

## REVIEW ARTICLE

# LEGAL REGULATION OF THE INSTITUTE OF TRANSPLANTATION IN UKRAINE

DOI: 10.36740/WLek202307126

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## ABSTRACT

**The aim:** The aim of the study is to generalize the established by scientists features of the legal regulation of the institute of transplantation in Ukraine and other countries.

**Materials and methods:** The article examines the institute of transplantation, its medico-legal character, and the problems of implementing the institute in Ukraine. In the study, the authors applied general scientific methods, which include system analysis, system modeling, dialectical method. The authors used the following materials: laws, decrees of the President of Ukraine, resolutions of the government and ministries of healthcare, dissertations and articles by scientists, assessments of leading experts in the field.

**Conclusions:** Theoretically, the legal aspect of the study of the institute of transplantation is important for formulating the general patterns of its emergence, developing prospects for its functioning and strategic directions for its further development, building a system for protecting the rights of all participants in this legal relationship. Different aspects of transplantation can be considered separately: medical or surgical; biological; psychological. But there is an equally important aspect – the legal one, which reveals the institute of transplantation from the standpoint of the protection of human dignity.

**KEY WORDS:** transplantation, biological material, implant, medical service, donor

Wiad Lek. 2023;76(7):1685-1693

## INTRODUCTION

It can be said without a doubt that the perfection of legislation that regulates any sphere of activity is an important condition for the effective performance by the state of its functions. Activities in the field of health care, medicine and in such a significant area as the transplantation of human anatomical materials are no exception. After all, the life and health of every member of society is recognized as the highest value, which determines the relevance of the chosen topic.

Transplantology poses a number of moral and ethical, legal and religious questions to society, the answers to which may be contradictory from the point of view of morality, religion and law. However, the existence of real legal relations in the field of transplantation gives rise to the need to find compromises between the specified systems of social rules. That is why the issue of regulation of this activity at the legislative level is important. Practice proves that, for the most part, the lack of clear rules and responsibility in the field of transplantation gives rise to illegal trade in organs or tissues, forced donation and even killing for the purpose of extracting organs or tissues from a person. All these negative factors and possible consequences encourage

us to regulate medical and legal activities related to transplantation within the limits of the law.

If a person's health is at risk and/or he or she is disturbed by thoughts of a fatal disease, it is difficult to focus on anything else, to think about economic benefits, procreation, personal development, career growth. Staying alive and being healthy becomes a person's priority above all listed above [1]. The quality of life of the population significantly depends on the level of development of medicine, in particular, such a field as transplantology. The need for donor organs grows every year, which requires the development of an effective mechanism for regulating legal relations in this area [2].

Today all over the world transplantation is considered an extremely effective and generally non-alternative method of treatment for diseases of vital organs, including heart, kidneys, liver, lungs, and others. That is why transplantation in developed countries is one of the most dynamically developing areas of medicine. The problem of legal regulation of human organ transplantation is being solved to a greater or lesser extent by Ukrainian and foreign scientists: H. Anikina [3], O. Gel [4], S. Grinchak [5], V. Shulga [6], D. Zadykhailo, V.

Milash, V. Yarotskyi [7], O. Shevchuk [8, 9], V. Trofymenko, I. Martynivskyi, G. Honcharenko, D. Zatinatskyi [8], O. Lysoded, I. Borysenko, O. Bababeva [9] and others.

The flourishing of successful transplantation practices in the developed countries of the world at the end of the 20th and the beginning of the 21st centuries and pronounced lag in it in Ukraine lead to an urgent need to investigate the problem. The sphere of health care is one of the most important areas that require legal regulation and control, based on the fact that human life and health are the highest social value [10]. In addition, transplantation concerns two people at the same time – the donor and the recipient, and in the opinion of O. Stets, O. Bylochenko and Yu. Chabanenko, medical personnel as well, which brings it closest to legal science and requires the “clearer” legal regulation among all medical disciplines” [11, 8]. The extreme importance of the problem is also confirmed by the decisions of various international organizations, which define the basic principles of transplantology, which are recommended to all states [12]. In the context of integration into the European Union, Ukraine undertook to make efforts to harmonize its legislation with the legislation of the European Union, including in matters of human organs transplantation [13]. The national legislation on transplantation of human organs consists of a large number of normative legal acts, which leads to the problem of inconsistency of some norms and the need to make the necessary changes to the current legislation.

## THE AIM

The aim of the study is to generalize the established by scientists features of the legal regulation of the institute of transplantation in Ukraine and other countries. The materials of the article are valuable for and can be used by transplantologists, students of medical universities specializing in this area, medical law teachers of legal educational institutions, students of the relevant profile and all those who are interested in the raised issues.

## MATERIALS AND METHODS

The article examines the institution of transplantation, its medico-legal character and legal regulation, the problems of implementing the institution, the mechanisms of its implementation in a modern democratic society. The methodological basis of the research is general scientific methods, which include system analysis, system modeling, and the dialectical method.

In order to determine the characteristic features of the laws of Ukraine on the transplantation of human organs, the authors used the following materials: laws,

decrees of the President of Ukraine, resolutions of the government and ministries of healthcare, dissertations and articles of scientists, assessments of leading experts in the field, as well as theoretical scientific methods and techniques of research. The comparative-legal method contributed to the generalization of the experience of developed countries in the field of transplantation. The historical-legal method was used in the study of the formation and development of the administrative-legal regulation of the institute of transplantation in Ukraine. The formal-legal method provided an analysis of the powers of subjects of state management of transplantation in Ukraine. The technical-legal method was used to interpret the provisions of law of the institute of transplantation. The method of legal forecasting was used to determine a complex of possible options for the development of transplantology in Ukraine.

## REVIEW AND DISCUSSION

Despite the ongoing war on the territory of our country and the current special legal regime [14], scientists of the country are trying to pay due attention to the vital issues of the development of medical and legal institutes in Ukraine, and the institute of transplantology is no exception. Transplantation is a specialized method of treatment, which is that the organs or cells from one person (donor) are transplanted to another (recipient). Today, scientists predict that in 30 years, 60% of surgical interventions will be related to transplantation. These forecasts are based on the global rate of growth in the number of transplant operations. There is no country on the planet in which the institution of transplantation is prohibited. The World Health Organization notes that 104 countries of the world have the financial, material, technical and human resources to carry out the transplantation of organs or cells from the donor to the recipient [15]. P. Humel and his colleagues, conducting an assessment of the functions of national ethics committees around the world, systematized bioethical topics discussed on websites and contents of well-known authors. The search was conducted in English, French and Spanish. Discussion topics were grouped into thematic categories through an iterative regrouping process to come to a core set of topics. The five main topics of these publications were: research ethics (124; 9%), genetics and genomics (62; 6%), organ transplantation (58; 5%), assisted reproductive technologies (49; 4%) and end of life (36; 3%) [16]. We see that the topic of organ transplantation is a relevant and widely discussed topic in scientific doctrine.

More than 24,000 organ or cell transplant operations are performed annually in the USA, more than 4,000 are performed in Spain, and more than 1,500 transplantations are performed in Poland [17, p. 66]. This branch of medicine is actively developing in the Baltic countries, in particular, in Estonia, where the rate of organ and cell transplantation per 1 million population is 46.2, the rate in Latvia – 36.2, in Lithuania – 22 [15].

The era of modern organ transplantation was “historically opened” by our compatriot Professor Yu.Yu. Voronim (1895-1962) [18], who in 1933 performed the world’s first cadaveric kidney transplant to a person in the city of Kharkiv (where he was undergoing an internship). It was the first attempt in history to transplant a whole organ into a person. An elderly man with a severe brain injury was brought to the clinic; he died peacefully in the emergency room. On the same day, a young woman who attempted suicide was dying in the clinic: she had taken a fatal dose of sulema. Unfortunately, the girl was hospitalized only four days after the suicide attempt. Her body was sick for four days, the kidneys were not functioning. The surgeon performed extirpation of the right kidney of the corpse, transferred it to the operating room to the patient. After applying vascular sutures, the blood circulation in the kidney was restored, the blood supply was sufficient. The kidney was included in the blood circulation and began to function on its own. The first recipient lived with the new organ for only 48 hours [19].

Today, the annual need for organ transplantation in the country is 3,653 cases, of which 2,115 are kidneys, 830 are liver, 30 are pancreas, 89 are pancreas and kidney together, 328 are heart, 240 are lungs, 3 are heart and lungs together, intestines are 42 cases. At the same time, transplant operations part is 0.8% of all surgical interventions. According to the Ministry of Health, 5 liver transplantations, 2 kidney transplantations, and 93 complex transplantations were performed in Ukraine in 2016 [20].

The material base for this extremely important branch of medicine was developing in Ukraine. Six centers received the right to perform operations on the transplantation of human organs: the National Institute of Surgery and Transplantation named after O. O. Shalimov, Lviv Regional Clinical Hospital, Odesa Regional Clinical Hospital, Regional Clinical Center of Urology and Nephrology named after V. I. Shapoval (Kharkiv), Zaporizhzhia Regional Clinical Hospital, Dnipropetrovsk Regional Clinical Hospital named after I. I. Mechnikov, which are able to carry out up to 1,000 organ transplantations per year [21].

The legislative framework for the implementation of human organ transplantation was also developing. The basis of the regulation of this legal institution is laid down in the norms of the Constitution of Ukraine [22] and the Civil Code of Ukraine [23]. For a more detailed clarification of the mechanism of regulation of the organ and cell transplantation institute, we should refer to the Law of Ukraine “On the Application of Transplantation of Anatomical Materials to Humans” [24], Fundamentals of the Legislation of Ukraine on Health Care [25], which, in turn, play a role of the medical activity code. In order to quickly regulate medical activities in the field of transplantation, by-laws of executive authorities are adopted, including, for example, the order “On establishing diagnostic criteria for brain death and procedures for determining the moment of death of a person” [26].

The adoption of the Law of Ukraine “On the Application of Transplantation of Anatomical Materials to Humans” [24] became the basis for the formation of the newest stage of transplantology in Ukraine. Changes in legislation in the field of organ and cell transplantation allowed:

- to improve the terminological apparatus of this institute;
- to make changes to the criminal legislation regarding increased liability for illegal removal and transplantation of anatomical materials to a person (Article 143 of the Criminal Code of Ukraine [27];
- to define the concept of “the moment of irreversible death” by making appropriate changes to the basic norms of health care. The “moment of irreversible death” is proposed to mean the biological death of a person or the moment of the death of his or her brain. In practice, the ascertaining of death is confirmed by a council of doctors and the drawing up of a legal act signed by all council participants. The specified legal document is kept in the patient’s medical records.

In international law, issues regarding the institution of transplantation are regulated by the Helsinki Declaration of the World Medical Association “Ethical Principles of Medical Research Involving Human Subjects” from 1964 [28], which states that progress in medicine is based on works that ultimately include research with the participation of a human as an object of research. The purpose of such research is the need to explain the causes and consequences of diseases, to improve existing preventive, diagnostic, and therapeutic measures. The following international document establishing the principles of legal regulation of the institution of transplantology is the International Declaration on Transplantation of Human Organs of 1987 [29], which

declares that both the donor and the recipient are patients, and therefore all measures must be taken to protect the rights of both. Finally, the 1997 Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine [30] and its Protocols emphasize that modern biology and medicine are developing at an accelerated pace, and their improper use can lead to actions that threaten human dignity. Therefore, progress in these fields should be used for the benefit of present and future generations, while the interests of an individual should be higher than the interests of the entire society or science.

Systematizing the problems of the institute of transplantation, three main aspects should be highlighted.

First, the Law of Ukraine "On the Application of Transplantation of Anatomic Materials to Humans" [24] establishes the mandatory consent of relatives (a spouse, children, parents, brothers, sisters) for the removal of biological materials from the human body for transplantation and the production of implants. In the absence of relatives, consent for transplantation can be given by a person who has the duty to carry out a person's burial. In the event of the death of a person under the age of 18, consent to the selection of materials is given by the child's parents or the legal representatives. As a rule, such consent is not given in practice. And in cases where consent is given, the need to prepare a large number of legal documents plays a negative role as a psychological and emotional factor and affects decision-making.

When obtaining consent for donation, a significant role is assigned to the coordinator, who organizes communication with the persons giving consent for the removal of organs and cells from the donor. The coordinator first contacts the persons who can give consent to transplantation by phone, finds out the degree of their family connection with the donor, their place of residence, and then organizes a personal meeting. During the meeting, the coordinator informs the authorized person about the provisions of the current legislation of Ukraine, explains the goals of removing the organs or cells of a deceased person, informs about the voluntariness of consent to the donation of anatomical materials that must be taken with awareness of the meaning of the actions, without any coercion. During the meeting with the coordinator, other close relatives and family members or other legal representatives of the deceased may be present. If it is necessary to provide additional explanations regarding donation, brain death, biological death, the coordinator can involve doctors of other specialties in such explanations.

Obtaining consent from the relatives of the deceased is of great importance for the observance of the rights of all participants in legal relations concerning organ transplantation. This thesis is revealed, in particular, in the decisions of the European Court of Human Rights. And although the Convention on the Protection of Human Rights and Fundamental Freedoms does not directly provide for the protection of the right to health, applying for the protection of this right is possible on the basis of Articles 2, 3, 5, 8 of the Convention. Thus, in the case "Petrova v. Republic of Latvia" [35] the applicant pointed to the fact that after the death of her son as a result of a traffic accident, his kidneys and spleen were removed for the purpose of organ transplantation without her consent or her son's prior consent to these actions. The applicant became aware of what had happened nine months later during the criminal proceedings regarding the traffic accident in which her son had died. The country's authorities emphasized that such actions corresponded to the current Latvian legislation, since at the time of the applicant's son's death, the provisions of the law were in force, which did not oblige medical professionals to search for and inform relatives of the deceased about the possible removal of organs, as well as clarify their right to object against the removal of his organs or tissues. The European Court of Human Rights emphasized that Latvian legislation was not formulated clearly enough and did not provide effective protection against arbitrariness. A similar situation is reflected in the case "Elberte v. Republic of Latvia" [36], which concerned the removal of the body tissues from the applicant's deceased husband and their transfer to a pharmaceutical company in Germany for medical experts without her knowledge and consent. Elberte became aware of this situation only two years later, when a criminal investigation was launched in the Republic of Latvia in connection with the assumption of large-scale illegal removal of organs and tissues from the dead.

Here we should mention the above Convention on the Protection of Human Rights and Dignity of Human Being with regard to the Application of Biology and Medicine. This Convention is the completion of the codification of the principles of bioethics and the starting point for the development of the transplant institution in the future. Currently, 35 countries have signed the Convention, 29 of them have ratified it. The main achievement of it is that it became the first legally binding international instrument that covered a huge range of ethical issues in the field of biological research, indicated a wide range of ethical and legal principles applicable to medical actions and new

biomedical technologies. Article 29 of the Convention provides for the right of the European Court of Human Rights to formulate conclusions on legal issues regarding the interpretation of the text of the Convention. Many principles of the Convention are directly related to private law and categorical requirement to obtain consent for medical intervention. The Convention can be called a treaty on patient rights, which acts as a codification of the principles of medical practice. The focus of the norms of the specified international document is expressed in the protection of the dignity and individual integrity of a person, guaranteeing the observance of the inviolability of the person in connection with the application of the achievements of biology and medicine. The Convention introduces four key principles of bioethics: the primacy of a person, providing equal access to health care, the need for consent to medical intervention (and the protection of those who are unable to give it), confidentiality.

Transplantation of organs from a deceased person today is a more expedient and justified form of donation, because under such conditions the life and health of a living donor is preserved. It should be noted that the risk of postoperative complications for the donor is always quite high. In addition, organ transplantation from a deceased donor is less expensive, which is often of great importance to recipients. Postmortem transplantation allows for a greater number of transplants to recipients (one donor can give biomaterial to several patients at once) and to perform surgical interventions that are impossible from a living donor. Therefore, today, the increase in the number of surgical interventions for the transplantation of organs and cells should be carried out at the expense of the increase in the number of posthumous donors. The insufficient number of posthumous donors in Ukraine, in turn, necessitates the search for biomaterials in other countries [31]. International regulation of biomaterial exchange and transplantation operations is carried out on the basis of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism [32]. In the mentioned Declaration, it was proposed to take measures to increase the efficiency of donation from the dead, as well as measures to combat transplant tourism, commercialization of transplantation, and organ trafficking; measures to ensure the protection and safety of donors' lives [13].

Secondly, the legislation of Ukraine provides for a limited list of persons who can become donors of organs or tissues. The existing list makes it impossible to donate between cousins, third cousins, godparents, as well as persons who are willing to become donors for people who are not relatives of the recipient. It

is about the functioning of the so-called "family donation", to which only close relatives have the right to provide their biomaterial for transplantation. It is precisely such legal norms in Ukraine that force Ukrainians to use foreign medical services and, as a result, not to support the domestic medical sphere. It is a well-known fact that material from a living donor takes root better in a patient than the material from a cadaver donor. But the humaneness of replacing cadaver donation with an altruistic one remains an open question from the standpoint of human dignity, legal values, moral and ethical beliefs.

It should be noted that the procedure for granting the consent of the donor for the removal of biomaterials, the expression of will for the legal representative regarding the removal of implants from the body of the deceased in Ukraine is regulated by the Decree of the Cabinet of Ministers of Ukraine of December 27, 2018 No. 1211 "Some issues of implementation of the Law of Ukraine "On the Application of Transplantation of Anatomical Materials to Humans" [33].

Thirdly, it should also be noted the lack of sufficient control by law enforcement agencies over the transplantation institute. It is necessary to develop surveillance to identify and bring to justice persons who carry out "brokerage" or other illegal activities (especially through the Internet) in the field of extraction of anatomical materials for transplantation and manufacturing of bio-implants. A monitoring system for the detection of advertisements for the sale or purchase of human organs or tissues can be an effective mechanism for regulating the institute of transplantation.

As S. Grinchak points out, it is very difficult to bring to justice medical staff who perform actions in the field of transplantation that have signs of a crime. This indicates a high level of latency of such crimes and significantly complicates the assessment of their real state. And if we take into account that only a small part of criminal proceedings regarding crimes in the field of providing medical services come to the stage of trial, then we can conclude that the country does not have a sufficiently effective mechanism for combating such crimes [5].

Based on world experience, two options for the development of this institute can be identified:

- the first way is a person's lifetime consent to be a donor after death. Germany, Poland, France, and Spain have long used such a system, where a person is asked about the possible use of his or her organs after death while he or she is still alive.
- the second way is to introduce a system of "presumption of consent", when all residents of the country

are potential donors, but if they are not ready to be donors after death due to some moral-ethical, religious or other beliefs, they must notify the special institutions that put such persons into a special register.

Such systems have a number of advantages:

- 1) the lists of potential donors is formed.
- 2) a national register of persons who, during their lifetime, spoke against the transplantation of their organs in case of death is formed; this person's organs must not be removed under any circumstances.

For example, in Ukraine, in accordance with the Resolution of the Cabinet of Ministers of Ukraine dated December 23, 2020 No. 1366 "On approval of the Regulation on the Unified State Information System for Transplantation of Organs and Tissues" [34] there is the Unified State Information System for Organ and Tissue Transplantation operates, the task of which is to identify donor-recipient pairs, provide the participants of the national organ transplantation system with effective and expedient (in real time) information on potential donors of human anatomical materials, available human anatomical materials intended for transplantation and/or production of bio-implants, persons in need of medical assistance with the application of transplantation, persons in need of medical observation in connection with the transfer of transplantation, as well as other information necessary for the normal functioning of the transplantation system in Ukraine. Access to the registers of the Unified System is free.

The functioning of the system is provided at the expense of the state budget. The Unified State Information System of Organs and Tissues for Transplantation contains information on the voluntary consent of a person or his or her representative to the removal of anatomical materials or the manufacture of bio-implants, data on donors and recipients, information on medical institutions that have the right to real opportunities to perform transplant surgeries, data on transplants coordinators.

The first registry of cell donors appeared in the United States of America, the Americans were the first in the world to use the method of bone marrow transplantation. Initially, similar registries functioned separately in each state, but this made it difficult to find the necessary donor or material. In order to improve the search system, such separate registers were combined into the National Register of the United States of America. Over time, such information bases also appear in Europe, Asia, and Australia. However, the creation of domestic registries did not always provide an opportunity to find the right donor or anatomical

material. This led to the creation of relevant international databases (for example, in Europe – European Marrow Donor Information System), and then the formation of a worldwide network – Bone Marrow Donors Worldwide.

European Marrow Donor Information System is an open network between different bone marrow donor registries for patients waiting for a transplant who do not have compatible family donors. The network consists of the same system in all countries. Email addresses are used as a method of communication. Bone Marrow Donors Worldwide is a voluntary joint association of bone marrow donor registries and umbilical cord blood banks to provide centralized and anonymous information on phenotypes, other data of unrelated bone marrow and umbilical cord blood donors; ensuring easy access to this information by doctors and recipients needing stem cell transplants. The system includes 51 bone marrow donor registries from 37 countries and 29 cord blood registries from 19 countries.

Separately, it is worth paying attention to the medical services that can be provided at the transplantation institute:

- 1) the first of them consists in the provision of medical assistance with the application of transplantation, that is, in fact, transplantation services (transplantation of anatomical material), which are provided in transplantation centers;
- 2) the second is the implementation of activities related to transplantation: medical services for the extraction of anatomical materials from living donors; removal of anatomical materials from a cadaver donor; storage and transportation of human anatomical materials intended for transplantation, storage and transportation of such materials for the manufacture of bio-implants.

The innovative provision of the Law of Ukraine "On the Application of Transplantation of Anatomical Materials to Humans" [25] allows health care institutions and scientific institutions of all forms of ownership to carry out transplantation activities today. Before the entry into force of the new law, such actions could only be carried out by state and communal health care institutions. The new law gives the right to all health care institutions that have a license to carry out economic activities in the field of medical practice (including the right to provide medical assistance with the application of transplantation and to carry out activities related to transplantation) to carry out such medical activities. This provision opens wide prospects directly for medical institutions and doctors working in private hospitals.

## CONCLUSIONS

Organ donation is a legal relationship that has not yet been properly substantiated in legal and medical practice in Ukraine, and society's acceptance of the institute of transplantation as an innovative one is accompanied by many opposing views. The legal aspect of the study of the institute of transplantation is important for formulating the general patterns of its emergence, developing prospects for its functioning and strategic directions for further development, building a system for protecting the rights of all participants in this legal relationship.

When transplanting organs in humans, different aspects of the problem can be considered separately: medical or surgical, which includes the method and procedure of transplanting biological material; biological, which reveals compatibility or suppression, rejection of transplanted biomaterial by the human body; psy-

chological, which answers the question of how to live a person with an implant in the future. But there is an equally important aspect – the legal one, which reveals the institution of transplantation from the procedure of conducting the procedure, providing medical services, protecting human dignity, and the rights of all participants in the legal relationship.

Transplantation is a modern challenge to the civilized world. Members of world society must realize the need for donation today, as a component of modern medicine, as a means of treating diseases incurable by other means, a person must understand that his or her organs after death can save someone's life. The discussion of this issue in society can contribute to the fact that the lists of potential donors will increase along with the number of consents given for the removal of donor material from a relative after death for transplantation, which in turn will give a sick person a chance to prolong his or her life.

## REFERENCES

1. Mernyk A, Yaroshenko O, Inshyn M et al. Vaccination: human right or duty. *Georgian Medical News*. 2021;6(315):135–141.
2. Dyakovych M, Mykhayliv M. Legal mechanism of regulation of the status of donor bodies as an object of civil law. *Journal of the National Academy of Legal Sciences of Ukraine*. 2021;28(1):128–136.
3. Anikina G. Peculiarities of legal regulation of organ transplantation from a deceased donor. *Legal Ukraine*. 2010;10:68–75.
4. Gel A. Development of domestic legislation in the field of transplantation. *Entrepreneurship, economy and law*. 2020;5:6–12.
5. Hrynchak S. Criminal liability for illegal transplantation: past, present, future. *Problems of legality*. 2021;154:244–256.
6. Shulga V. Formation and development of state regulation of transplantation in Ukraine. *Bulletin of the National Academy of Public Administration under the President of Ukraine*. 2012;1:153–160.
7. Zadykhaylo D, Milash V, Yarotskyi V. Sovremennoe sostoyanie reformy zdorovohraneniya v Ukraine v usloviyah evrointegratsii [Current status of health care reform in Ukraine in conditions of eurointegration]. *Georgian medical news*. 2020;12(309):172–176 (in Russian).
8. Shevchuk O, Trofymenko V, Martynovskiy V et al. Realization of the human right to palliative care in Ukraine: problems and legal issues. *Georgian medical news*. 2019;4(289):168–173.
9. Shevchuk O, Lysodyed O, Borysenko I et al. Legal support of the patient's right to innovation in health. *European Journal of Sustainable Development*. 2020;9(4):337–350.
10. Ilyuschenkova K. Evolution of legal regulation of reproductive cell donation in Ukraine. *Scientific journal of the National Academy of the Prosecutor's Office of Ukraine*. 2017;2:76–83.
11. Stets O, Biloshenko O, Chabanenko Yu. Current issues of organ and tissue transplantation in Ukraine. *Die wichtigsten Vektoren für die Entwicklung der Wissenschaft im Jahr*. 2020;2:64–67.
12. Ostrovska B. Mizhnarodno-pravove rehuliuвання prava liudyny na zhyttia v konteksti bioetyky [International legal regulation of the human right to life in the context of bioethics]. *Kyiv: Logos*. 2019, 604 p. (In Ukrainian).
13. Novytska M. Implementation of international principles and standards in the field of transplantation of anatomical materials into the national legislation of Ukraine. *Law and society*. 2019;4:217–223.
14. Bukhanevych O, Mernyk A, Petryshyn O. Approaches to understanding the category «special legal regimes». *Journal of the National Academy of Legal Sciences of Ukraine*. 2021;28(1):71–78.
15. Bezzub I. Reforma systemy transplantolohii v Ukraini [Reform of the transplantology system in Ukraine]. *Public opinion on law-making*. 2018;9(153):10–23. (In Ukrainian).
16. Hummel P, Adam T, Reis A, Littler K. Taking stock of the availability and functions of National Ethics Committees worldwide. *BMC Medical Ethics*. 2021;22(1):56.
17. Komarov M, Nikonenko O, Salyutin R, Palyanitsa S. Rozvytok transplantatsii v Ukraini – problemy ta shliakhy yikh podolannya [Development of transplantation in Ukraine – problems and ways to overcome them]. *Modern medical technologies*. 2013;4:64–68 (In Ukrainian).
18. Kobza I, Chopyak V, Zhuk R, Petrov V. Transplantatsiia orhaniv v Ukraini – istoriia v osobystostiakh ta podiiakh [Organ transplantation in Ukraine – history in personalities and events]. *Medical sciences*. 2018;52(1):25–32 (In Ukrainian).

19. Kalita V, Voronoy Yu. Health of Ukraine. <http://health-ua.com/pics/pdf/17/72-73.pdf>. [date access 26.08.2022] (in Russian).
20. Novytska M. Osnovni zminy do zakonodavstva Ukrainy u sferi transplantatsii anatomichnykh materialiv liudyni [Main changes to the legislation of Ukraine in the field of transplantation of human anatomical materials]. *Entrepreneurship, economy and law*. 2018;9:132–137 (In Ukrainian).
21. Kraynyk G, Sachuk B. Problematyka rozvytku transplantatsii v Ukraini [Problems of transplant development in Ukraine]. *A young scientist*. 2018;4(2):700–703. (In Ukrainian).
22. Konstytutsiia Ukrainy vid 28.06.1996 [Constitution of Ukraine of June 28, 1996]. (In Ukrainian).
23. Tsyvilnyi kodeks Ukrainy vid 16.01.2003 № 435-IV [The Civil Code of Ukraine of January 16, 2003 № 435-IV]. (In Ukrainian).
24. Zakon Ukrainy vid 17.05.2018 № 2427-VIII «Pro zastosuvannya transplantatsii anatomichnykh materialiv liudyni» [Law of Ukraine of May 17, 2018 № 2427-VIII «On the application of transplantation of anatomical materials to humans»]. (In Ukrainian).
25. Zakon Ukrainy vid 19.11.1992 № 2801-XII «Osnovy zakonodavstva Ukrainy pro okhoronu zdorovia» [Law of Ukraine of November 19, 1992 № 2801-XII «Fundamentals of Ukrainian legislation on health care »]. (In Ukrainian).
26. Nakaz Ministerstva okhorony zdorovia Ukrainy vid 09.11.2020 № 2559 «Poriadok konstatatsii ta diahnostychni kryterii smerti mozku liudyny» [Order of the Ministry of Health of Ukraine of November 9, 2020 № 2559 «Procedure for establishing and diagnostic criteria for human brain death»]. (In Ukrainian).
27. Kryminalnyi kodeks Ukrainy vid 05.04.2001 № 2341-III [The Criminal Code of Ukraine of April 5, 2001 № 2341-III]. (In Ukrainian).
28. Helsinska deklaratsiia Vsesvitnoi medychnoi asotsiatsii «Etychni pryntsyipy medychnykh doslidzhen za uchastiu liudyny u yakosti obiektu doslidzhennia» vid 01.06.1964 [Declaration of Helsinki of the World Medical Association «Ethical principles of medical research with the participation of a person as an object of research» of June 1, 1964]. [https://zakon.rada.gov.ua/laws/show/990\\_005#Text](https://zakon.rada.gov.ua/laws/show/990_005#Text). [date access 05.08.2022] (In Ukrainian).
29. Deklaratsiia stosovno transplantatsii liudskykh orhaniv [Declaration on transplantation of human organs]. <https://regulation.gov.ua/documents/id207538>. [date access 19.08.2022] (In Ukrainian).
30. Konventsiia pro zakhyst prav i hidnosti liudyny shchodo zastosuvannya biolohii ta medytsyny: Konventsiia pro prava liudyny ta biomedytsynu vid 04.04.1997 [Convention on the Protection of Human Rights and Dignity in the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of April 4, 1997]. [https://zakon.rada.gov.ua/laws/show/994\\_334#Text](https://zakon.rada.gov.ua/laws/show/994_334#Text). [date access 28.07.2022]. (In Ukrainian).
31. Palianytsia S. Rozvytok transplantolohii v Ukraini: isnuuyuchi dosvid ta perspektyvy [Development of transplantology in Ukraine: existing experience and prospects]. <https://health-ua.com/article/63756-rozvitok-transplantolog-vukran-snuuyuchij-dosvd-taperspektivi>. [date access 17.08.2022]. (In Ukrainian).
32. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey, April 30–May 2, 2008 <https://www.declarationofistanbul.org/the-declaration>. [date access 11.07.2022].
33. Postanova Kabinetu Ministriv Ukrainy vid 27.12.2018 № 1211 «Deiaki pytannia realizatsii Zakonu Ukrainy “Pro zastosuvannya transplantatsii anatomichnykh materialiv liudyni”» [Resolution of the Cabinet of Ministers of Ukraine of Desember 27, 2018 № 1211 «Some issues of implementation of the Law of Ukraine «On the Application of Transplantation of Anatomical Materials to Humans»]. (In Ukrainian).
34. Postanova Kabinetu Ministriv Ukrainy vid 23.12.2020 № 1366 « Pro zatverdzhennia Polozhennia pro Yedynu derzhavnu informatsiinu systemu transplantatsii orhaniv ta tkanyn» [Resolution of the Cabinet of Ministers of Ukraine of Desember 23, 2020 № 1366 «On the approval of the Regulation on the Unified State Information System of Transplantation of Organs and Tissues»]. (In Ukrainian).
35. Case of Petrova v. Latvia (application no. 4605/05). <https://hudoc.echr.coe.int/fre#%22itemid%22:%22002-9531%22>. [date access 10.08.2022]
36. Case of Elberte v. Latvia (application no. 61243/08). <https://hudoc.echr.coe.int/fre#%22itemid%22:%22002-10354%22>. [date access 10.08.2022]

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#### Conflict of interest:

The Authors declare no conflict of interest.