedure for the provision of medical care in the field of surgery (transplantation of organs and/or human tissues) by the Order of the Ministry of Health of Russia dated October 31, 2012 No. 567H; conduct an audit and, if necessary, equip medical institutions carrying out medical activities related to organ donation for the purpose of transplantation, in accordance with the requirements of the Procedure for the provision of medical care to the adult population in the profile for anesthesiology and resuscitation by the Order of the Ministry of Health of the Russian Federation of November 15, 2012 No. 919H.

Medical institutions are to ensure compliance with the qualification requirements for experts involved in the provision of medical care for organ transplantation and/or the implementation of medical activities related to organ donation for transplantation; ensure compliance with qualification requirements in accordance with the Procedure for the provision of medical care for surgery (transplantation of organs and/or human tissues) by the order of the Ministry of Health of Russia dated October 31, 2012 No. 567H; ensure compliance with regulatory requirements for additional training of experts involved in the provision of medical care for organ transplantation and/or the implementation of medical activities related to organ donation for transplantation; ensure compliance with the requirements for additional training of experts in accordance with the Procedure for the provision of medical care for surgery (transplantation of organs and/or human tissues) by the Order of the Ministry of Health of Russia of October 31, 2012 No. 567H. For example, a pathologist of a medical organization providing medical assistance for organ transplantation needs to be additionally trained on pathological anatomy in patients after organ transplantation for at least 72 hours.

For the effective implementation of organ transplantation, donor activities in medical institutions, it is recommended, in addition to creating specialized clinical departments (in accordance with the requirements of the above Procedure), to form functional medical teams responsible for organ (kidney, liver, heart) transplantation programs and for donation coordination.

Organ donation and transplantation in medical institutions are recommended to be organized in such a way that different experts are responsible for the provision of medical care for organ transplantation and implementation of medical activities related to organ donation for transplantation (order to prevent delinquency and

conflict of interest). It is not recommended to combine organ donation and transplantation services in one center.

The regulatory legal act of the regional health authority is recommended, to organize a regional center for coordinating organ donation on the basis of a subordinate medical organization licensed to work (provide services) for the removal, storage of human organs and/or tissues for transplantation, as well as for their transportation. It is advisable to provide interaction between the regional coordinating center for organ donation, the regional vascular center, and the regional trauma center with the possibility of obtaining real-time data on potential donors. It is recommended to organize, on the basis of the regional coordination center of organ donation, regular training for resuscitators of medical institutions involved in medical activities related to organ donation for transplantation. It is recommended to register hospital mortality in intensive care units of medical institutions involved in medical activities related to organ donation for transplantation with regard to the patients aged 18–65 with isolated vascular and/or traumatic brain damage who die within 7 days after admission to the intensive care unit. It is necessary to introduce into the practice of medical institutions involved in medical activities related to organ donation for transplantation, the ascertaining of a person's death based on the diagnosis of brain death by the Order of the Ministry of Health of Russia of December 25, 2014 No. 908H). It is recommended to provide conditions (experts, medical equipment) for performing the procedure for diagnosing brain death on a 24/7 basis.

The Center recommends that regional health authorities approve, as one of the performance indicators of the chief physicians of subordinate medical institutions involved in medical activities related to organ donation for transplantation purposes, the indicator of the number of identified potential organ donors.

It is necessary to introduce into the practice of medical institutions providing medical care for organ transplantation, carrying out medical activities related to organ donation, standardized protocols for the diagnosis, treatment and prevention of patients (donors and recipients) in transplantation, based on the clinical guidelines of the Russian Transplant Society.

Medical institutions need to ensure internal quality control of medical care for organ transplantation, including quality control of medical records. It is recommended to check all medical records of recipients and live organ donors without exception. It is recommended to ensure the pathological and anatomical autopsies of patients who die in the hospital and can be effective donors (to exclude death in connection with medical and diagnostic measures, paragraph 5 of Appendix No. 1 to the Order of the Ministry of Health of Russia of June 6, 2013 No. 354H). It is advisable to provide histological control of organ transplants aimed at disposal.

The Center recommends that medical institutions organize the maintenance of the Patient Log on the Organ Transplant Waiting List, the Organ Transplant Patient Log, the Organ Transplant Medical Care Record Book / Transplant Coordinators.

Medical institutions providing medical assistance for organ transplantation, carrying out medical activities related to organ donation for transplantation should organize their work as to ensure compliance with patient confidentiality in terms of data on the donor and recipient (Law of the Russian Federation of December 22, 1992 No. 4180-I, Article 14).

If there is a commission in the region for the selection of patients for renal replacement therapy, it is recommended to include a chief external transplant expert.

In medical institutions providing medical care for kidney transplantation, it is recommended to Provide conditions for HLA typing of all kidney donors and recipients by three loci (A, B, Dr). A direct cross test for compatibility between the donor and the potential recipient (crossmatch reaction) should be performed by lymphocytotoxic test (serological method) or by flow cytometry. To perform the lymphocytotoxic test, the presence of an inverted microscope in the medical institution providing medical assistance for organ transplantation must be ensured.

It is advisable to provide informing and rational referral of patients needing organ transplantation to federal medical centers of the Ministry of Health of Russia, considering their territorial location, specialization by types of transplantation, and the volume of high-tech medical care for transplantation.

The regional health authority should ensure funding medical care for organ transplantation including work related to organ donation from the regional budget. Such authorities are provisioned by parts 2, 9.1, 9.2 of Article 83 of the Federal Law of the Russian Federation of November 21, 2011 No. 323-ФЗ On the basics of protecting the health of citizens in the Russian Federation. In particular, targeted spending of funds allocated for financial support of work related to organ donation must be foreseen.

On the basis of the approved standards of medical care and clinical guidelines, it is necessary to calculate and approve the rates of compulsory medical insurance for the provision of medical care to patients under dynamic observation in the waiting list for organ transplantation as well as their dynamic observation after organ transplantation.

It is necessary to provide an acceptable level of donor and transplant activity. The target value of the indicator of the number of effective organ donors at planning the development of organ donation in the region for a period of up to 5 years should not be less than 15 per 1 million population. The target value of the indicator of the number of kidney transplants at planning the development of

organ transplantation in the region for a period of up to 5 years should not be less than 30 per 1 million population. It is necessary to work out a strategy and/or an action plan for the introduction in the region (in a medical institution) of high-tech methods of treating diseases with transplantation of extrarenal organs (liver, heart, lungs, pancreas). It is necessary to develop a strategy and/or an action plan for the rational use of organs from cadaver donors suitable for transplantation but not in demand in the region (in a medical institution).

It is necessary to ensure the introduction of a methodology for laparoscopic removal of a donor kidney from a live donor in case of related kidney transplantation in a medical institution.

It is necessary to ensure monitoring the blood immunosuppressants concentration in patients after organ transplantation in accordance with the standards of medical care at the expense of compulsory medical insurance funds (the Order of the Ministry of Health of Russia of December 28, 2012 No. 1575H). It is necessary to exclude the addition of doses of drugs of different trade names within one international nonproprietary name in patients with transplanted organs under guidance of the clinical recommendations of the Russian Transplant Society, Drug monitoring and interchangeability of original and generic immunosuppressants with a narrow therapeutic index.

It is necessary to provide remote consultations with the Center in accordance with the approved list of diseases (conditions) in the amount of at least 10% of profile patients, to include remote consultations in the system of monitoring the effectiveness, safety and quality of pharmacotherapy.

It is necessary to regulate and ensure control by the regional health authority of cases of transfer of donor organs unclaimed but suitable for transplantation to medical institutions located in other subjects of the Russian Federation, to regulate and ensure control by the regional health authority of cases of disposal of donor organs unclaimed but suitable for transplantation.

It is advisable to publish on the regional health authority, subordinate medical organizations official websites a link to the official resource of the Russian Ministry of Health on organ donation and transplantation at donorstvo.org.

If there is a state medical university in the region, it is advisable to organize an educational course on Fundamentals of donation and transplantation of human organs for medical students (6th year). It is recommended to use the guidance paper of the Department of Transplantology and Artificial Organs of the I.M. Sechenov First Moscow State Medical University of the Ministry of Health of Russia.

It is recommended to ensure cooperation with public organizations in the region and in the Russian Federation representing the interests of patients in need of organ

transplantation as well as patients after organ transplantation, to ensure collaboration with public organizations representing the interests of the professional medical community in the field of organ donation and transplantation in the region and in the Russian Federation.

CONCLUSION

When solving the problem of organizing or developing a program for organ donation and transplantation in a subject of the Russian Federation, top managers and experts of health authorities and medical institutions face a wide range of management issues that require resource and legal support, monitoring and administration.

In this regard, Shumakov National Medical Research Center of Transplantology and Artificial Organs, Moscow, Russian Federation, recommends solving these problems through a roadmap (plan) for the development of organ donation and transplantation in the region, allowing for ensured stability and consistent development, planning a resource base for advance and ensuring coordination and control.

The results of the analysis of materials collected at the field trips in the regions and summary reports made by Shumakov National Medical Research Center of Transplantology and Artificial Organs, the Ministry of Health of Russia prepared standard solutions for regional health authorities and medical institutions to improve the organization of medical care for transplantation in the subjects of the Russian Federation. With this, a methodological basis for the development of road maps (plans) for the development of organ donation and transplantation in the regions has been proposed.

Shumakov National Medical Research Center of Transplantology and Artificial Organs will further continue to provide methodological assistance to top managers and experts of regional health authorities and medical institutions on preparation and implementation of road maps (plans) for development within the framework of implementation of its authorities as the national medical research center for transplantation.

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