

Historical evolution of the legal regulation of transplantation in ophthalmology

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Background: Studying the history and current state of the legal regulation of transplantation in ophthalmology is required for solving the issues on the subject.

Purpose: To investigate the genesis of legal regulation of transplantation in ophthalmological practice, and to identify the issues and prospects for further evolution in this area.

Materials and Methods: Dialectic, systemic-and-structural, comparative legal and comparative historical methods of research were used. Regulatory legal acts of the Soviet period and those of the independent Ukraine after 1991, and relevant legal practice and works of domestic and foreign scientists were examined.

Results: A comparative legal study of the legal framework on transplantation in ophthalmology both in the Soviet period and that of the independent Ukraine was conducted. The basic legal regulation criteria for performing transplantation in ophthalmology were subjected to analysis.

Conclusion: Periodization of the evolution of legislation for transplantation in ophthalmology was introduced. Proposals for improving current legislation on transplantation in ophthalmology were offered.

Introduction

Nowadays, transplantology is one of the leading disciplines of medicine, and exploits the most recent advances in surgery, gene engineering, biomechanics, immune genetics, cryoconservation of organs and tissues, etc. The rapid development of transplantation medicine reveals the need for the incorporation of its advances into everyday life. With an increasing gap between the demand for transplantation procedures in Ukraine and the number of these procedures actually performed in this country, there is a need to solve a number of issues relating to the legislative regulation of transplantation.

Developing regulation mechanisms for transplantations has been historically associated with legal and ethical issues. Although both domestic and foreign authors within the area of medical, civil, criminal and administrative law have contributed to research on the genesis and current state of the legal regulation of transplantation, the level of research on the issues pertaining to legal regulation of organ and tissue transplants is still to be improved and is considered inadequate by both medical and legal practitioners. Moreover, to my best knowledge, no study

has investigated the evolution of legal regulation of ophthalmic transplants.

The purpose of the study was to investigate the genesis of legal regulation of transplantation in ophthalmological practice, and to identify the issues and prospects for further evolution in the area.

Materials and Methods

The relevant legal, empirical and theoretical frameworks were examined. In particular, numerous regulatory legal acts of the Soviet period and those of the independent Ukraine after 1991, relevant legal practice and works of domestic and foreign scientists like S.V. Grinchak, P.P. Gorelyk, A.P. Gromov, D.P. Kobiakov, M.I. Kovaliov, N.Ie. Krylov, N.A. Margatska, V.A. Saganovych, V.P. Salnikov, O.V. Sapronov, S.G. Stetsenko, S.S. Tikhonov, G.V. Chebotariov, et al were examined. Dialectic, systemic-and-structural, comparative legal and comparative historical methods of research were used.

Results

In the early 20th century, there was a demand for implementing human organ and tissue transplants in practice in Ukraine, which caused a need for legal support of human organ and tissue removal.

The onset of domestic transplant science has been associated with the name of M.I. Pirogov, a distinguished surgeon, who delivered a lecture "On plastic surgery in general and rhinoplasty in particular", and conducted an analysis of the issues relevant to human organ and tissue transplants as early as 1835.

Mastering a technique of blood transfusion is considered essential for transplanting success, and, the first blood transfusion institute in the world was established by O.O. Bogdanov in Moscow in 1926. The surgical removal of a pathologically altered organ or tissue has become the next stage in the development of transplant science and practice. This was followed by the replacement of a particular dysfunctional organ or tissue with a functional one (the first experimental kidney transplantation in animals was performed by Emmerich Ullmann in 1902) [1].

Therefore, practical advances in the transplantation caused issues that had to be legislatively arranged such as notion of transplantation; notion of donation; legal status of a donor; procedure for obtaining a consent for transplantation; determination of the time of death of the individual; transplantation types and methods; transplant rules and algorithm; state regulation for transplantation activities, etc.

In the early 20th century, legislators' objectives included challenges such as developing and implementing general and special legislation to regulate particular types of tissue and organ transplantation. In addition, this legislation would have to emerge as practical advances in medicine evolve.

The first regulatory legal acts of common legislation for transplantation were as follows:

- Decree of the All-Russian Central Executive Committee and the Council of People's Commissars of the RSFSR On the Professional Work and Rights of Medical Workers issued on December 19, 1924, which enshrined the requirement for obtaining a patient's consent for any surgery [2];
- Regulations for Forensic Examination of Corpses approved by the People's Commissariat for Health of the RSFSR on December 19, 1928 and by the People's Commissariat for Justice of the RSFSR on January 3, 1928. These regulations enshrined the concept of the starting point for the period when postmortem removal of organs and tissues can be carried out. Article 10 of the regulations stipulated that autopsy for research purposes was allowed to be carried out no later than 12 hours but not until half an hour after a person's death, in the presence of three doctors who had to draw up a report indicating both a reason for performing the autopsy and evidence of death. In

addition, the regulations stipulated that the consent of deceased person's next of kin was not required for tissue removal. However, obtaining the forensic expert's approval was required with regard to the corpse subject to forensic expert examination, and the consent of morgue director was required with regard to the corpse delivered to the morgue but not subject to forensic expert examination [3];

- Decree of the Council of People's Commissars of the RSFSR (dated April 22, 1935) On Donors [4];
- Decree of the Secretariat of the All-Union Central Trade Unions Council (dated July 8, 1935) On Social Insurance Benefits for Donors (Individuals who Choose Voluntarily to Donate their Blood for Medical Purposes) [5, 6];
- Resolution No.1607 of the Council of People's Commissars of the USSR (dated September 15, 1937) On the Procedure for the Conduct of Medical Operations, which stipulated the possibility to remove organs from a dead body for transplantation (including cadaveric corneal transplantation, blood transfusion, transplantation of isolated organs, etc.) [7];
- USSR Ministry of Health Instructions (dated May 3, 1956) On Medical Examination and Registration of Blood Donors and on the Blood Donation Procedure [8];
- Letter of the Chief Forensic Expert of the USSR Ministry of Health No.392 (dated April 12, 1957) On Provision of Traumatology Institutes and Blood Transfusion Institutes with Some Types of Tissues from Deceased Persons [9]; the letter stressed on initiating the development of preservation procedures for some types of cadaver tissues, on the importance of this event both in research and practical aspects, and on its importance for promoting health and saving life;
- Regulations (dated March 3, 1956) On the Activities of Departments Responsible for Questions of Health and Red Cross and Red Crescent Societies with Regard to Encouragement of Donors approved by the USSR Ministry of Health on May 26, 1958 [10];
- Regulations on Referring to and Accepting, Examining, Storing and Delivering Corpses at Forensic Morgues as an Appendix to the Order of the USSR Ministry of Health No.166 (dated April 10, 1962) On Measures for Improving the Performance of Forensic Expert Examination in the USSR [11]; Article 20 of the Regulations allowed removal of cadaver tissues (skin, costal cartilages, bones, etc.) to medical establishments for preparing and preserving some tissues for the purposes of transplantation;
- Order of the USSR Ministry of Health No.600 issued on August 2, 1966, [12] which stipulated that, in any medical institution of the USSR, transplantation of an organ (kidneys, liver, etc.) from a deceased or living person or animal could be conducted only if approved by the USSR Ministry of Health;

- Basic Health Law of the USSR and its Republics adopted on December 12, 1969, [13];
- Order of the USSR Ministry of Health On Improving the Provision of Medical-and-Prophylactic Institutions and Clinics with Cadaver Tissues, Bone Marrow and Blood issued on June 14, 1972 [9];
- Instructions of the USSR Ministry of Health On Medical Examination of Blood Donors issued on October 17, 1978 [5, 6];
- and Order of the Ukrainian SSR Ministry of Health No.236 On Further Development of Clinical Transplantation in the Republic issued on February 17, 1987 [12], etc.

Filatov became the first to perform corneal transplantation from cadaver in the clinic in 1931, which was followed by the transplantation of mucous membrane in 1935 and that of skin in 1937. Thereafter, special regulatory legal acts on ocular transplantations were issued.

Since 1936, the Filatov Institute has been the leading corneal transplantation center in Ukraine. Donor corneas preserved in most chambers as per the method introduced by Filatov were used to perform keratoplasty at the institute until 2014. Since 2014, they have been using a medical purpose product, a biological corneal implant manufactured by Bioimplant State Enterprise of the Ministry of Health of Ukraine, to perform keratoplasty. It should be noted that, although patients used to obtain donor cornea for transplantation free of charge, today they have to buy it from Bioimplant State Enterprise, and some of them refuse transplantation surgery for financial reasons, and thus cannot improve their disabled status.

Order of the USSR Minister of Health No.88 On Widespread Adoption of Corneal Transplantation Surgery in Clinical Practice was issued on February 16, 1954. The order required ophthalmological institutions (including, first and foremost, institutes for eye disease and eye clinics of medical refresher institutes) to perform corneal transplantations in all necessary cases, and to organize receipt of cadaver eyes for this purpose [9]. In addition, it approved the Instructions of the USSR Ministry of Health On the Use of Cadaver Eyes for Corneal Transplantations to Blind Recipients [9]. The instructions were a very important document since they regulated important issues with regard to this type of surgery. They stipulated that ophthalmologists of adequately equipped eye clinics and hospitals of the USSR were allowed to harvest corneas from cadavers for transplantations to patients requiring this surgery. In addition, the use of cadaver globes for corneal transplantations was allowed in the absence of contraindications (like history of syphilis, sarcoma, acute infectious diseases, etc.) relevant to the cadaver. Moreover, no consent of next-of-kin was required for cornea removal from corpses (a) of individuals who died at a medical treatment facility or (b) that were delivered to a morgue, but disfiguration of the donor corpse was prohibited. A cadaver globe was allowed to be removed for the purposes

of corneal for transplantation no later than 10 hours but not until 2 hours after a person's death that had to be certified by the written report of two doctors. Furthermore, for globe removal, morgue director's consent was required with regard to the corpse delivered to the morgue, and forensic expert's consent was required with regard to the corpse subject to forensic expert examination. Morgue director's refusal to give his/her consent was to be substantiated in writing.

A special report was to be drawn up with regard to globe removal, and signed both by the doctor who performed the removal and a representative of the institution where the corpse was kept [5].

The Basic Law on Health Care in Ukraine was adopted on November 19, 1992, and became the first act of present-day Ukrainian legislation with regard to transplantation [14]. This law stipulates that transplantation of donor's organs and other anatomic materials to the recipient is subject to the consent of the donor or donor's legal representative, and is performed in accordance with the procedure established by law, if other means and methods of life support or health restoration or improvement have failed, and donation is expected to result to a less loss to the donor than a potential loss to the recipient from failure to perform transplantation (Article 47).

The basic special law relating to transplantation ("On Transplantation of Human Organs and Other Anatomic Materials") was adopted on July 16, 1999 [15]. The Ministry of Health of Ukraine adopted Order No.392 On Approval of Regulatory Legal Acts On Transplantation on September 25, 2000 [16], to improve legal regulation of basic transplantation-relating issues. The order approved the Instructions on Declaring Death of a Person on the Basis of Brain Death (Two acts, Brain Death Determination Protocol to be certified by all persons participating in the council of physicians, and Certificate of Death of a Person on the Basis of Brain Death in accordance with Form No. 012/0, were approved by MoH of Ukraine Order No. 184 of July 26, 1999, On Approval of Accounting Statistics Record Forms Used in In-Patient Departments of Medical-and-Prophylactic Institutions [17]). In addition, MoH of Ukraine Order No. 821 [18] of September 23, 2013 approved:

- Diagnostic Criteria for Brain Death and Procedure for Statement of an Individual's Time of Death;
- Instructions for Removing Organs from a Donor Corpse;
- Instructions for Removing Anatomic Structures, Tissues and their Components or Fragments from a Donor Corpse;
- List of Human Organs that are Allowed to be Removed from a Donor Corpse;
- List of Anatomic Structures, Tissues and their Components or Fragments That are Allowed to be Removed from a Donor Corpse or Dead Human Fetus;
- Instructions on Manufacturing Biological Implants;

- Conditions for Safeguarding Anatomical Materials During Their Transportation, etc. [12].

The Cabinet of Ministers of Ukraine adopted Decision No. 695 of October 24, 2000, Some Issues of Implementation of the Law of Ukraine on Transplantation of Human Organs and Other Anatomic Materials [19] with the purpose to develop a mechanism for implementation of the Law on Transplantation. That decision (a) approved the list of public health and academic institutions authorized to perform the removal of organs and other anatomic materials from living or cadaver donors and their transplantation to the human recipient, and (b) authorized the MoH of Ukraine to approve appropriate regulations. MoH of Ukraine Order No. 96 [20] of May 4, 2003, On Approval of Regulatory Legal Acts on Transplantation of Organs and Other Anatomic Materials to Humans, was issued in accordance with the decision, and approved the following acts:

- Regulations for Transportation of Human Anatomic Materials within Ukraine and Abroad;
- Regulations for Removal, Preservation, and Use of Bone Marrow;
- and Medical and Biological Requirements for Animals and Their Housing Conditions, and Regulations for Removal of Xenografts from Them.

In the early 2000s, a number of regulatory legal acts were adopted, including the following relating to regulation of institutions authorized to provide transplantation services:

- MoH of Ukraine Order No. 432 [21] of November 29, 2002, On Approval of Regulations on the Unified State Transplantation Information System;
- MoH of Ukraine Order No. 261 [22] of May 24, 2004, On Regulations for the Ukrainian Transplantation Service;
- MoH of Ukraine Order No. 374 [23] of July 26, 2004, adopted Model Regulations for Medical Centers (Departments) for Transplantation of Organs and Other Anatomic Materials which determine the basic tasks, functions and rights of such centers;
- and MoH Regulations No.812 [24] of July 6, 2005, On the Coordinating Center for Transplantation of Organs, Tissues and Cells.

In the mid-2000s, the following acts were approved on the national level:

- State Program for the Development of Transplantation in 2002-2005 (approved by the Cabinet of Ministers of Ukraine Decision No. 1339 of September 12, 2002 [25]);
- Concept of the State Program for Transplantation in 2006-2010 (approved by the Cabinet of Ministers, Ordinance No. 416-p of July 20, 2006 [26]);
- and Targeted State Social Program for Transplantation for the period until 2012 (approved by the Cabinet of Ministers of Ukraine, Decision No. 894 of October 8, 2008 [27]).

MoH of Ukraine Order No. 250 [32] On the Homograft Donation by the Living Next-of-Kin Donor [28] was

issued on April 10, 2012, and approved Instructions on the Homograft Donation by the Living Next-of-Kin Donor. The Instructions stipulate that only one of a set of paired organs, or part of a single organ, or part of other anatomic material, may be removed from a live donor for homografting. In addition, an adult person with legal capacity who has volunteered to be a donor must be informed by the treating physician of (a) all the risks for donor's health involved and (b) the rights accorded to the donor with regard to execution of donor functions.

Transplantation of human organs and tissues is internationally regulated by the following soft-law instruments adopted by the World Medical Association:

- Statement on Live Organ Trade (1985) [29] which condemned the purchase and sale of human organs for transplantation and called on governments to prevent the commercial use of human organs;
- Statement on Human Organ Donation and Transplantation (1987) [30] which stressed that no physician may therefore assume a responsibility in organ transplantation unless the rights of both donor and recipient are protected;
- and Resolution on Physicians' Conduct Concerning Human Organ Transplantation (1994) [31].

It is noteworthy that Ukraine signed the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin of January 24, 2008 [32].

In addition, two draft laws amending the legislation on transplantation of human organs and other anatomic materials were submitted in parallel to the Verkhovna Rada in 2015.

The draft law On Amending Some Legislative Acts of Ukraine Concerning Public Health and Transplantation of Human Organs and Other Anatomic Materials of July 16, 2015, No. 2386-a [33] provides for the establishment of a "presumed consent" system for donation after death.

The draft law On Amending Some Legislative Acts of Ukraine Concerning Public Health and Transplantation of Human Organs and Other Anatomic Materials of August 4, 2015, No. 2386a-1 [34] provides for the right of a private medical institution to perform activities relating to transplantation. In addition, it provides for legal regulation of conditions for implementation of "mixed donorship" when taking a homograft, and does not provide for changing from the explicit consent principle provided by validly enacted legislation to the presumed consent principle [35].

It should be noted that today there is no special legal act governing transplantation in ophthalmology. The list of special public health and research institutions authorized to conduct activities associated with human tissue transplantation in ophthalmology in Ukraine includes the Filatov Institute of Eye Disease, National Academy of Medical Science (Odesa); Kyiv Municipal Clinical Eye Hospital "Eye Microsurgery Center"; Kyiv Municipal Center for Endocrine and Vascular Disorders of the Eye,

Kyiv Municipal Clinical Hospital No.1; Odesa Municipal Hospital No.2 (Eye Trauma Center of Odesa Medical University); and Dnipropetrovsk Regional Clinical Eye Hospital. The list of special public health and research institutions authorized to conduct activities associated with human cell transplantation in ophthalmology in Ukraine includes the Filatov Institute of Eye Disease, National Academy of Medical Science (Odesa) and Kyiv Municipal Clinical Eye Hospital "Eye Microsurgery Center" [19].

It is worth to note that Appendix 2 for Instructions for Removing Anatomical Structures, their Components and Fragments from the Donor Corpse (approved by Ukrainian MoH Order No.226 of September 25, 2000) includes an example of the Act on Removal of Anatomical Structures, their Components and Fragments from the Donor Corpse, and clause 5 of this example specifies "eye globe or its components".

Removal of the eye globe or its components is allowed in accordance with the List of anatomic structures, tissues and their components or fragments that are allowed to be removed from a donor corpse or dead human fetus (approved by Ukrainian MoH Order No.226 of September 25, 2000).

Therefore, the Ukrainian legislation in effect provides for the possibility of transplantation of globe components from a donor corpse in the presence of either the inter vivos consent of the donor or consent of deceased person's next-of-kin to cadaveric donation.

The removal of the donor corneolimbic rim is conducted by the medical institutions authorized for this activity according to the decision of the Cabinet of Ministers of Ukraine. Subsequently, the disk is transferred to the Dnipropetrovsk Branch of Bioimplant State Enterprise of the Ministry of Health of Ukraine to be subjected to numerous biological, virological and microbiological

tests, and to endothelial cell tests. This is followed by the production of a high-quality and safe medical preparation, a biological corneal implant. The latter is used to provide patients with special ophthalmological care in order to restore their sight and capacity to work and to improve their quality of life after serious corneal injuries, trauma and numerous corneal disorders requiring surgery [36].

Conclusion

The period of the evolution of Ukrainian legislation on transplantation of human organs and tissues can be divided into two subperiods, the Soviet subperiod and the current subperiod. During the Soviet period, (a) neither the inter vivos consent of the donor nor the consent of deceased person's next-of-kin to cadaveric donation was required for transplantation from a donor corpse, (b) special laws were adopted to govern transplantation of some types of human organs and tissues, and (c) transplantation surgery could be conducted only if approved by the USSR Ministry of Health. More advanced legislation for (a) state regulation of transplantation-related activities and (b) special state programs on the subject have been developed in the current period. The main issues still to be solved by in Ukraine regarding the legal regulation of transplantation are the following: making a legislator's choice between using opt-in and opt-out systems; improving the legal regulation of cadaver donation; building a state program to guide cadaver donation policy; providing a system to guide the efforts to improve cadaver donation policy; providing for allocation of national budget resources for transplantation-related activities; setting up the certification and licensing procedures applied to medical establishments for performing transplantation; establishing a National Transplantation and Organ Donation Service; developing and approving template agreements and supporting documents regarding donation, etc.

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