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LEGAL AND MORAL AND ETHICAL PROBLEMS OF TRANSPLANTATION IN UKRAINE

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ABSTRACT

The article analyzes the legal acts, modern scientific approaches to the implementation of transplantation as an alternative method of treatment of many diseases, as well as the state policy in this area, identifies the main legal and moral and ethical problems of transplantation in Ukraine, and makes recommendations for improving the state policy in the field of transplantation in order to solve them.

Results. The main legal and bioethical problems of transplantation in Ukraine are: the absence of a legal definition of the concept of human death, specific methods of its detection; operating mechanisms of the national system of

providing transplants (transplantation infrastructure), including the Unified state information system of transplantation, a mobile application to it, transplant coordinators, proven procedures, and so on; an effective state information policy aimed at promoting transplantation as a modern alternative method of treatment; proper legal regulation and effective state mechanisms for implementing bioimplantation.

Methods. When writing the article, *methods* of search, analysis, synthesis, systematization and generalization of information, as well as the sociological method were used.

Results. To solve legal and ethical problems of transplantation in Ukraine to improve the effectiveness of this treatment, it is necessary to implement a number of measures aimed at improvement of state policy in the field of transplantation. This is, first of all, the adoption of the Law of Ukraine "About death", which would define its clear criteria and methods of pronouncement. It is also necessary to adopt and actively implement the state program for the development of transplantation, which provides specific measures to digitalize this area, the introduction of clear procedures for the implementation of transplantation, the state information policy to promote transplantation and the development of bioimplantation.

The end of the XX century was distinguished by the rapid development of classical Sciences and the formation of new scientific directions, one of which was the young medical science of transplantology, which today introduces alternative methods of treatment of severe diseases.

The term "Transplantology" is derived from lat. "transplantatio", and in the legal sense, transplantation is a special method of treatment that involves the transplantation of human anatomical material from a donor to a recipient and is aimed at a human health resumption [1].

Since its formation, Transplantology has raised a number of issues of biological, legal, moral and ethical nature that humanity has not had to solve yet.

The theoretical basis of the research is represented by the scientific works of such famous scientists as A. Goldfarb-Rumyantsev (2006), S. Grinchak (2017), V. Denisov (2011), A. Musienko (2010), O. Reznik (2019), etc. Without encroaching on the theoretical significance of the works of these scientists, unfortunately, we have to recognize the insufficient degree of development of this issue from the standpoint of scientific research. Despite the great relevance of this applied problem, science has not yet formed a sufficiently effective way to solve it.

The purpose of this article is to analyze normative legal acts, as well as to summarize the results of theoretical research on current legal, moral and ethical problems of transplantation, and to identify ways to improve public policy in the field of transplantation.

When writing the article, *methods* of search, analysis, synthesis, systematization and generalization of information, as well as the sociological method were used.

Such scientists and practitioners as M. Zharova [2], O. Galibin and I. Belyaeva [3], and A. Belyaeva write in their works about serious social problems of transplantation, which are of medical, moral, ethical, legal, and even religious nature. Schastny and E. Mikhnevich [4], E. Bryzgalina [5], A. Shunkina [6], Yu. Karimova and D. Savitskaya [7], Albert R. Jonsen [8].

The main moral and ethical and socio-psychological problems of transplantation are in the following aspects. Compliance with the ethical principle of "Primum non nocere" in cases where a donor is a living person is almost impossible in Transplantology. The doctor is faced with a contradiction between the moral principles of "Primum non nocere" and "do good". As for post-mortem donation, some researchers believe that the situation in which a doctor should ask relatives for permission to donate immediately after the news of death is extreme and exceeds the permissible psychological burden on both relatives and the doctor. However, it should be noted that there are already approaches to solving this problem in the world medical practice. The law obliges doctors in these cases to contact the relatives of the deceased with a proposal to remove organs and tissues for transplantation [9] in some American States.

As noted by S. F. Bagnenko and O. N. Reznik, the main feature of organ transplantation is the ability to give life to a doomed patient at the expense of the organs of a deceased person who is not dependent on a person who needs a transplant [10].

In addition, a significant bioethical problem is the discussion and ambiguity of the issue of determining the death of the human brain. The American Association of Neurology believes that public confidence in the precise definition of brain death and the ability of courts to rule on controversial cases will be underpinned by the same laws, policies, and practices regarding brain death. Accordingly, the AAN supports legislation modeled on the Nevada Charter, and efforts to develop unified institutional policies for determining brain death in US medical institutions, training programs for doctors that determine brain death, certification mechanisms for doctors involved in determining brain death, regardless of specialty, institutional policies that ensure that doctors comply with medical standards for determining brain death, research that expands the knowledge base about brain death and its accuracy, and improve professional and civic education for these reasons [11].

Therefore, legislation, namely the Law of Ukraine "Fundamentals of legislation of Ukraine on health care" should have a clearly prescribed norm that defines irreversible death of a person, clear criteria for determining death, clearly prescribed means of determining death, medical standards in this matter. We emphasize that the above-mentioned concepts and conditions should be defined by the law, and not by-laws and regulations, since this issue, as in direct. so in a figurative sense it is a matter of life and death, in many

respects it determines the most important human right - the right to life, since it has a direct influence on the legal definition of the temporal boundaries of human life. Therefore, we believe that there is even a need to adopt a separate Law of Ukraine "About death", where the above-mentioned aspects of the problem will be spelled out in detail.

In our opinion, the main reason for the small number of transplants in Ukraine is the lack of mechanisms for transplantation, the so-called transplant infrastructure, which should include: an information system for transplantation; professionals who are engaged in the coordination of transplantation; clear procedures governing the various stages of transplantation; state and public institutions that would be engaged in information policy in the field of transplantation conduct educational and informational events and popularize transplantation.

Rafael Matesanz, Director of the organ transplantation organization of Spain (Organización Nacional de Trasplantes), has repeatedly stressed that, in his opinion, the huge success in the development of donation and transplantation in Spain has been achieved mainly due to the organizational structure of the transplant system, not the legislation. One of its key elements is to actively attract resources from all hospitals where potential donors are located. Introduction of the position of donor coordinator has proved to be an effective way to achieve this goal, and the European Committee on Organ Transplantation (CD-P-TO) and the European Union have in recent years supported this approach in all European countries. CD-P-TO have been working on an overall strategy for the development of intravital donation programs in Europe with a focus on donors' health and safety, including the sociological and psychological aspects of lifetime donation. In recent years, in the European Union, intravital donation rates have increased by more than 10%, which is an important contribution to self-sufficiency in terms of donation and transplantation [12].

Among the main reasons for the insufficient number of donor anatomical materials, and in particular in Ukraine, the legal regulation of the procedure for obtaining consent or disagreement to the explanation of the deceased is often called. In world practice, two main legal models for obtaining consent to the removal of anatomical material from the deceased are successfully used - "presumption of approval" and "presumption of refusal".

The presumption of approval to the grafting does not require the permission of the donor himself or his legal representatives, if during his lifetime he did not make any statements in which he would object to such actions.

The presumption of refusal is applied in Ukraine, and according to it, every legally capable adult can give written consent or disagreement to become a donor of anatomical materials in the event of his/her death. [1]

In our opinion, the "approval" model also has the right to exist in accordance with the proper legal justification and its effectiveness. This position is due to the understanding of life and health as the highest social value in Ukraine and

the world, which is enshrined in article 3 of the Constitution of Ukraine [13] and a number of international legal norms, and therefore the use of organs or other anatomical materials of a deceased person, who did not object to it during life, to preserve the life and health of a living person, is considered justified. Of course, the procedure for removing anatomical materials must comply with modern ethical and legal standards. However, due to the high level of corruption, the introduction of the "approval" model in Ukraine is currently premature. Therefore, it is necessary to increase the effectiveness of both the national anti-corruption policy and the level of anti-corruption management in healthcare institutions [14].

In this situation, according to the authors, it is necessary to improve the procedure for obtaining and recording the voluntary consent of the donor for the removal of anatomical material and the mechanism of state control, while maintaining the current legal model for obtaining approval.

In support of the authors' opinion, we present the results of our own statistical observation, during which we conducted a survey of 300 people who have legal education. The analysis of the survey showed that 85% of the respondents had not heard about cases of illegal withdrawal of donor anatomical materials, but at the same time, 90% of the respondents assume the existence of an illegal market for human organs and tissues in Ukraine. The source of information for 60% is the Internet. At the same time, 80% of respondents consider the conditions for the withdrawal of donor material "transparent", and the main reason for violations of the legal procedure for the withdrawal of donor anatomical material 60% of respondents consider insufficient control, and 40% see the problem in imperfect legislation.

However, the most significant point, according to the authors, is the attitude of the respondents to the legal model of obtaining consent to withdrawal. The opinions of the respondents on fixing the "presumption of approval" and "presumption of refusal" in the legislation were equally divided, which indicates their equivalence and the priority value of the state policy on their implementation. At the same time, the authors remain in the position of preferential value of the "presumption of refusal" in Ukraine.

According to the authors, such comprehensive actions in the future can significantly improve the situation with donor material and will, importantly, prevent the criminalization of transplantation.

This opinion is confirmed by our own survey of 200 people with higher medical education, which was carried out as part of the preparation of this article. According to the results of the survey, only 4% of respondents know about cases of illegal seizure of donor anatomical materials, 34% believe that there is an illegal market for donor organs, and 94% received such information from the media and the Internet. Only 8% of respondents define the probability of becoming a victim of illegal organ transplantation as more than 50%, and 38% believe that this probability is close to zero. 54% believe that the conditions for the withdrawal of donor anatomical material are transparent, and the main reason for violations of the legal order of such withdrawal is

considered by 50% to be imperfect legislation, and 46% - insufficient control. 70% of the surveyed doctors supported the "presumption of approval" for the removal of donor anatomical materials, and only 22% support the "presumption of refusal". 66% of the surveyed medical professionals are against the fact that consent to the removal of organs or anatomical materials of a deceased donor is provided by the person who carries out the burial of the deceased.

Obviously, in order to improve the quality and quantity of transplants, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "on the use of human anatomical materials transplantation" (hereinafter - the Law), which regulates the right to grant consent or disagreement to the removal of anatomical materials from the deceased in article 16 to their relatives [1]. Although such a rule is no longer a presumption of disagreement in its purest form, the authors consider it permissible.

Such activities related to Transplantology as the production of bioimplants require close attention from the state. This activity, in particular, is carried out by the state research and production enterprise "Bioimplant" of the Ministry of Health of Ukraine. The financial audit of this enterprise, which was carried out by the State audit service for the fourth quarter of 2019, revealed a number of shortcomings of an organizational and legal nature in its activities. The Ministry of health of Ukraine, in particular, haven't developed any requirements for the material and technical base, equipment, training and skills of health institutions and scientific institutions that carry out activities related to transplantation, without support of a Unified state information system of transplantation that provided by applicable law. In addition, there is no state order for the production of bioimplants, which makes it impossible for the company to achieve its statutory goal [15].

Under these conditions, the activities for the production of bioimplants are not sufficiently regulated and transparent, which increases the corruption risks of activities related to transplantation.

Thus, the legislative definition of death, specific methods of finding is the key ethical and legal problem transplantation, because most of it falls on the transplantation of organs from dead people. The question is, to what point should medical professionals fight for the life of a person and what exactly is considered death: the death of the entire brain or the death of its axis. If it is incorrect to determine the moment of donor's death, then organ harvesting from such a donor, in fact, can be considered as killing him, which is a criminal offense. Since organ transplantation is a rather expensive procedure, legislative uncertainty in this area contains corruption risks with a high priority.

The question of the effectiveness of public policy in the field of transplantation is primarily not in the sphere of legal presumptions of "approval" or "refusal", but in the issues of creating an appropriate transplant infrastructure. We are referring not only to the legal establishment of a Unified state information system for transplantation, transplant coordinators, and procedures necessary

for the implementation of transplantation, but also to their real and effective functioning. But to do this, it is necessary to draw up a regulatory framework and fix the project method of public management of transplantation.

In addition, an important component of public policy in the field of transplantation is information and communication activities in this direction. The relevant state authorities, local self-government bodies, institutions of higher medical education, public organizations, and other public and private institutions should join it.

When building the transplant infrastructure, it is necessary to take into account the concept of development of Ukrainian society and the state called "the state in the smartphone", which should fit seamlessly into the overall concept of digitalization. This is important because with the help of mobile apps, everyone can easily express their will on donation issues, including posthumous ones.

Results. Thus, in order to resolve the legal and moral and ethical problems of transplantation, as well as to improve the effectiveness of public policy in this area, the following measures should be implemented.

1. Adopt the Law of Ukraine "About death", which provides an exhaustive definition of the concept of "irreversible death of a person", establish clear criteria for death, clear methods and forms of its definition, as well as other issues of establishing the fact of death. Before such an important legal act is adopted, it should be carefully prepared and widely discussed, especially in medical and legal circles.

2. Develop and approve at the highest state level a national program for the development of Transplantology in Ukraine, which is a national project with all the necessary components, namely: problem statement, goal, objectives, action plans and responsible persons, temporal limits, as well as measurable results and other necessary components.

3. the National program for the development of Transplantology should take into account the following features: the creation and operation of an effective information and communication system for ensuring transplantation, which would be available for use by every citizen of Ukraine, including through mobile applications; clearly prescribed procedures that ensure transplantation; a large-scale information policy of the state and civil society to promote transplantation as an effective and alternative method of treatment; legal regulation and regulation of the production of bioimplants.

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