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ENSURING NATIONAL INTEREST: LEGAL AND ETHICAL ISSUES OF ORGAN TRANSPLANTATION IN RUSSIA

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Abstract

Improving demographic indicators and supporting public health are one of the most important national interests of Russia, ensuring sustainable development of the country. Transplantation of human organs and tissues, being an effective medical manipulation, has contributed and will continue to improve the health map of the country's population. At the same time, transplantation and donation in Russia today require effective legal regulation taking into account its bioethical rethinking. This need is caused by the introduction of new technologies, the best medical opportunities against the background of outdated and non-evolving legislation, which hinders and does not allow to realize all the progressive achievements of medicine. The article identifies the key issues of current legislation related to the consent systems for donation and the establishment of the fact of death. These issues are also considered in the bioethics, including dialogue with patient representatives, preparation for donation and much more. Legal transplantology of children's organs has become one of the most principal issue since Russia has restricted a live donation of children and unresolved legal and ethical gaps for the organization of post-mortem child donation. In this connection, children become the most vulnerable group having the national interest in their security of the right to life and medical care. The authors cite international legislation experience (US practice on key issues, the positions of several countries of the European Union) whose progressive experience can serve as a good starting point for the evolution of the law and bioethics of domestic transplantology in Russia.

Keywords: Bioethics, donation, donor-child, legal regulation, transplantation, tacit consent

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1. Introduction

The development of medicine is fundamental to ensure such key national interests as strengthening public health and positive dynamics in a demographic situation. The current level of health care development requires the evolution of law on medical sphere, as well as an appeal to bioethics. Against the background of impressive technologies, the law adapts to new challenges, and the moral law, being absolute, sets the necessary vector for improving the subsystems of society. So medicine became one of the first areas that declared the need for the interaction of law and bioethics. Medical practice, initially based on traditional medical ethics, is today seeking legal support for the use of technologies such as bioprinting, genome editing through CRISPR, and the creation of human and animal chimeras.

Although ultramodern technologies should be followed by clarification and improvement of normative acts in the context of bioethics which is one of the most important issues in classical medical manipulation: transplantation of organs and (or) human tissues. This area is also directly related to the issues of bioethical and legal regulation of donation in the Russian Federation. Both the issues of transplantation and donation can be considered a practical and illustrative example, when ethics should not and cannot really be disconnected from the law. Moral ethical principles determine the assessment of the interests of all participants in a relationship, and the law delimits these interests and legalizes them. Apparently, law and bioethics are not harmonized enough, which undermines both the state strategy for the development of national medicine and the level of support for human health guaranteed.

2. Problem Statement

Nowadays the legal and ethical aspect of modern classical transplantology face a range of problems. Fundamental flaws can be identified related to the rare and non-progressive updating of the regulatory framework, there are private medical and legal issues related to obtaining the consent of the recipients and the will of the donors, the establishment of the fact of death, organizational and legal flaws in the algorithm for implementing medical procedures and the lack of a donor registry. Special attention is given to the status of the child in transplantology, namely the consequences of the indiscriminate prohibition of live donation of children in Russia and the possibility of transplantation of children's organs in general.

Apparently, these flaws are closely intertwined with morality: setting age limits for donor purposes, conducting dialogue with relatives or legal representatives of the patient, meeting the expectations of the donor and recipients and others.

3. Research Questions

The subject of the study is the legal and bioethical norms that determine the procedure for transplantation of organs and tissues in the Russian Federation, the status of donors and recipients, the level of protection in communication with a medical institution. Overall, the study revealed the following provisions:

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Key gaps in the current legislation and accompanying criticism of tacit consent theory to posthumous donation, including through judicial practice; problems of determining the fact of brain death and its mismatch with biological death.

The status of a minor in domestic transplantology, including the study of the rules governing the indiscriminate prohibition of donation during life and restrictions on donation after death. As a result, the chosen restrictive approach leads to a reduction in the number and types of operations performed in Russia, which indicates the inadequate exercise by minors of the right to life and medical care.

4. Purpose of the Study

The purpose of the study is a legal study of the development of transplantology in the Russian Federation, including transplantation and donation of children's organs, in order to identify the need of modifications, outdated regulatory approaches within bioethical aspect and determine strategic directions for legal and ethical improvement of national health system.

5. Research Methods

The authors analyze Russian legislation on donation and transplantation, draft amendments to it, as well as judicial practice. The analysis includes applicable provisions of international law and a comparative legal study of the regulatory acts mainly in European Union, the United States to study the most progressive and applicable experience. Statistical and informational materials are used to compare the effectiveness of transplantation and donor procedures in Russia and abroad.

6. Findings

As for the fundamental problem in the field of transplantology, there is a need to update legal regulation, though over the past years there has been national congresses and nationwide discussions on the topic. Apparently, there are no clear results yet. Until now, a priority law for medicine has been devoted to one law adopted almost 30 years ago: Law of the Russian Federation of December 22, 1992 No. 4180-I “On Transplantation of Human Organs and (or) Tissues” *(hereinafter – Law No. 4180-I of 1992).* Partially applicable to transplantation issues are general provisions of the Federal Law “On the Basics of Protecting the Health of Citizens in the Russian Federation” dated November 21, 2011 No. 323-FL. In contrast to the early regulatory acts, the recently adopted Federal Law “On Biomedical Cellular Products” dated June 23, 2016 No. 180-FL, innovative within medical revolution, does not extend to relations arising from the donation of human organs and tissues for transplantation, blood donation and its components.

Several by-laws are responsible for the implementation of algorithmic manipulations in practice: Order of the Ministry of Health of the Russian Federation dated December 25, 2014 No. 908n “On the Procedure for Establishing a Diagnosis of Human Brain Death”, Orders of the Ministry of Health of the Russian Federation on the procedure for transplantation actions (Ministry of Health of the RF, 2012), and accounting donor organs (Ministry of Health of the RF, 2016) and lists of institutions involved in organ transplantation (Ministry of Health of the RF, 2019). At the same time, acts of the relevant Ministry of the

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declared problematic issues of the organization of donation and transplantation do not regulate in detail. The development of transplantation and donation in the subjects of Russia are faced with similar legal gaps in regional legislation. Therefore, medical representatives draw up recommendations for improving legal regulation (Gauthier & Khomyakov, 2017).

There have been many attempts to update the legislative framework and full in the gaps. Deputies of the State Duma considered proposals for amending Law No. 4180-I of 1992. However, most of the initiatives were either withdrawn by the subjects of the legislative initiative or irrevocably transferred for revision. The biggest breakthrough for medical industry was adopted amendments on child post-mortem donation, along with updating by-laws regarding the diagnosis of human brain death, including in children who have reached the age of one year.

The text of the new Federal Law "On organ donation and transplantation" was also previously developed by the Ministry of Health of the Russian Federation but did not reach the parliament. On the eve of the new year 2020, a bill of the same name was introduced, designed to replace the 1992 Law. Since there was no official information on the website of the State Duma, information on the development of the document was confirmed by the Deputy Minister of Health of Russia. The authority explained that the new text of the law is designed to provide the missing legal and ethical balance in the relations of recipients, donors, their close circle. In particular, the bill includes discussion provisions on the will for posthumous donation (Russian newspaper, 2020).

With a positive fate of the bill and its mandatory detailed study, it is worth hoping that the private medical and legal problems posed above will be solved right away. The will of the individual to become a donor is a decision of an initially ethical character. Most European countries adhere to this practice, including the long-term regional leader in terms of number of donors per population – Spain. In 2019–2020, the United Kingdom completes the transition from the requested consent model to tacit consent (European Day, 2019). In the same period, heated debates on model change are taking place in Germany, where the Parliament has not adopted amendments at the moment, maintaining the previous model of "requested consent" (Hallam & Prange, 2020). It is worth noting that half of Europeans from countries with tacit consent model criticize the established practice of organ harvesting (European Day, 2019).

In Russia, on the basis of legal registration, the issue of will is decided in favor of the presumption to the posthumous donation. The current version of Section 8 of Law No. 4180-I of 1992 prohibits seizure only with an openly published statement by a potential donor or his close relatives or legal representatives. Therefore, as in most European countries, in Russia human organs can be transported without his will, including from ignorance of the current legislation.

The other side of this problem in relation to the Russian legal system is the controversial passivity of the healthcare institution. It is easier for medical personnel to keep silent about the impending harvest of organs than to ask whether or not to transport dead patient's organs to another person. Usually surgeons are to save one's life and not to clarify the thoughts and beliefs of the patient and his relatives. In contrast, there is a separate system of psychologists created in India for them to contact representatives of badly sick patients on donation issues (Gazeta.ru, 2019).

In Russia, the Constitutional Court of the Russian Federation was entrusted with the search for a balance of ethics and law in tacit consent for a posthumous donation. The Constitutional Court addressed

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the issue for the first time in 2003 at the request of the court. Then the model of unsolicited consent was justified by the inhumanity of the issue of organ harvesting with relatives, asked at the same time as reporting the death of a loved one or immediately before any other medical intervention or manipulation (Definition, 2003). The Constitutional Court also referred that the level of medical system development at that moment does not allow spending much time for transplantation to find out the real will of interested parties. The recommendations of the Court in the legal position on the need for a detailed study of the mechanisms for informing citizens about the current legal regulation remained only on paper.

In 2016, the Constitutional Court was given the opportunity to assess the current state of the legal system and transplantology in the secret removal of Alina Sablina's organs. However, the position of the Court has not changed for the last fifteen years. Emphasizing the moral and ethical aspect of the issue and the need to achieve the proper balance, the Court defends the model of alleged consent by stimulating donation and transplantation in the country, as well as by the fixed norm of Article 8 of Law No. 4180-I of 1992. It means, not knowing the published norm by citizens does not exempt them from the burden of the consequences of the possible transportation of a deceased person's organs.

The arguments of the Constitutional Court on the active involvement of the professional community and the public in solving the problem collides with sociological studies conducted by representatives of the patient's relatives (Brower & Burkov, 2017). The case is currently pending for the European Court of Human Rights.

It is impossible to keep silence about the ethical interpretation of Article 8 of Law No. 4180-I of 1992 regarding the possible refusal of a donor in his organs to a specific recipient. The question of whether, the consent of the donor (even if requested) can be absolute, has not been studied in scientific professional sphere. This is the next step towards developing a balanced mechanism for organ transplantation. How ethical will it be to refuse to become a donor for a certain group of people, provided that for everyone else a person is ready to become a donor? Often, for example, saving life of the culprit and the victim of an accident may require medical intervention. Does the manipulation of the organ transplant of the deceased victim laid down in the law today meet the moral support and find public support? It is impossible to ignore the omissions regarding the recipient's consent to accept an organ or tissue from an unknown donor. The patient gives written consent, but it is limited by the conditions of medical intervention and notification of possible complications (Law, 1992).

Disputes about the uncertainty of the medical and legal mechanism of establishing the fact of death also goes on. The Additional Protocol to the Convention on Human Rights and Biomedicine regarding the transplantation of human organs and tissues establishes that organs and tissues cannot be removed from a deceased person unless that person has been declared dead in accordance with the law (Article 16) (Additional Protocol, 2002). And only the clarifications to the protocol allows to establish the fact of death through brain death (Explanatory Report, 2002). In Russia, brain death is equivalent to human death. Despite the 2016 changes in the Procedure for Establishing a Diagnosis of Human Brain Death (Ministry of Health of the RF, 2014), the problem of the inconsistency of the term "brain death" with the term "biological death" has not exhausted yet. The point is not theoretical studies, but the actual difficulties for the employee of the medical institution in conducting a dialogue with relatives about the preparation of the body of the deceased for organ transplantation. For medical personnel, the patient is

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already dead, for a relative – not. In addition, the Order procedure itself cannot rule out a medical error, including a belated death statement. For example, the period for successful heart transplantation – from the time of organ harvesting to transplantation to the patient – is very short, and often does not exceed four hours. At the same time, the artificial heart apparatus supports the life of the recipient for a waiting period of an organ for only a few hours (Pashkov & Maltsev, 2019). The Order establishes long-term monitoring up to a day for a secondary lesion to establish a clinical picture of brain death. Timing can be shortened or extended, but this is a complex human factor, since a living heart can be withdrawn at the wrong time.

Both posed private medical and legal problematic questions about the establishment of the fact of death and expression of will become absolutely impossible for a breakthrough in medicine to be a stumbling block when it comes to the status of minors in transplantology.

Nowadays, law is unlikely to ensure the success in transplanting organs and tissues to minors. Only a couple of years ago, the first lung transplant was performed on a child, provided that attempts have been made since 1993 (Gauthier & Golovinsky, 2017). In Russia, virtually no heart transplants are performed on small children, but they are sent to foreign countries at the expense of the federal budget. Kidney transplant operations are performed but are not massive. The main two obstacles to the development of domestic medicine are the long ban on posthumous donation, which was partially lifted three years ago, and the absolute ban on the removal of children's organs when alive.

In Russia, organs from adult donors are transplanted to the child recipient by reducing them, since initially the size of adult transplants exceeds the size required by the child. And if for kidneys, liver and lungs, medicine was able to find technologies and knowledge on anatomical resection, surgical reduction, then for the heart (and some other organs) these methods are not applicable, while others have not yet been developed. Teenage minors may hypothetically have been transplanted a small cadaveric heart of an adult in the territory of the Russian Federation, however, the younger the age or, for example, the finer the complexion of a child, his right to life and medical care will be realized outside the country.

To overcome the first obstacle in matters of cadaveric donation of children, a definite breakthrough in the law is considered to be the possibility of stating the death of a child’s brain. However, according to the Procedure for Establishing a Diagnosis of Brain Death, the developed rules for stating the death of a human brain apply only to children aged 1 year and older (Ministry of Health of the RF, 2014). It is assumed that this age-related omission in the rule of law was deliberate, since the developers did not find the very ethical grounds for declaring the patient’s death. At the same time, medicine may be holding back itself from developing other, more detailed, clinical criteria for the death of a baby’s brain, since it is also a challenge to neonatalogy. On the other hand, the statistics of other countries that have decided on such a step makes sense. For example, in the United States in 2018, more than 100 organs vital to recipients were posthumously removed from infants under 1-year-old.

Unlike adult donation, for minors the legislator has provided a model of “requested consent”, which makes the practice of applying the alleged consent for adults, protected by the Constitutional Court, no longer so unambiguous. However, from the legal point of view, there is another uncertainty in the regulation of posthumous donation of minors in the subject of the publication of consent. Part 8 of Article 47 of the Federal Law of November 21, 2011 No. 323-FL “On the Basics of Protecting the Health

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of Citizens in the Russian Federation" allows you to ask the consent of parents. Accepting the medical practicality incorporated in this norm, there is a possibility that the fact that the opinion of the parents may not coincide. Hence, one must take into account the status of family relations is the marriage current or terminated, is the parent giving the parental rights, with whom the deceased child donor predominantly lived. Naturally, the doctor should not find out these questions personally. But in order to avoid litigation and moral suffering of other participants, all these issues should be reflected in documents filled in by the patient or his relatives.

The second obstacle to the development of transplantology is connected with absolute prohibition of alive children's organs transplanting. This ban is reluctantly under discussion. But it is precisely the absolute and indiscriminate nature of the ban that makes it vulnerable to bioethics and law. The immunity of the ban rests on the general provisions of international instruments, according to which donors who have not reached the age of majority own special rights as a vulnerable category of people as a whole. However, the same WHO Guidelines for the transplantation of human cells, tissues and organs allow exceptions provided in national legislation (WHO Guidelines, 2010).

The Convention on Human Rights and Biomedicine, despite the general prohibition on the removal of organs or tissues from a person who is not able to give consent, also allows medical intervention for a minor with his consent, depending on his age and maturity, permission of his representative, authority or person or institution defined by law. Additionally, the Convention proposes criteria for the living donation of a minor. In particular, a minor may become a donor in case of regenerative tissue transplantation (1); if the recipient and the donor are close relatives (2); if there is no other compatible adult donor (3); if the transplant saves the recipient's life (4); the procedure was legalized through the permission of the authorized body or the consent of interested parties (5); the minor donor himself does not object (6) (Convention, 1996). The provisions of the Convention are not binding on Russia, since Russia has not signed or ratified the document. At the same time, the document is widely discussed at the domestic discussion platforms, considered by the professional community for the development of biomedical science.

The breadth of interpretation of the text of international acts and the direct assignment of regulation of this issue to national legislation caused a variety of practices around the world. In the USA, for example, intravital donation of minors is regulated at the state level. Michigan allows to its residents to become a kidney donor from the age of 14 by donating it to a close relative with judicial permission (Hakim et al., 2010). However, permission of the legal representative is not required. In other states, such consent is already required. A similar evolutionary approach is found in Canadian law: in some provinces (Ontario, Prince Edward Island) the threshold for intravital donation has been reduced to 16 years. The practice of the countries of the European Union is completely different: from a similar indiscriminate ban similar to the one in Russia, Austria (Bundesgesetz, 2012), Germany (Transplantationsgesetz, 2007) to possible deviations in the legislation of Denmark (Thys & Assche, 2016), Estonia (Procurement Act, 2015), Finland (Act on the Medical Use of Human Organs, 2001). In addition, the legislation of Luxembourg, Norway, Sweden and the United Kingdom should be highlighted. In these countries, the regulations on transplantation are worked out in more detail, casually, based on criteria proposed by the international community. In particular, governments differentiate the age of a minor, without giving all

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individuals the same level of maturity from birth to 18. In Norway, intravital donation is allowed at the age of 12 years (Lovdata, 2015), in the UK (England and Wales) – at the age determined by court order. In these states, the practice of obtaining independent authorization or authorization of medical intervention. In Luxembourg, a committee of three experts is appointed by the Ministry of Health, two of which must be pediatricians (Loi, 1982). In Norway, the district governor gives consent. In Sweden, the State Directorate of Social Welfare. In addition, there is a restriction on the type of transplanted organ (as a rule, it applies only to transplantation of the liver and lungs or regenerative tissues), and also a circle of recipients is established: relatives, close relatives. However, in Norway and the UK this criterion is not applied, expanding the circle of recipients to the maximum. Additional classical criteria are written about the mutual benefit of the recipient donor, low risks for the donor, and the absence of another potential adult donor (Thys & Assche, 2016).

7. Conclusion

Foreign experience indicates that the Russian Federation has not yet resolved the issue of the ethics of an absolute prohibition, since the required organ or tissue is rarely can be transplanted from alive twin to a second twin or juvenile blood siblings under existing developed procedure. At the same time, an absolute ban prevents a sick minor in Russia even with the consent of the minor donor and the family from realization the right to life and medical care at the place of residence at the state's expense. Hence, the legal status of minors as living or deceased donors seems to be a special subject of attention, awaiting renovated approaches.

Current Russian transplantology system is modified and improved only by highly qualified personnel and expensive techniques and technologies. There would be a great success in this sphere, if both the medical and legal communities are involved in solving the indicated problems. Do not forget about the necessary involvement of both specialists in determining the tasks of the moral system in order to maximize the bio-ethics of proposals, as well as professionals in the field of information technology for the development of missing registers and their further implementation. The national interests of the state are focused on the person. Therefore, the life of many people directly depends on the consolidation of efforts in the consideration and study of transplantation and donation issues in Russia.

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