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¹A.O.Yanchuk, ²S.O. Kuznichenko, ³Yu. V. Gradova
¹Ministry of Health of Ukraine, ²Legislation Institute of the Verkhovna Rada of Ukraine
³V.N.Karazin Kharkiv National University

HUMAN ORGAN TRANSPLANTATION: LEGAL SYSTEM MONITORING

E-mail: olga_sovgiria@ukr.net

The study focuses on human organ transplantation that is a significant issue in medical law. The paper presents the overview of the international and national legislation in the field of human organ transplantation. The new Law of Ukraine "On human anatomical transplantation" has been analyzed.

Key words: organ transplantation, transplantology, donor, recipient, human organ trafficking, anatomical material, medical law.

On 17 May, 2018, the Deputies of the Verkhovna Rada of Ukraine adopted 255 votes in favor of the long-awaited draft law on organ transplantation, which will come into force on 01 January, 2019. The adoption of this law is welcomed nationwide, since donor organ transplantation might be the live-saving for those who need it. The draft law was exactly designed to reduce the mortality rate among the critically ill patients and ensure the implementation of the constitutional and absolute human right to life and health\ care. The development of transplantology is a significant achievement of medicine, but without proper legal regulation it can turn into mass crime against the human life, health and safety. Organ transplantation, which, according to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, is one of the wonders of the twentieth century, involving two areas of science: medicine and law. Apparently, the scientists should join their efforts to solve a number of problematic issues in transplantation: health professionals, in collaboration with lawyers, can legally implement all the intricacies associated with this field of medicine. It is the medical law that conjoins two completely different branches of science, when physicians and lawyers speak the same language. Obviously, the concern regarding the legal regulation of organs and tissues transplantation has been raised at the stage of clinical transplantation, when the development of medicine and jurisprudence resulted in the rationale to legal protection of all participants of transplantation: the donor, the recipient and medical professionals [4]. Notably, the advanced development of medicine enables transplantation of almost any human organ. Currently, transplantation is considered as a very effective and almost non-alternative way of treating diseases and injuries of such vital organs as the kidney, liver, pancreas, lungs, heart, etc. Globally, more than 1 million people who underwent organ transplantation are leading an active lifestyle. The global growth rates of number of transplantation surgeries predict that in 20-30 years, 50% to 60% of all surgical interventions will be associated with the organs, tissues and cells transplantation [10].

Noteworthy, transplantation in Ukraine compared to European countries is extremely underestimated. The world's leader in human organ transplantation is the USA with 34 768 transplant surgeries made in 2017.

Approximately the same number of the operations has been made in the European Union, in contrast to Ukraine, where 130-140 transplants are made annually.

The statistics on the number of donors per million populations (it is this figure that is taken into account by the WHO) shows that Spain has been rating first over 25 years with approximately 43 donors per one million people. In the USA, France and Germany this rate is 28.2, 28.1 and 10.9 donors, respectively. The successful experience of transplant surgeries carried out in the progressive countries of the world, the increase in the number of patients for whom organ transplantation is the only way to save live, prompts legislation to be brought in line with the standards of the XXI century [6].

The paper presents the overview of the international and national legislation in the field of human organ transplantation. This topic is very relevant to date; G.V. Anikina, MI Gorelik, SV Hrinchak, N.V. Korobkova, M.S. Malein, M.A. Maleina, I.V. Mischuk, A.V. Musienko, O.V. Saponov are among domestic scientists who have been engaged in legal issues of transplantology. Issues on human organ transplantation (shortage of donor organs, transplant tourism, human organs trafficking in the “black market”) are often raised by international society at various summits and conferences. For Ukraine, this issue is also relevant; the problems raised cause organ transplant crime, characterized by high latency and low detection.

The paper is aimed at monitoring of the international and national legislation including the analysis and estimate of the passed Law of Ukraine “On human anatomical transplantation”.

Over the past fifty years, organ transplantation has become a common practice worldwide, which is of great benefit to hundreds of thousands of patients [2]. Transplantation as an ad hoc method of treating a number of the most severe human diseases is used when other methods of treatment failed to eliminate the danger to life or recover the patient’s health. In compliance with the WHO’s guidelines for the transplantation of human cells, tissues and organs, “the constant improvement of medical technology, especially in overcoming the organ and tissue rejection, has led to an increase in demand for them. At the same time, demand has always exceeded the supply, despite the significant increase in the delivery of organs from deceased donors, as well as the use of organs from living donors, which has increased in recent years” [7]. 40 to 60 potential donors per million population accounting for approximately 3 thousand donors, die annually in Ukraine [1]. Organs removed from one donor could save lives of 8 and improve it to 50 individuals. The rate of organ transplantation in Ukraine is very low. Thus, in 2014, only 134 organ transplants were carried out in Ukraine, including 16 kidney transplants (with annual demand exceeding 2500); 17 liver transplants (in demand of 1000-1500). Over the past 20 years, only 8 heart transplants have been conducted in Ukraine (with a total demand of 1,000-1,500 per year) [10]. Regarding the terminology, it should be noted that transplantation refers to a process aimed at restoring certain functions of the body through the transplantation of the organ removed from a donor to a recipient [2]. The national legislation considers transplantation as the ad hoc method of treatment, when donor’s human anatomical material is transplanted to the recipient, aiming at human health recovery [7]. The monitoring of the legislation in the field of transplantation enables to distinguish several groups of normative legal acts in this area, namely, international, regional and national. International legislation on the transplantation of human organs involves the Declaration on Human Organ Transplantation, 1987; the Statement on Live Organ Trade, 1985; the Transplantation of Human Organs and Tissues Act, 1994; the WHO Resolution 57.18 “Human Organ and Tissue Transplantation” of the 2004 World Health Assembly; the Changsha Communiqué 2008; the WHO Guiding Principles on Human Cells, Tissues and Organs Transplantation, 2010; the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008; the Declaration of Sydney on Death, 1968, etc.

The Declaration on Human Organ Transplantation states that the primary concern of physicians must at all times be the health of their patients. The allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another.

The Statement on Live Organ Trade condemns the purchase and sale of human organs for transplantation. The resolution on the attitude of physicians to the problem of human organ transplantation condemns the participation of physicians in the transplantation of human organs or tissues removed from the bodies of prisoners, executed for the death penalty without first obtaining their consent or without giving them the opportunity to refuse, or from the bodies of the deceased disabled people, the death of which was expected to be accelerated to facilitate the removal of their organs, or from the bodies of small children kidnapped for this purposes. The WHO Resolution 57.18 “Human Organ and Tissue Transplantation” contains provisions for the performance of allogeneic and xenogeneic transplantations. Allogeneic transplantation requires implementation of the effective national oversight of the procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability. Xenogeneic transplantation urges to allow xenogeneic transplantation only when effective national regulatory control and surveillance mechanisms overseen by national health authorities are in place.

The Changsha Communiqué 2008 emphasizes the successful xenotransplantation that has the potential to treat a wide range of serious diseases such as diabetes, heart and kidney disease. At the same time it should be remembered that xenotransplantation is a complex process that carries a risk, including transplant rejection, inadequate transplant function, and the transmission of recognized or unrecognized infectious diseases to the recipient [13]. The WHO Guiding Principles on Human Cells, Tissues and Organs Transplantation determine the eleven provisions that should form the basis of the national legislation on transplantation, including: grounds for organ removal from a deceased person; favoring the removal of organs from a deceased person in relation to a living donor; preventing the removal of organs, cells or tissues from a minor or incapacitated living donor (with the rare exception); voluntary and unpaid donation, etc.

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism has proposed measures needed to increase the effectiveness of deceased donation, as well as measures to combat transplant tourism, transplantation commercialization and organ trafficking; measures to ensure the protection and safety of living donors and recognition of their nobility.

The Declaration of Sydney on Death defines one of the guiding principles implemented in many international legislative acts on the transplantology: "If transplantation of an organ is involved, the decision that death exists should be made by two or more physicians and the physicians determining the moment of death should in no way be immediately concerned with performance of transplantation" [8].

The regional legal documents regarding organ transplantation, adopted by the Council of Europe or the European Union, involve the 1978 Council of Europe Resolution "on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances"; the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine (1997); the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin (2002); The Charter of Fundamental Rights of the European Union (2000); the Directive of the European Parliament and of the Council 2010 on standards of quality and safety of human organs intended for transplantation; Council of Europe Convention against Trafficking in Human Organs (2015).

The Council of Europe Resolution on the harmonization of legislation of member states relating to removal, grafting and transplantation of human substances contains the provisions urging the member states to conform their legislation and introduce appropriate sanctions to ensure their implementation. The Resolution dealt with issues such as the mandatory voluntary consent obtained from of the living donor for the removal of the human substances and such removal from incapacitated persons should be limited; any human substances offered for profit is prohibited; the removal of substances from the deceased donor is prohibited in the presence of the open or presumed objections on the part of the deceased; the identity of the donor must not be disclosed to the recipient and the identity of the recipient to the family of the donor.

The Convention on Human Rights and Biomedicine emphasizes that "removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness" [3].

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin sets up a number of essential rules for the regulation of transplantation, namely, the distribution of organs only among patients from the official waiting list; the order of removal of organs and tissues in the living and deceased person; prohibition of financial gain, etc.

The Charter of Fundamental Rights of the European Union sets out the prohibition on making the human body and its parts as such a source of financial gain. The Directive of the European Parliament and of the Council 2010 on standards of quality and safety of human organs intended for transplantation determines a number of provisions related to the standards of the quality and safety of organs, their transportation; protection of the donor and the recipient; obligations of the competent authorities and exchange of information; organ exchange with third countries and the European organ exchange organizations.

Council of Europe Convention against Trafficking in Human Organs, which came into force on 1 March, 2018, urges the governments of the member states to prevent and combat the trafficking in human organs by providing for the criminalisation of certain acts; to protect the rights of victims of the offences established in accordance with this Convention; to conduct preventive measures to ensure a transparent and equitable access to organ transplantation; to facilitate cooperation at the national and international level to prevent and combat trafficking in human organs.

National legislation on the transplantation of human organs involves the Constitution of Ukraine, the Law of Ukraine "About organ transplantation and other human anatomical materials", effective by 1 January, 2019, the Law of Ukraine "On human anatomical transplantation", which will come into force on 1 January,

2019, the Law of Ukraine "Fundamentals of the legislation of Ukraine on health care", the Law of Ukraine "On burying and undertaking", the Criminal Procedure Code of Ukraine and the Criminal Code of Ukraine.

Part 2 of the Article 28 of the Constitution of Ukraine state that no person shall be subjected to medical, scientific or other experiments without his/her voluntary consent. According to the Article 49 of the Constitution everyone has the right to health protection, medical care and medical insurance. Health care is ensured by the state funding of the relevant socio-economic, medical and sanitary, health improvement and prophylactic programs. The state creates the conditions for effective medical service accessible to all citizens.

The Law of Ukraine "On human anatomical transplantation" defines the conditions and procedure on transplantation, ensures the observance of human rights in Ukraine and the protection of human dignity in case of transplantation and the implementation of other activities related to it. The adoption of the Law enforces new standards for the regulation of transplant-related activities, changes the system of the state control and increases the level of protection of information regarding the donors and recipients.

The novelties in the transplant legislation involve the following:

1. Extended terminology in the field of transplantation, due to the definition of: autotransplantation; close relatives and family members; teams undertaken the removal of the human anatomical material; removal of anatomical material; transplant-related activities; hematopoietic stem cells; donation of anatomical material; deceased donor; the Unified State Information System for Transplantation; living donor; immunological compatibility; list (waiting list); cross-over donation, deceased person (deceased), potential donor, transplant-coordinator, transplant-coordination.

2. The basic principles of application of transplantation, such as: voluntary; humanity; anonymity; provision of donor organs to potential recipients on medical indications; unpaid donation (except for hematopoietic stem cells); adherence to the priority (except for family and cross-over donation); a decent attitude towards the human body in case of deceased donation.

3. Newly introduced articles in which the subjects of the organization and provision of medical care through transplantation and transplant-related activities and their authorities have been designated. Among them are the Cabinet of Ministers of Ukraine; the central executive body, which ensures the formation and implementation of the state policy in the field of health care; a central executive body that implements the state policy in the field of health care through transplantation and transplant-related activities; health care facilities that have a corresponding license; bureau of forensic medical examination; transplant-coordinators.

4. Introduction of the position of the transplant-coordinator amongst healthcare workers, who identifies the potential donor, finds out the presence of consent or refusal on deceased donation in the Unified State Information System for Transplantation, obtains consent for the removal of anatomical material from the potential donor, organizes removal, storage and transportation of human anatomical material, collaborates with the competent authorities of the central executive body and health care facilities, involved into transplantation.

5. Living donation is one of the essential novelties introduced stating that everyone has the right to give the lifetime written consent or refusal to donate anatomical material after his/her death. If no consent/refusal obtained, the decision on removal of the anatomical material is possible only by written consent of the other spouse or one of the close relatives (parents, children). In this case, the person has the right at any time to withdraw his/her consent or refusal on the removal of any anatomical material. The forwarded application cancels the previous decision of the person. Such information is submitted to the Unified State Information System for Transplantation, which is due to be established by 1 October, 2018. The introduction of such a system is a significant step towards the improving the situation in the field of transplantology. Obviously, the availability of the unified database, containing data on individuals who have provided the consent or refusal on deceased organ donation, data on human anatomical material for transplantation, data on living donors, recipients and individuals with transplanted anatomical material will significantly accelerate the process of organ transplantation.

6. Cross-over donation has been newly introduced, which means the exchange of living immunologically compatible donors between the recipients. For example, in the event that transplantation cannot be performed to the recipients from a living donor amongst his/her close relatives or family members, a decision may be made to apply cross-over donation, which is applied between the recipients who are included to the Unified State Information System for Transplantation.

7. The age of the recipient is lowered from 15 to 14 years.

8. The list of living individuals for whom the removal of anatomical material is prohibited is extended due to the individuals held in places of pre-trial detention and are pregnant.

9. Transplantation of organs and other animal anatomical material to a human being is prohibited. However, the use of xenografts is allowed.

10. Removal of anatomical material from deceased individuals belonging to the category of orphans and children deprived of parental care, incapacitated persons, unidentified persons, as well as persons who died as a result of anti-terrorist operation and other military actions is prohibited. In addition, organs shall not be used in case if law enforcement officers, the forensic examiner or the court have objections against it.

11. The state shall conduct an active information policy promoting transplantation of human anatomical material to form a positive attitude towards living and deceased donations among the population. Important provision in the field of state policy related to transplantation is the ensuring of medical care free of charge through transplantation.

12. Concluding or offering the conclusion of contracts stipulating the sale and purchase of human anatomical materials as well as any advertising of such material is prohibited.

13. International collaboration is foreseen in the field of transplantation of human anatomical material in the following areas: exchange of human anatomical material; exchange of information on available human anatomical material; implementation of research and investment programs on transplantation; exchange of technologies, medical equipment and scientific information.

Another national legal act in the field of transplantation is the Law of Ukraine “Fundamentals of the legislation of Ukraine on health care”. It stipulates that organ and/or other anatomical material transplantation to a human being is carried out in compliance with the law, in the presence of the consent of the donor and the recipient or the consent of their legal representatives, and under conditions that no other therapeutic methods are available to produce the desired outcome, and harm caused to the donor is less than that which threatened the recipient. A donor of organs and other anatomical material may be an individual with full civil capacity. Such a person may give written consent or refusal to the donation of his/her anatomical material in the event of his/her death.

The Law of Ukraine “On burying and undertaking” specifies the right of the citizens to bury their bodies and their will for respectful attitude to the body after death. The will can be expressed by: the consent or refusal on conducting autopsy; consent or refusal on removal of organs and / or other anatomical material; the will to be buried in a certain place, according to certain customs, near the certain previously deceased or being subjected to cremation; the power of attorney, etc. In the absence of the will of the deceased, removal of organs and / or other anatomical material is carried out in accordance with the procedure established by the law. The Criminal Code of Ukraine stipulates for liability: in the infringement of the legal order of human/animal organ and (or) other anatomical material transplantation; for removal of organ and (or) other anatomical material from a person for the purpose of their transplantation by coercion or deception; for illegal trade in human/animal organs and (or) other anatomical material.

In addition, the legal basis for organ transplantation involves the subordinate legislations, namely, the Resolution of the Cabinet of Ministers of Ukraine of 27April, 1994 No. 257 “On the establishment of the Coordination Center for Organs, Tissues and Cells Transplantation”; the Resolution of the Cabinet of Ministers of Ukraine of 5 September, 2007, No. 1100 “On Measures Aimed at Organization the Activities of Health Care Facilities and Scientific Institutions Related to Transplantation of Organs, Tissues and Cells”; the Order of the Ministry of Health of Ukraine No. 96 on the “Procedure for the procurement, storage and use of the bone marrow” and the “Procedure for transportation of human anatomical material within Ukraine and beyond”, adopted on 4 May, 2000; the Order of the Ministry of Health of Ukraine No. 226 of 25September, 2000 “On Approval of the Instruction on Removal of Human Organs from Deceased Donor”; the Order of the Ministry of Health of Ukraine No. 432 of 29 November, 2002 “On Approval of the Provision on the Unified State Information System for Transplantation”; the Order of the Ministry of Health of Ukraine No. 261 of 24 May, 2004 “On the Regulation of the Transplant Service of Ukraine”; the Order of the Ministry of Health of Ukraine No. 812 of 11 December, 2006 “On Approval of the Provision on the Coordination Center for Organs, Tissues and Cells Transplantation”; the Order of the Ministry of Health of Ukraine No. 650 of 28 September, 2006 “On Improving the Regulatory Framework and Adapting Ukrainian Legislation to European Standards in the Field of Transplantation of Organs, Tissues And Cells” and others.

Conclusion

In summary, the overview shows a fairly extensive current system of legislation in the field of transplantation of human organs in Ukraine. However, this does not solve all the problems in this area. First, there is a problem of shortage of donor organs, since not so many of our compatriots want to become living or deceased donors. Notwithstanding the statistics for 2017, provided by the “Rating” sociological group and reporting about 63% of respondents who support the human right to donate their organs after death in order to save or improve the lives of others, 25% of those who do not support it and 12% of respondents who have not decided yet [5], the data have not been confirmed by the reality. At the same time, the shortage of donor

organs does not depend on the model of transplantation; the WHO reports about 28.9 and 32.8 transplants per one million populations annually that are carried out in the countries with the “presumption of refusal” and “presumption of consent”, respectively. Obviously, the solution of this problem is only in the effective national support, promotion and the formation of a positive attitude towards donation as a single and non-alternative way of saving lives of the fatal case patients.

The second problem, closely related to the first one, is the illegal removal of human organs and their trade. In judicial practice, crimes committed in the field of human organs or tissue transplantation, are not yet common. In particular, about 50 criminal cases on the illegal trade of human organs are commenced worldwide annually and only 20% of them have been detected [4]. The official statistics, provided by the Prosecutor General’s Office of Ukraine, reports that over the 2014-16 period eight criminal offenses were registered under Article 143 of the Criminal Code of Ukraine, related to the illegal removal of human organs and tissues. During January, 2017, no criminal offences related to illegal activities on human organs and tissues were registered [12]. But again, the statistics do not reflect the real picture, since the rates of “black transplantology” are much higher. The reason is in the unstable economic situation in the country, when people in search of easy money address to dishonest individuals, offering big money for organ donation. The political situation in which hundreds of thousands of Ukrainians lost their homes and property as a result of military aggression in the East of Ukraine also contribute to trade in organs in the “black market”. One case out of hundreds of cases is registered by statistics; currently, no reliable data is available that would confirm the true extent of this criminal phenomenon. The major part of victims does not appeal to law enforcement agencies, bawaring of punishment or public blame.

Currently, transplant tourism is thriving globally, and Ukrainians act as donors and recipients who are ready to pay big money for the opportunity to obtain donor organ illicitly. In most of these cases, donors are impoverished and unhealthy local residents (Filipinos, Indians, Pakistani people). Consequently, the quality of the organs obtained in this way, as well as the quality of surgeries done, in terms of remote outcomes, is significantly worse in comparison with legal operations in clinics of the developed countries. The findings of the research show that 9% and 78% of patients-supporters of transplant tourism experienced post-transplant complications within a year and ten years, respectively, following transplantation. At the same time, post-transplant complications were experienced by 2% and 56%, respectively, of patients who have been transplanted kidneys during the planned operations [9].

The analysis of transplant legislation shows that both international and national legal acts condemn the trade in human organs. Transplantation as the only way for many sufferers to prolong life should not be a way of gaining profit on someone’s misfortune. If there were enough donor organs for all patients in the world, trafficking in human beings for the purpose of transplantation of their organs disappeared as unnecessary. Therefore, the solution of this problem depends only on public awareness of the positive aspects of organ donation and transplantation when everyone reviews their opinion on transplantation and gives consent to deceased donation, only then we can talk about positive results in the field of transplantation.

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Реферати

ТРАНСПЛАНТАЦІЯ ОРГАНІВ ЛЮДИНИ: МОНІТОРИНГ ЮРИДИЧНОЇ СИСТЕМИ

Янчук А.О., Кузніченко С.О., Градова Ю.М.

Дослідження присвячено важливій тематичі в медичному праві – трансплантації людських органів. У статті проведено моніторинг міжнародного і національного законодавства у сфері трансплантації органів людини. Проаналізовано новий Закон України «Про застосування трансплантації анатомічних матеріалів людини»

Ключові слова: трансплантація органів, трансплантологія, донор, реципієнт, торгівля органами, анатомічні матеріали, медичне право.

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ТРАНСПЛАНТАЦИЯ ОРГАНОВ ЧЕЛОВЕКА: МОНИТОРИНГ ЮРИДИЧЕСКОЙ СИСТЕМЫ

Янчук А.О., Кузниченко С.О., Градова Ю.М.

Исследование посвящено важной тематике в медицинском праве - трансплантации человеческих органов. В статье проведен мониторинг международного и национального законодательства в сфере трансплантации органов человеку. Проанализировано новый Закон Украины «О применении трансплантации анатомических материалов человеку».

Ключевые слова: трансплантация органов, трансплантология, донор, реципиент, торговля органами, анатомические материалы, медицинское право.

Рецензент Шепітько В.І.