

Legal Regulation of Organ Transplantation in Ukraine and the European Union

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Abstract

The purpose of our study is to determine the role of legislative regulation of transplantation in Ukraine in its development by comparing it with legal regulation in the European Union countries and ways of its possible effective change. For this purpose, the following materials were used: international standards in the field of human organ and tissue transplantation, relevant laws, by-laws and scientific articles. Among the methods and principles of scientific research, comparative legal, systemic, structural-complex, historical-legal and formal-legal methods, as well as methods of legal forecasting and content analysis were used. It was established that in Ukraine in recent years in the field of legal regulation of transplantation, the necessary legal prerequisites for the further development of this important area of medical activity have been mainly created, but they are not always effective. In European countries, there is a stable transplantation coordination service staffed by highly qualified personnel, and post-mortem donation is regulated. In addition, these countries show the opposite situation both in the field of legal regulation of processes and in its specific results. In particular, Ukraine has not yet created a comprehensive system of successful human organ transplantation, and the legal regulation of transplantology has proved ineffective. At the same time, in the member states of the European Union, the filling of measures for the legal regulation of transplantology with rational content led to the creation of an effective transplantation system.

Keywords: *transplantology; posthumous donation, European Union; presumption of consent; presumption of non-consent.*

Правове регулювання трансплантації органів в Україні та країнах Європейського Союзу

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Анотація

Метою нашого дослідження є визначення ролі законодавчого регулювання трансплантації в Україні в її розвитку шляхом порівняння його з правовим регулюванням в країнах Європейського Союзу та шляхів його можливої ефективної зміни. Для цього були використані такі матеріали: міжнародні стандарти у сфері трансплантації органів і тканин людини, відповідні закони, підзаконні акти та наукові статті. Серед методів і принципів наукового дослідження використовувались порівняльно-правовий, системний, структурно-комплексний, історико-правовий і формально-юридичний методи, а також методи правового прогнозування та контент-аналізу. Встановлено, що в Україні останніми роками у сфері правового регулювання трансплантації в основному створені необхідні правові передумови подальшого розвитку цього важливого напрямку медичної діяльності, однак вони не завжди ефективні. В європейських країнах функціонує стабільна, укомплектована висококваліфікованими кадрами служба трансплантаційної координації, врегульовано посмертне донорство. Крім того, в цих країнах виявлено протилежність ситуації як у сфері правового регулювання процесів, так і в його конкретних результатах. Зокрема, в Україні наразі не створено всеохопну систему успішної трансплантації органів людини, правове регулювання трансплантології виявилось неефективним. Водночас у країнах – членах Європейського Союзу наповнення раціональним змістом заходів з правового регулювання трансплантології зумовило створення ефективної системи здійснення трансплантації.

Ключові слова: трансплантологія; посмертне донорство; Європейський Союз; презумпція незгоди; презумпція згоди.

Introduction

Today, transplantation is considered to be an extremely effective and, in some cases, non-alternative method of treatment for diseases of vital organs, primarily the heart, kidneys, liver, lungs, etc. That is why transplantation

in developed countries is one of the areas of medicine that demonstrates the best dynamics. Ukraine is far behind such countries.

The flourishing of successful transplantation practice in the developed world in the late twentieth and early twenty-first centuries and the pronounced lagging behind in Ukraine have led to an urgent need to study this problem. The scientific and practical interest in transplantation in Ukraine is due to a large number of problems in the field. The health care sector is one of the most important sectors that require legal regulation and control, based on the fact that human life and health are the highest social value [1, p. 1]. In addition, transplantation concerns two persons at the same time – the donor and the recipient, and, in the opinion of O. Stets, O. Bilochenko and Y. Chabanenko, also medical personnel, which brings it closer to legal science and requires, among all medical disciplines, "the most clear legal regulation" [2, p. 65; 3, p. 57].

The extreme importance of the problem is also confirmed by the decisions of various international institutions, which define the basic principles of transplantology, which are recommended to all states [4, p. 308-320]. After Ukraine declared its intentions to integrate into the European Union, Ukraine pledged to take efforts to harmonize its legislation with that of the European Union, including in the area of human organ transplantation [5, p. 5]. Thus, according to Art. 428 of the Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their member states, on the other hand, "Ukraine is gradually bringing its legislation and practice closer to the principles of the EU *acquis*, in particular in the field of infectious diseases, blood services, tissue and cell transplantation, as well as tobacco. The list of relevant EU *acquis* acts is set out in Annex XLI to this Agreement" [6].

At the same time, the national legislation on human organ transplantation, despite the huge number of regulations, has problems that need to be addressed immediately by making the necessary changes to the legislation [7, p. 42]. That is why most studies are devoted to the problems of legal regulation of transplantation and criminal liability for violation of laws [8, p. 154].

The full-scale invasion of the territory of Ukraine by the Russian Federation in 2022 significantly aggravated the situation with transplantation in our country. On the one hand, the cancellation of air transport in Ukraine caused the problem of the impossibility of timely and prompt delivery of organs for transplantation, on the other hand, the war contributed to a significant increase in the number of people in need of organ, limb, and skin transplants. This applies to both military personnel and the civilian

population, who received various bodily injuries as a result of explosive and gunshot injuries, characteristic of the period of hostilities [9]. Therefore, the relevance of the problem to which this article is devoted is undoubted.

The novelty of the study consists in generalization of the features and reasons marked by the researchers for Ukraine's lagging behind the countries of the European Union in transplantology and the possibilities of effective change of the situation. The materials in this article are valuable for legislators, transplantologists, students of legal and medical institutions specializing in this area, teachers of legal and medical universities, and anyone interested in this issue.

Literature review

The problem of legal regulation of human organ transplantation has been studied to varying degrees by Ukrainian and foreign scholars: G. Anikina [10], A. Gel [11], S. Hrynychak [12], V. Shulga [8], O. Rumiantsev [13], I. Bezzub [14], V. Pishta [15], B. Pipchenko [7], A. Golovko, K. Kukharchuk [3], K. Iliushchenkova [1], M. Komarov, O. Nikonenko, R. Saliutin, S. Palianytsia [16], G. Krainyk [17, 18], M. Novitska [5, 19], B. Ostrovska [4], L. Zherzh [20], L. Dorosh [21], O. Iliashenko [22], A. Musienko [23], M. Bryukhovetska [24], A. Shevchuk [25, 26], D. Zadykhailo, V. Milash, V. Yarotskyi [27], A. Mernyk [28, 29], I. Kobza [30], I. Ptashnyk [31], O. Kyseliova [32], O. Klymenko, G. Shokha [33], O. Iliushyk, M. Baran [34], M. Dyakovykh, M. Mykhayliv [35], O. Bukhanevych [36], Y. Razmetaeva, O. Sydorenko [37], B. Baluk [38], G. Didkivska [39] and others.

Thus, G. Anikina considered the peculiarities of the legal regulation of organ transplantation from a deceased donor, which is most often preferred in the modern world. In the work of A. Gel the development of Ukrainian legislation in the field of organ transplantation is examined. S. Hrynychak devoted several works to the study of criminal liability for illegal organ transplantation in historical retrospect. It was the imperfection of legislation in this area that provoked a huge amount of illegal organ harvesting for clandestine organ transplantation operations. V. Shulga studied the formation and development of state regulation of transplantation in Ukraine, O. Rumiantsev in his dissertation investigated the administrative and legal regulation of transplantation in Ukraine, its evolution and features, I. Bezzub analyzed the reform of the transplantation system in Ukraine, noted its shortcomings and possible ways to improve the situation in this area.

V. Pishta studied the legal regulation of cross-donation in Ukraine and foreign countries, he identified and grouped the shortcomings of the 2019 Law of Ukraine on Transplantation of Human Organs and Materials. B. Pipchenko addressed the controversial aspects of consent to organ

and tissue donation for transplantation, A. Holovko and K. Kukharchuk focused on the political and legal aspects of the specifics of transplantation in Ukraine, K. Iliushchenkova studied the evolution of legal regulation of reproductive cell donation in Ukraine. M. Komarov, O. Nikonenko, R. Saliutin, and S. Palianytsia also tried to systematize historical milestones in the development of transplantation. G. Krainyk tried to outline the main problems in the development of transplantation in Ukraine. M. Novytska considered the implementation of international principles and standards in the field of transplantation of anatomical materials into the national legislation of Ukraine. In her monograph, B. Ostrovska highlighted the international legal regulation of the human right to life in the context of bioethics in a systematic form. L. Zherzh considered the issue of illegal trafficking in human organs or tissues committed by prior conspiracy by a group of persons or transnational organizations. L. Dorosh and I. Potapenko also addressed the issues of illegal trafficking in human organs or tissues in his works. AT. Iliashenko outlined the state and trends of illegal trade in human organs and tissues in Ukraine, A. Musienko investigated the fight against crimes in the field of transplantation of human organs or tissues.

M. Bryukhovetska studied the problem of posthumous organ donation both with the presumption of consent and non-consent. A. Shevchuk in his works touched upon the issue of the right to palliative care and the peculiarities of its realization. D. Zadykhailo, V. Mylash, V. Yarotskyi characterized the current state of health care reform in Ukraine in the context of European integration. A. Mernyk considered certain issues of legal regulation of organ transplantation in Ukraine. I. Kobza and his co-authors examined organ transplantation in Ukraine in terms of personalities and events. I. Ptashnyk addressed the issues of legislative regulation of organ transplantation in the European Union. O. Kiselyova tried to compare the administrative and legal regulation of human organ and tissue transplantation in Ukraine and some foreign countries. O. Klymenko and G. Shokha devoted their research to the history of the development of legal regulation in the field of organ transplantation in the UK, the USA and European countries. O. Iliushyk and M. Baran addressed the issues of legal regulation of organ transplantation from a deceased person.

At the same time, there have been almost no comparative studies of the state of transplantology in Ukraine and the countries of the European Union. That is why the authors of this article set this very *goal*.

Materials and Methods

In order to determine the differences in the legal regulation of human organ transplantation in Ukraine and in the countries of the European Union, the

authors used the following materials: international standards in the field of organ transplantation, laws, regulations of governments and ministries of health of the countries under study, articles by researchers, assessments by leading industry experts, as well as various theoretical legal and general scientific methods, i.e. various methods and research techniques.

First and foremost, the *comparative legal method* contributed to the generalization of the experience of Ukraine and European countries in the field of transplantation, and it was this method that contributed most to the achievement of the goal. Comparison is a cognitive operation that helps to find out whether there are identities or differences between objects or degrees of development of the same object. It is also the basis for the analogy of the logical method and serves as the starting point of the comparative legal method, which allows, by comparison, to identify the common and the different in history phenomena, to learn different degrees of development of the same legal phenomenon or different coexisting phenomena. The comparative legal method involves comparing different legal systems, institutions, and categories in order to identify similarities or differences between them. As a result of the comparison, the qualitative state of the legal system as a whole or individual legal institutions and norms is established. It was its application that helped to identify differences in the legal regulation of organ transplantation in Ukraine and the European Union, as well as its peculiarities. The *principles of determinism and retrospective analysis* helped to establish cause and effect relationships between the processes.

The *system method* contributed to the consideration of Ukraine and the countries of the European Union as equivalent units, in accordance with the requirements of which the research problem was formulated. The use of the *principle of historicism* made it possible to identify the significance of processes in the context of different periods. This principle in the study of the transplantation problem contributed to the knowledge of the legal nature of the above groups of legal acts, and to the knowledge and understanding of their content and meaning. The *method of objectivity*, along with the principle of historicism, contributed to the avoidance of assessments of events, facts, state systems, etc., traditional in Soviet science.

The *structural and complex method*, the method of classification, the dogmatic legal approach, the principles of analogy and logical analysis made it possible to study the legal acts of different states into separate groups, to identify their significance in the process under study, to formulate general conclusions, to establish differences in the legal regulation of organ transplantation in Ukraine and the European Union and to determine their

specific results. The *method of content analysis* allowed for a quantitative analysis of the texts of legal acts and scientific articles in order to further interpret the patterns in the development of the organ transplantation process in the studied countries.

The *historical and legal method* is used in the study of the formation and development of organ transplantation in Ukraine and the European Union and its administrative and legal regulation. This method made it possible to better understand the dynamics of the research process and to draw certain conclusions about the influence of the past on the current state of development of the organ transplantation institute. The *formal legal method* provided an analysis of the powers of the subjects of public administration of transplantation in Ukraine, and allowed to clarify the main concepts and categories in the field of human organ transplantation. The *method of legal forecasting* was used to determine a set of possible options for the development of transplantology in Ukraine and options for improving the state of this field. The *statistical and mathematical method* made it possible to obtain and process quantitative data on organ transplantation, to find out the dynamics of this process both in Ukraine and in the European Union.

Results and Discussion

Peculiarities of organ transplantation in Ukraine

The era of modern organ transplantation was "historically opened" by our compatriot Professor Yu. Voronyi (1895-1962), who in 1933 performed the "world's first" cadaveric kidney transplant in Kherson" [30]. In 1942, Voronyi performed a unique operation – the replantation of an arm that had been blown off in an explosion. After the war, the surgeon received a letter from a grateful patient that began with the words "I am writing with your right hand" [30].

How did transplantology develop in Ukraine later compared to other countries? More than 24,000 transplants are performed annually in the USA, more than 4,000 in Spain, and more than 1,500 in Poland [16, p. 64]. This field of medicine is also actively developing in post-Soviet countries, among which Belarus is ahead of all, with 50 transplants per 1 million inhabitants annually. In Estonia, this figure is 46.2 transplants per 1 million people, in Latvia – 36.2, in Lithuania – 22 [14, p. 1].

Ukraine is far behind these countries. "The situation in Ukraine, where only 3.1 transplants per 1 million people per year are performed, can be called catastrophic, even compared to its neighbors, emphasizes I. Bezzub. And this is one of the worst indicators in the world" [14, p. 1]. For 19 years, this field of knowledge has been almost forgotten by the legislator and

the relevant ministry. The issue of legal regulation of transplantation of anatomical materials is extremely important today [5, p. 2]. "The legislator's prolonged neglect of the transplantation sphere", emphasizes M. Novytska, "has led to a situation in Ukraine in which more than 90 000 Ukrainians need a transplant of an organ, and most of them are doomed if they do not receive it" [19, p. 8].

The annual need for organ transplants in Ukraine before the full-scale invasion of Russian troops was 3,653, including 2,115 kidneys, 830 livers, 30 pancreas, 89 pancreas plus kidney complexes, 328 hearts, 240 lungs, 2-3 heart-lung complexes, and 42 intestines. After February 2022 these figures increased sharply both among the military personnel who stood up to defend the sovereignty of Ukraine, and among the civilian population.

At the same time, some organ transplants accounted for only 0,8% of all surgeries by 2020. According to the Ministry of Health of Ukraine, in 2016, only 5 liver transplants, 2 cadaveric kidney transplants and 93 related transplants were performed in Ukraine [17, c. 8]. Over the past twenty years, only 8 heart transplants have been performed in Ukraine, while 1500 are needed [17, p. 701]. G. Kraynik and B. Savchuk call the situation with transplantation in Ukraine "too sad" and "too critical" [17, p. 701-703; 16, p. 64]. I. Bezzub states that "one of the most important reasons for this state of affairs is the legislative one" [14, p. 2].

Since 2020, the number of such operations in Ukraine has increased, and Ukrainian citizens are almost never sent abroad for organ transplants. In 2021, 316 operations were performed, including 231 kidney transplants (126 from living donors, 105 posthumous), 51 liver transplants (19 from living donors, 32 posthumous), 32 heart transplants, 1 lung transplant, and 1 cornea transplant. In 2022, the number of transplant operations in Ukraine increased further, 384 such operations were performed, that is, 20 percent more than in 2021: 274 kidney transplant operations (of which 134 were from a living donor, 140 posthumously), 74 operations with liver transplants (36 from a living donor, 38 posthumously), 36 heart transplant operations (*calculated by the authors*) [40].

Ukraine has gradually developed the material base for this extremely important branch of medicine. Initially, six centers were authorized to perform human organ transplants: The National Institute of Surgery and Transplantation named after A.A. Shalimov, Lviv Regional Clinical Hospital, Odesa Regional Clinical Hospital, V.I. Shapoval Regional Clinical Center for Urology and Nephrology (Kharkiv), Zaporizhzhia Regional Clinical Hospital, and Dnipro Regional Clinical Hospital named after I.I. Mechnikov, which are capable of performing up to 1000 organ transplants per year [41]. In

Spain, which has the same number of residents as Ukraine, there are more than 40 centers that perform 4,500 operations per year.

Since 2020, there has been an expansion of the network of institutions that carry out transplantation of human organs and tissues in Ukraine. This was due to the adoption in 2020 of the Cabinet of Ministers Resolution "Some Issues of Implementation of the Law of Ukraine "On Transplantation of Organs and Other Anatomical Materials to Humans"" of April 24, 2000 No. 695, which approved the list of state and municipal health care institutions and state research institutions authorized to carry out activities related to the transplantation of organs and other anatomical materials to humans, which significantly increased the number of institutions authorized to transplant human organs and tissues [42]. In particular, the specified Resolution of the Cabinet of Ministers of Ukraine grants the right to conduct transplantations to healthcare and scientific institutions: activities related to the transplantation of organs and other anatomical materials to humans – to 12 institutions and establishments; activities related to human organ transplantation – to 4 institutions and establishments; activities related to human tissue transplantation – to 21 institutions and establishments; activities related to human cell transplantation – to 22 institutions and establishments; activities related to human tissue and cell transplantation for burn injuries – to 31 institutions and establishments [42].

The legislative framework for the human organ transplantation was also developed. After Ukraine gained independence, it adopted three laws regulating the transplantation process: July 16, 1999, May 17, 2018. and February 28, 2019 [43-45]. They were to be improved and supplemented by the Resolutions of the Cabinet of Ministers of Ukraine. This task was addressed by the Orders of the Ministry of Health [46-49]. The issues were also regulated by the Agreement of the Ministry of Health of Ukraine and Belarus of 17 July, 1995, the Instruction of the Ministry of Health of 25 September, 2000, and Resolutions of the Cabinet of Ministers [50; 51].

Comparing the Laws on Human Organ Transplantation in Ukraine of 1999 and 2018, it can be concluded that the latter is much more advanced than the former, together with the regulations adopted to clarify it. At the same time, we should not expect global changes in transplantology in modern Ukraine due to the fact that the new law is incomplete and creates a number of problems that will arise after its introduction [47, p. 9; 46, p. 8]. For certain reasons, the Law of 2018 could not work in full force and did not provide the expected results, that is why the legislator was forced to amend it several times in 2019 [15, p. 2]. In particular, to ensure the implementation of the provisions of the 2018 Law a number of by-laws were not adopted, the software for the Unified State Transplantation Information

System was not made, the procedure for accessing information was not defined, and the electronic resources with which it will exist are not known; there was no effective transplant coordination system in Ukraine. Also, the relevant body that implements the state policy in the provision of medical care with the use of transplantation and that carries out transplantation-related activities, its composition, procedure for formation, subordination, etc. are not defined; there is no specific order of priority for obtaining consent from close relatives and family members of the donor in the event that there are several subjects from the number specified by law or radically different views of family members regarding the removal of anatomical material from their deceased relative; there is no Card of the donor of anatomical material with the content of a note on the provision of consent or non-consent on which transplantation and related activities should be carried out, the requirements for technical coverage of the equipment of these subjects, the number of accompanying documents; there is no replacement of the concept of consent with the concept of non-consent. According to M. Novytska, all this requires further work on improving legislation in the field of human organ transplantation [19, p. 9].

A. Gel disagreed with M. Novytska's statement about the absence of bylaws that were relied upon and did not fulfill the task of improving laws. This is what led to the adoption of the 2019 Law. "There is no doubt", he emphasized, "that the main purpose of this law was an attempt by the authorities to hide their inaction behind the next numerous changes in legislation, most of which cannot be called anything other than "legislative spam" [11, p. 8], that is, unwanted messages in any form that are sent in large numbers.

These shortcomings of the 2018 Law necessitated the adoption of the 2019 Law. Most of the provisions of the 2019 Law can be assessed as useful and motivated. Basically, we can talk about the completion of the legislative framework for the further development of transplantation. At the same time, for its full functioning, it is necessary to create and fill the state information system of organ transplantation along with the adoption of a number of bylaws, especially the introduction of the principle of "presumption of consent" into Ukrainian legislation [11, p. 1].

The main problem with the 1999 Law was the approval of the "presumption of non-consent". This is one of the two existing principles of donation used in international practice. The *presumption of consent* is understood in the following way: a person who does not wish to be a donor after his or her death must write a corresponding statement. In the absence of such a statement, it is assumed that the deceased agreed to donate by default. The presumption of non-consent, on the other hand, requires that a person

document his or her consent to become an organ donor after death. In Ukraine, the *presumption of non-consent* is in effect [14, p. 3]. All laws that followed the 1999 law were aimed at improving it. According to I. Bezzub, domestic legislation generally allows for the transplantation of human organs and tissues. At the same time, the Laws, Resolutions of the Cabinet of Ministers and Orders of the Ministry of Health of Ukraine "constitute only a general concept of transplantation. And this makes it necessary to bring Ukrainian legislation in line with the standards of the 21st century" [14, c. 2].

Completing such a task requires some time. R. Saliutin, the Deputy Director of the Institute of Surgery and Transplantology named after Shalimov, is sure that the adoption of only one law will not be able to solve long-standing problems in one moment. This task will take time to accomplish. In his opinion, such a process will take two to three, or even five years. This issue seems to be very deep, complex and needs to be addressed not only at the legislative level, but also at the level of bylaws, at the level of public perception, and at the level of appropriate funding [14, p. 15].

The Ministry of Health is also not sure about the possibility of rapid changes in connection with the adoption of the law, where they admitted that nothing had been done in this direction for twenty years, in particular, no modern equipment was purchased, transplant doctors were not educated and trained, no information systems or registers of donors and recipients were created [14, p. 15].

In 2020, V. Pishta identified and grouped the shortcomings of the 2019 Law, the main problems of formation of the state policy in the field of transplantation, including the systematic lack of necessary funding; the actual lack of organizational and legal mechanisms to ensure the functioning of the transplantation system in Ukraine (lack of a transplant coordination system and the Unified State Transplantation Information System); lack of public understanding of the importance of transplantation as a method of saving lives and improving health, which is a consequence of the passive information policy of the Ministry of Health of Ukraine: lack of qualified doctors and medical staff involved in transplantation operations; lack of modern medical technologies and medicines used in transplantation operations; lack of effective international cooperation in the field of transplantation [15, p. 2-3].

At the end of 2020, the Specialized State Institution "Ukrainian Center for Transplant Coordination" (according to the Order of the Ministry of Health of Ukraine of October 28, 2020) and the Unified State Information System of Organ and Tissue Transplantation were finally launched in Ukraine based on the of the Regulation on the Unified State Information System of

Organ and Tissue Transplantation adopted on December 23, 2020 [50; 51]. The Resolution of the Cabinet of Ministers of July 07, 2021 No. 698 "On Amendments to the Resolutions of the Cabinet of Ministers of Ukraine of December 18, 2019 No. 1083 and March 3, 2021 No. 181" [51] contributed to a change in the situation regarding payment for transplantation operations (the vast majority of such operations should be carried out at the expense of the state).

Before the beginning of the armed aggression of the Russian Federation against Ukraine, the Republic of Belarus was Ukraine's main strategic partner in the field of transplantation, due to the high level of transplantation development in this country. An agreement was concluded between the Ministries of Health of the two countries to clearly regulate relations between them on referring patients to specialized medical centers for consultations and transplantations [13, p. 2].

Thus, in recent years, in the field of legal regulation of transplantation, the necessary legal prerequisites for the further development of this important direction of medical activity have mainly been created. At the same time, legislators often ignore the principles of law-making and the rules of legal technique, which significantly complicates, and sometimes makes impossible to apply the law.

Scientists see the main reason for the ineffectiveness of legal regulation of human organ transplantation in Ukraine in the imperfection of the legislation intended to solve the problem. What role did the relevant legislation play in the countries of the European Union?

European experience of organ transplantation

In Europe, the legal regulation of organ transplantation initially took place at the national level in individual countries. The first European country to legislate organ transplantation was Italy, which in 1932 established a ban on testicular transplantation in its Civil Code. Three decades later, in the 1960s and 1970s, European countries began to make the first attempts to legally regulate donation by adopting relevant laws on lifetime donation: Czechoslovakia (1966), Denmark (1967), Hungary (1972), Bulgaria (1973), France (1976) [33, p. 1-2].

At the European level, the Council of Europe first considered the issue of organ transplantation in 1978 in Recommendation R (78)29 on organ transplantation and the harmonization of the laws of the Member States relating to the removal, transplantation and retrieval of organs. A year later, in 1979, the Council of Europe adopted the Recommendation on the facilitation of the transport and international exchange of human organs and tissues [31, p. 71-72].

In 1997, the Council of Europe adopted the Convention on Human Rights and Biomedicine, which stated that preference should be given to the harvesting of organs from a deceased donor [46, Art. 19]. The main achievement of this Convention (the Oviedo Convention) is that it became the first legally binding international treaty to cover a huge range of ethical issues in the field of biological research, including transplantatology. It establishes the general framework for the protection of human rights in medicine and biology. This main focus is expressed in its Art. 1: "The Parties to the present Convention shall protect the dignity and identity of all human beings and shall guarantee to everyone, without discrimination, respect for their integrity and for other rights and fundamental freedoms regarding the use of biology and medicine" [53, Art. 1].

The official website of the Council of Europe emphasizes that the Convention on Human Rights and Biomedicine has created a legal basis for many ethical principles for the protection of patients and citizens that apply to any medical act (including transplantation). It emphasizes that the Convention establishes four key principles of bioethics: (1) the primacy of the human being; (2) equal access to health care; (3) the need for consent to medical intervention (and protection of those who are unable to give it); (4) confidentiality, i.e. ensuring the inviolability of private life and personal data [53].

Octavi Quintana-Trias, former Chair of the Council of Europe's Steering Committee on Bioethics, emphasizes that the Oviedo Convention is a binding treaty that is concluded at the intersection of general conventional human rights in the sense of the Convention for the Protection of Human Rights and Fundamental Freedoms and Health Rights; it takes a comprehensive approach to bioethics and defines minimum harmonization between states in this area. This makes it possible to understand that bioethics and research ethics are inextricably linked to the principles of human rights and protect them. Thus, the answers to many questions that arise in the course of the progress of the science of life, in one way or another, relate to one of the most important questions: how do we - both an individual and society as a whole - want to live? And this question cannot be solved on the basis of rational arguments alone: emotions, cultural traditions, spiritual beliefs and worldview are also important for answering it [54].

The Oviedo Convention also establishes important standards of legitimacy and legality of transplantation:

– the sole purpose of removing organs and tissues from a living donor for the purpose of transplantation is the treatment of the recipient;

- a mandatory factual (medical) condition is the absence of the necessary organ or necessary tissue of the deceased person and other alternative method of treatment of comparable effectiveness;
- a mandatory legal condition is the free and informed consent of the donor for transplantation, which must be given clearly and specifically;
- proper protection of persons who are unable to give consent to organ removal;
- prohibition for the donor to receive financial benefit from transplantation.

It is believed that mandatory consent and the prohibition of financial gain are positive features of charity policy that respect individual autonomy and gives people the opportunity to perform significant acts of generosity [55, p. 122].

It is important to note that the Oviedo Convention laid the foundation for the adoption of the more detailed Additional Protocol on Organ Donation and Transplantation, as well as the Council of Europe Convention against Trafficking in Human Organs. An additional protocol on transplantation of organs and tissues of human origin was signed in Strasbourg on January 24, 2002, and the Convention of the Council of Europe against trafficking in human organs was concluded in Santiago de Compostela March 25, 2015 [56].

The next and one of the main acts in the field of transplantation of human tissues and organs in Europe was Directive No. 2010/45/EU of the European Parliament and the Council of the EU on the standards for quality and safety of human organs intended for transplantation, Strasbourg, (2010). This directive addresses the concepts of organ transplantation, standards for quality and safety, organ preparation organization, organ preparation procedure, organ and donor characteristics, organ transportation, organ transplant centers, the state of organ tracking, information system, transplantation process with serious adverse manifestations and reactions, medical personnel, protection of donors and recipients, principles of organ donation, voluntariness requirements, issues of quality and safety of living donors, protection of personal data, confidentiality and security of their processing, responsibilities of competent authorities and exchange of information, organ exchange organizations with third countries, European organ exchange organizations, sanctions for violation of national regulations adopted pursuant to this Directive, etc. [56]. One of the drawbacks of the Directive is the lack of attention to the regulation of xenotransplantation [31, p. 73].

The evolution of legal regulation of transplantation in the European Union has been influenced by international organizations such as the World

Health Organization and the World Medical Organization. In 1991, the first of them adopted the Guidelines for Human Transplantation, which focused on the principles of voluntary donation, non-commercialization of donation, and the preference for transplantation from a deceased donor and relatives [31, p. 73-74]. The World Medical Organization in its acts paid attention to the protocols that are important for doctors performing transplantation [57].

I. Ptashnyk distinguishes three groups of EU legislation in the field of transplantation: 1) legislation and guidelines regulating transplantation and blood donation; 2) legislation and guidelines governing organ transplantation and donation; 3) legislation and guidelines regulating transplantation and donation of cells and tissues [31, p. 75]. The second group (regarding transplantation and organ donation) consists of: "Communication from the Commission to the European Parliament and the Council organ donation and Transplantation: policy actions at EU level"; "Action plan on organ donation and transplantation (2009-2015). Strengthening cooperation between Member States"; "Recommendation Rec (2004)7 of the Committee of Ministers to Member States on organs trafficking" [31, p. 75].

In European countries, the legislation has not yet resolved the issue of determining who can be a donor. Therefore, the vast majority of countries use the WHO Guidelines for the Transplantation of Human Cells, Tissues and Organs, which state that it is preferable to take organs for transplantation from deceased persons. In cases where living donors are involved, it is better to give preference to close relatives of the recipient. The Guidelines emphasize that "patients must have a genetic, legal or emotional connection, with the exception of tissues with regenerative functions" [33, p. 2; 58].

In Europe, some countries allow the harvesting of organs from donors who are not related (have no genetic connection), provided that the donation is altruistic and free of charge (e.g., France, the Code of Public Health) [33, p. 2-3].

An important step in the development of transplantation and cooperation in this area in Europe was the creation of the International Foundation EUROTRANSPLANT in 1967. The Center received information about kidney donors and gradually this led to a huge improvement in the survival rate of kidney transplants. At the end of the 1970s of the 21st century Eurotransplant operated in 68 transplant centers in six countries: Austria, Belgium, Luxembourg, Germany, the Netherlands and Switzerland. Since the 1970s, Eurotransplant has started work with the extraction of liver, later – heart and pancreas, since 1988, – lungs, since 1999 – intestine [59].

Cooperation with Eurotransplant provides an opportunity to move the level of transplantation services to a much higher level. As of today, Eurotransplant is mainly engaged in the provision of transplant organ services from deceased, is an intermediary between donor hospitals and transplant centers and includes Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia. About 139 million people are currently served by Eurotransplant [59].

Cooperation with Eurotransplant significantly speeds up the search for donors for people in need of organ transplants, so one of the future steps of the government of Ukraine is the policy of joining this international organization.

In European countries, organ and tissue transplants are used primarily from deceased donors, with different principles of regulation of such donation. The "presumption of consent" ("presumed consent", "denial model") is used in Austria, Denmark, Belgium, Finland, Spain, Italy, France and provides that there is no need to obtain prior consent for donation after the death of a particular person. At the same time, the prior consent of a person or his or her close relatives ("presumption of non-consent") to the removal of organs for transplantation is required by the legislation of Germany, the United Kingdom, the United States, and Japan) [32, p. 48; 33, p. 4].

The "presumption of non-consent" is also supported by the European Court of Human Rights, which can be seen in its decisions [34, p. 177]. In the case of Petrova v. Latvia, a violation of the procedure for taking anatomical organs for transplantation was considered. The applicant's son, who died as a result of a car accident, had his kidneys and spleen removed after his death without his prior consent and without the consent of his mother. The court ruled on the violation of Art. 8 of the Convention on the Protection of Human Rights and Fundamental Freedoms, namely the right to respect for personal and family life. The Court also emphasized in the judgment "that the Latvian law on organ transplantation at the time of the applicant's son's death was not clear enough, which led to circumstances whereby the applicant, as the closest relative of her son, had certain rights regarding the removal of his organs, but was not informed, let alone given any explanation of how and when these rights could be exercised" [34, p. 177; 50].

Conclusions

Thus, in recent years, there has been a huge increase in the use of human organ transplants worldwide, and more and more attention and importance have been given to the legal regulation of the transplantation process. The comparative analysis revealed the opposite transplantation situation in

Ukraine and the European Union, both in the field of legal regulation of processes and in its specific results.

The development of legal regulation in Ukraine was controversial. On the one hand, the measures to implement legal regulation of transplantatology outwardly corresponded to the main international and European requirements. On the other hand, they did not achieve their goals, created an unattractive situation, and led to some of the worst statistical indicators in Europe. Laws, Resolutions of the Cabinet of Ministers and Orders of the Ministry of Health of Ukraine provide only a general idea of transplantation. One of the most important reasons for this situation is the imperfect legislative regulation of transplantatology issues. This is what led to the adoption of the 2019 Law. However, the Ministry of Health admitted that little had been done to implement its provisions. In addition, the agenda includes the problems of forming and implementing state policy in the field of transplantation, in particular: the systematic lack of necessary funding; lack of public understanding of the importance of transplantation as a method of saving life and improving health, which is a consequence of the passive information policy of the Ministry of Health of Ukraine; lack of qualified doctors and medical personnel involved in transplantation operations; lack of modern medical technologies and medicines used in transplantation operations; lack of effective international cooperation in the field of transplantation. Thus, to date, Ukraine has not created a comprehensive system for successful transplantation of human organs.

In the European Union, on the contrary, the rational content of the measures on legal regulation of transplantatology has led to the creation of an effective system for implementation of transplantation. Compliance with international standards in the field of transplantatology, consistent implementation of their provisions in the system of national regulations, participation in international organizations that facilitate the rapid exchange of information on possible donors and recipients, and the provision of organs for transplantation have shaped the practices of successful solutions to the problems of human organ and tissue transplantation. At the same time, it can be stated that there are certain differences in the legal regulation of organ transplantation in the European Union, such as the presumption of consent and non-consent, but in general this does not affect the high level of successful transplantations in these countries. Almost all countries of the European Union give preference to posthumous donation. It can be assumed that the accession of Ukraine to the European Union will contribute to the possibility of joining such international organizations as Eurotransplant, which will provide opportunities to significantly improve the situation with transplantation for citizens of Ukraine who need such operations.

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Suggested Citation: Pohrebniak, S.P., & Zinchenko, O.V. (2024). Legal Regulation of Organ Transplantation in Ukraine and the European Union. *Theory and Practice of Jurisprudence*, 2(26), 206-227. [https://doi.org/10.21564/2225-6555.2024.2\(26\).318578](https://doi.org/10.21564/2225-6555.2024.2(26).318578).

Submitted: 14.11.2024

Revised: 16.12.2024

Approved: 19.12.2024

Published online: 31.12.2024