

FEATURES OF LEGAL REGULATION TRANSPLANTATIONS IN UKRAINE

Svitlana Iasechko¹, Tetiana Stepanenko¹, Viktoriia Korolova², Nelia Makovetska², Olena Chernetchenko²

¹Department of Civil-Law Disciplines, Kharkiv National University of Internal Affairs, Kharkiv, Ukraine

²Department of State and Legal Disciplines, "KROK" University, Kyiv, Ukraine

Corresponding E-mail: iasechko.sv@gmail.com

Received: 12.04.2020

Revised: 13.05.2020

Accepted: 09.06.2020

Abstract

The scientific work is devoted to the urgent problem of native medicine development, and exactly to the transplantation service of Ukraine. The analysis of modern problems of transplantation industry was carried out by the authors' team in their work, the main problem is the absence of the unified organ law system. This article analyzes the state of legislative regulation of transplantation and mechanisms for their implementation. The article considers the main aspects of the development of contractual relations in the field of organ transplantation and legal acts that regulate the donation of organs and other human anatomical parts, which have expired and those which are valid today. Based on the analysis, the chronological development of donation and the evolution of legal regulation have been built. The problem is that, in fact, the relevant medical institutions provide services for organ and tissue transplantation, but there is no clear contractual regulation of these relationships. The advisability of using such agreements has been reasoned. The necessity of introducing changes in the legislation is substantiated, as well as the practical implementation of significant improvement and elimination of problems in the transplantation industry.

Key words: transplantology; status; donor; recipient; obligation; medical services

© 2020 by Advance Scientific Research. This is an open-access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>)
DOI: <http://dx.doi.org/10.31838/jcr.07.13.76>

INTRODUCTION

The topicality of the publication is that the problem in the world community in the legal regulation of transplantation and donation, their application and control, there are some differences. In the practice of European countries, various legal models of legal regulation of the removal of organs from deceased persons – “presumed consent” and “presumed disagreement” have emerged.

Nowadays, the transplantation of organs and other anatomical materials is one of the most common types of medical services that can restore the body functions and save someone's life. At the same time, the main problem of transplantation is the lack of appropriate anatomical material. The lack of the required number of organs for transplantation is one of the key problems for the treatment of patients. The aim of the article is to determine the current state of legal regulation of organ transplantation both in Ukraine and in European countries and to formulate proposals for its improvement.

MAIN MATERIAL

Given that our country has chosen the vector of its development, first of all, to the integration into the European

community, we should be clearly aware of the trends in the development of relations regarding organ transplantation in

European countries. It will allow to form an idea of how and in what direction the home civil legislation should develop, and, taking into account the general unification approaches, to accelerate the processes of European integration.

Public relations are in constant dynamics, so they require the reforming of old and regulating of new relations. The issue of regulating legal relations in the field of health care is especially acute, since life and health are the highest social values. In an era of change, the field of donation is also not standing still. At a time when the donation of organ and other anatomical human parts is at a very low level of development in Ukraine, it indicates the need to reform this field. Scientists propose to make changes in the legal regulation of the donation of organs and other

anatomical human parts, especially with regard to posthumous donation, namely the presumed consent. Therefore, it is necessary to analyse the evolution of legal acts that regulate the legal relationship of the donation of organs and other anatomical human parts to understand its dynamics and identify the ways of further reforming. The problems of legal regulation of the donation of organs and other anatomical human parts have been studied by many scientists, whose works have become the basis of this article. These include, first of all, O.S. Kizlova, V.V. Luts, R.A. Maidanyk, M.M. Maleyina, C.V. Mikhailov, I.R. Ptashnyk, I.I. Senyuta, R.O. Stefanchuk.

The active development of tissue, cell and organ transplantation has led to increased attention around the problems of ensuring the effective legal regulation in the area in question. For this purpose, the countries of the European Union (hereinafter – the EU) have developed the common minimum standards of quality and safety in the field of tissue and cells transplantation and related activities, which have been set out in the EU Directives known as the EU Tissue and Cells Directives (EUTCD). Ukraine is currently facing the task of fulfilling its obligations under the Association Agreement in terms of approximation of Ukrainian legislation and practice in the field of tissue and cells transplantation to the EU standards. A separate direction is taking into account the provisions of EU law in the field of organ transplantation, the implementation of which, although not required by the Association Agreement, yet is necessary for the development of transplantation in Ukraine according to the European standards.

Nowadays, the legal regulation of donation does not correspond to the level of development of medicine and needs to be reformed. A step to this was the adoption of the Law of Ukraine “On the Application of the Transplantation of Anatomical Materials to Person” [7], published in the newspaper “The Voice of Ukraine” on June 23, 2018, which comes into force on January 1, 2019.

Analyzing the evolution of legal regulation, it is important to pay attention to the fact that legislation is a regulator in the

development of medicine, and it can both promote and slow down the development.

The Law of Ukraine "On the Application of the Transplantation of Anatomical Materials to Person" provides for the presumed disagreement – the transplant material can be obtained from the body of a deceased person only if they agreed to the transplant during their lifetime. According to Art. 16 of the Law, every able adult person has the right to give written consent or disagreement to the removal of anatomical parts from their body for transplantation and/or production of bioimplants after their death. Anatomical materials may be taken from a living donor only with their voluntary and informed consent to the donation of anatomical materials provided in writing [9]. If the deceased did not consent or disagree with the posthumous donation during their lifetime, the consent to the removal of anatomical parts for transplantation is requested from the other spouse or one of the person's close relatives (children, parents, siblings). In case of the absence of such, the transplant coordinator requests the permission from the person who undertook to bury the deceased [8].

Transplantation is primarily a method of treatment of a sick recipient. Thus, the Art. 6 of the Law of Ukraine "On the Application of the Transplantation of Anatomical Materials to Person" defines transplantation as a method of treatment used only in the presence of medical indications and the consent of an objectively informed able patient only in cases where elimination of danger to life or restoration of the recipient's health by other methods of treatment are impossible [1]. Along with the development of transplantation, new legal relations – of posthumous donation, which require legal regulation – are emerging. Their peculiarity is the fact that after death a person cannot be a subject of law, i.e. legal relations arise between the family members of the deceased, the medical institutions, and the recipient. The reasons for the legal relationship of posthumous donation is the presence of a complex legal fact. It should be noted that this should not be a single legal fact, but a certain set of facts. Such grounds can be divided into two groups – medical and legal. The group of medical grounds includes: the recipient's illness, the death of the donor, compatibility of organs or other anatomical materials of the donor and the recipient. Legal grounds include: giving consent of a person in life or family members after the person's death; in case of the presumed consent, the absence of a person's objection in life or family members after their death. In addition to the aforementioned legal facts, in our opinion, we should single out another legal basis – the conclusion of an agreement.

So, one of the most common reasons for the emergence of legal relations in the field of transplantation is a transaction, consent as a unilateral transaction on the possibility of becoming a donor.

According to R.O. Stefanchuk, the legal possibility of giving consent to donation is mediated by granting permission for the corresponding intervention which is aimed at separating a certain organ or tissue from the body of an individual. Therefore, given its intangible nature, as well as taking into account that it is this permission that establishes the appropriate regime of access to the body of an individual, the possibility of granting permission to donate organs and tissues may well be included in the right to physical (corporeal, somatic) inviolability [5]. In his turn, A. Musiyenko also pointed out that each person should have the right to decide on the possibility of removal of organs from their body for transplantation after death, and the "consent system" realizes this right through the procedure of documenting consent in the form of a "donor card" for a person who agreed to have their organs removed from the body after death [3].

In the United States, the procedure of obtaining a "donor card" is usually carried out when issuing a driver's license. The Art. 16 of the Law of Ukraine "On the Application of the Transplantation of Anatomical Materials to Person" states that after entering data

into the Unified State Transplantation Information System the marks on the person's consent or disagreement to posthumous donation and change of this will at the request of this person are entered into the passport of Ukraine and/or the driver's license for the right to drive vehicles of Ukraine in the manner prescribed by law. It would be expedient to carry out a similar procedure both when a citizen obtains a driver's license and at the time of call-up for military service. Such an approach would reach the maximum number of adult, able, educated and progressive people, significantly improving the situation with donor bodies in Ukraine.

The basic issue of the current state of legal support in the field of donation and transplantation is the need to conclude a donation agreement or an agreement on the provision of medical services in the form of transplantation. According to the Law, the transplantation will be carried out on the principles of voluntariness, humanity and anonymity and guarantees a dignified treatment of the human body in case of posthumous donation. The Law gives the right to carry out transplantation activities to health care institutions and scientific institutions of all forms of ownership.

Thus, the organ and tissue transplantation is fundamentally different from other methods of traditional treatment, primarily in terms of subject composition. In addition to the health care provider (specialized medical institution authorized to perform appropriate surgical operations and the recipient patient who needs an organ (tissue) transplant according to medical indications). A donor whose will is crucial for conducting the transplantation is also present in the transplantation relations, that is, instead of the usual legal relationship that arises between two entities – the health care provider and the patient – there is a more complex legal relationship in transplantation, the participants of which in the first state are the donor and the health care provider, and then the health care provider and the recipient [3]. According to I.Y. Senyuta, the relations in the field of health care are civil in nature, as they arise on the basis of an agreement for medical services or an agreement for medical care under the program of medical guarantees and are aimed at personal intangible rights – the right to medical care and value-oriented key intangible benefits – life and health [4].

Transplantation is a special type of medical service and, along with the general rules on the provision of medical service, requires special legislation. For the emergence of legal relations in transplantology, it is necessary to have a certain legal fact, that is, a contractual form of relationship between the medical institution and the patient during organ and tissue transplantation is offered [6].

The Art. 21 of the Law of Ukraine "On the Application of the Transplantation of Anatomical Materials to Person", among other things, allows "the exchange of human anatomical materials (equivalent exchange or purchase and sale)". Ukraine will cooperate with other countries in transplantation issues, that is, such a rule is contrary to the principle of gratuitous transplantation, established in Art. 3 of this Law.

The purchase and sale option was added only in the second reading of the new Law, while the current Law of 1999, as well as the first version of the new Law, allowed only an equivalent exchange of anatomical materials. All multilateral international agreements concerning transplantation, in one way or another, enshrine the principle of non-commercialization of the human body [1].

In addition to this, given Ukraine's European integration aspirations, it is worth noting that the principle of non-commercialization of the human body is proclaimed both in the EU Charter of Fundamental Rights and in the Directive № 2010/45/EU in the EU.

CONCLUSION

The donation of organs and other anatomical human parts has undergone a rapid evolution of legal regulation, as it is a special method of treatment used in exceptional and urgent cases, so it requires changes in legal regulation along with the development of medicine.

So, it can be concluded that the legal relationship that arises in the course of activities related to posthumous donation has a number of specific features that are reflected in their legal nature. The application of contractual regulation of these legal relations is important for clear legal regulation and protection of the rights and interests of the family members of the deceased, health care workers, recipients, as well as the prevention of legal offenses in the field of donation in general.

The solution of this problem requires a comprehensive approach that would take into account the religious and ethical views of society and would be aimed at promoting the ideas of life and posthumous organ and tissue donation for transplantation. Conducting activities on legal education, raising the legal literacy of citizens will have a positive impact and help to form a culture of charity in our country, associated with the donation of organs after death.

Thus, the outlined normative controversies confirm the need to change and correct such errors aimed at regulating the new legal phenomena.

REFERENCES

1. Iasechko Svitlana, Zaitsev Oleksii, Viktoriia Kozhevnykova, Kostiantyn Melnyk. (2020). Transactions with the Personal Non-Property Right. *International Journal of Advanced Science and Technology*, 29(11s), 793-798. Retrieved from: <http://sersc.org/journals/index.php/IJAST/article/view/20048>
2. Iasechko Svitlana, Viacheslav Puzyrnyi, Natalia Puzyrna, Nataliia Kostyuk, Iryna Bakhnovska and Iryna Litvinova. 2020. The investigation of peculiarities of the occurrence of subjective civil rights in registration of a patent. *Journal of Advanced Research in Law and Economics*, Volume XI, Issue 3(49) Summer 2020, DOI: <https://doi.org/10.14505/jarle> Available from: <https://journals.aserspublishing.eu/jarle/issue/archive>
3. Hertz A. A. Negotiated goiters at the sphere of nadanny of medical services: dis. Cand. legal Sciences: 12.00.03 / Gertz Alla Anatolevna - Lviv, 2016. -- 421 p. -Page 216
4. Musinko A. Organ transplantation and tissue // Prosecutor's Office. *Lyudina. Power.* - 2004. - No. 5. - S. 84-89
5. Stefanchuk R. O. Special human rights to civil rights (witnesses, system, special life and hunting): monograph. / R.O. Stefanchuk; vidp. Vedas Y. M. Shevchenko. - K.: CST, 2008. -- 626 p.
6. Senuta I. I. National legal acts in Ukraine: medical theories and practices: author. dis. on the health sciences. *Doct. legal Sciences: special. 12.00.03 "civil law and civil process; family law; International Private Law "* / Senuta Irina Yaroslavivna - Kiev, 2018. - 36 p. - S. 15
7. The law of Ukraine on the preservation of transplant anatomical materiality: the law of Ukraine No. 2427-VIII from 05.17.2018 [Electronic resource] - Access to resources mode: <http://www.golos.com.ua/article/304548>.
8. Akimov Oleksandr, Troschinsky Vladimir, Karpa Marta, Ventsel Viktor & Akimova Liudmyla (2020) INTERNATIONAL EXPERIENCE OF PUBLIC ADMINISTRATION IN THE AREA OF NATIONAL SECURITY. *Journal of Legal, Ethical and Regulatory Issues*, Volume 23, Issue 3, 2020
9. Akimov, O., Karpa, M., Parkhomenko-Kutsevil, O., Kupriichuk, V., & Omarov, A. (2020). Entrepreneurship education of the formation of the e-commerce managers

professional qualities. *Journal of Entrepreneurship Education*, 23(S1).