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**ORGAN AND TISSUE TRANSPLANTATION DEFINITION:  
CIVIL LAW ASPECT**

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**Dziuba A. Organ and tissue transplantation definition: civil law aspect.**

This paper deals with the problem of defining the concept of organ and tissue transplantation in civil relations context. The fragmental definition of ‘organ and tissue transplantation’ presumes significant problems of this term’s legal interpretation. The core difficulty of such situation seems to be the usage of special medical terminology in indicated legal relations sphere. Simultaneously, it is well known that literal borrowing of medical terminology leads to a significant narrowing of the concept, as it does not take into account many legal aspects. The situation is complicated by the fact that Ukrainian and foreign scientists have no unambiguous views on the doctrinal interpretation of this term. Some legal scholars argue that the transplantation of human anatomical materials should be considered from the standpoint of the right to medical care, others tend to define transplantation as a special type of medical service. One more group of scientists are supporters of borrowing medical terminology to denote this item and are likely to interpret transplantation as a special method of treatment or system of medical manipulations. This article calls us into question of analyzing doctrinal legal approaches to understanding the transplantation concept in the context of civil law, as well as the interpretation of this term in national and international transplantation legislation. Special legal methods and logical tools are applied to present the solution of the article’s purpose. The complex analysis of special transplant legislation and doctrinal approaches has led us to the conclusion that national and international legislative definitions of transplantation tend more to the established medical terminology. A systematic analysis of the doctrinal considerations and legal provisions allows us to identify the following approaches to understanding transplantation: transplantation as medical manipulation (medical intervention); transplantation as a process of organ or tissue replacement; transplantation as a method of treatment; transplantation as medical care; transplantation as medical service. Such a variety of views on the interpretation of this concept is quite justified primarily due to the multifaceted nature of the transplantation phenomenon. All the above approaches seem to be correct, because they reflect it from different angles. Despite the lack of agreement, we believe our findings compare well with the opinion that medical service seems to be the best reflection of the civil law nature of the legal relations for the provision of medical care. Therefore, we suggest to define the term “transplantation” as medical service for the provision of highly specialized medical care by replacement of an organ and (or) tissue that has lost its vital functions on the basis of medical indications.

**Key words:** transplantation, definition, medical service, medical care, civil relations.

**Дзюба А. Поняття трансплантації органів і тканин: цивільно-правовий аспект.**

У статті висвітлюється проблема визначення поняття трансплантації органів і тканин у контексті цивільних правовідносин. Фрагментарне визначення означеного поняття спричиняє складнощі щодо правового тлумачення цього терміну. Складність ситуації обумовлена використанням спеціальної медичної термінології у зазначеній сфері правовідносин. Загальновідомо, що буквальне запозичення медичної термінології призводить до значного звуження поняття, оскільки не враховує низки правових аспектів. Ситуація ускладнюється тим, що українські та зарубіжні вчені не мають однозначних поглядів на доктринальне тлумачення цього терміну. Одні вчені-правники стверджують, що трансплантацію анатомічних матеріалів людини слід розглядати з позиції права на медичну допомогу, інші схиляються до визначення трансплантації як особливого виду медичної послуги. Ще одна група вчених є прихильниками запозичення медичної термінології для позначення цього поняття, адже тлумачать трансплантацію як особливий метод лікування або систему медичних маніпуляцій. Ця стаття спонукає до питання аналізу доктринально-правових підходів до розуміння поняття трансплантації в контексті цивільного права, а також тлумачення цього терміну як в національному, так і в міжнародному трансплантаційному законодавстві. Для вирішення мети статті використовуються спеціальні юридичні та логічні методи. Комплексний аналіз спеціального трансплантаційного законодавства та доктринальних підходів сприяє висновку, що національні та міжнародні законодавчі визначення трансплантації здебільшого тяжіють до усталеної медичної термінології. Системний аналіз дозволяє виділити такі підходи до розуміння трансплантації: трансплантація як медична маніпуляція (медичне втручання); трансплантація як процес пересадки органів або тканин; трансплантація як метод лікування; трансплантація як медична допомога; трансплантація як медична послуга. Таке різноманіття поглядів на трактування досліджуваного поняття цілком виправдане і зумовлене багатогранністю феномена трансплантації, однак усі наведені вище підходи видаються коректними, оскільки відображають це поняття з різних сторін. Незважаючи на відсутність узгодженості, ми вважаємо, що наші висновки корелюють з думкою про те, що саме медична послуга є найкращим відображенням цивільно-правової природи відносин з надання медичної допомоги. Тому ми пропонуємо визначати термін «трансплантація» як медичну послугу з надання високоспеціалізованої медичної допомоги шляхом пересадки органу та (або) тканини, які втратили свою життєдіяльність на основі медичних показань.

**Ключові слова:** трансплантація, визначення, медична послуга, медична допомога, цивільні правовідносини.

**The concept of organ and tissue transplantation: civil law aspect formulation of the problem.** Current data from the Ministry of Health of Ukraine [1] indicate that the national transplant system is in its infancy. This encourages lawmakers to a high-quality legal framework on the basis of the international legal norms and standards. The conceptual apparatus is the subject to coordination initially, because the sphere of relations in the field of organ and tissue transplantation is characterized by special medical terminology usage.

The special terms usage in legal science and regulations is quite natural. Scientists note that, if the normative act, which uses such terms, applies not only to professionals but to a wider range of people as well, it is advisable to give an accurate and complete definition of the terms used, and an important condition is that these terms should be understood in the meaning assigned to them in the relevant field of knowledge [2, p.66-67]. At the same time, it should be taken into consideration that the literal medical terminology borrowing leads to a significant narrowing of the concept, as it does not take into account many legal aspects.

The issue of an unified understanding of the transplantation concept as an object of civil law regulation is relevant in this framework.

**Overview of past-to-present literature.** Few studies in the field of law have been devoted to the definition of organ and tissue transplantation problem. The issue is complicated by the fact that Ukrainian and foreign scientists have no unambiguous views on the interpretation of the transplantation concept. Some legal scholars argue that the transplantation of human anatomical materials should be considered from the standpoint of the right to medical care [3, p.74]; others define transplantation as a special type of medical service [4, p.394; 5, p.82]. Another group of scientists are supporters of medical terminology borrowing to denote this concept and interpret it as a special method of treatment or system of medical manipulations [6, p.13; 7, p.138].

**The aim** of this article is to determine the concept of organ and tissue transplantation as an object of civil law regulation.

This paper re-examines doctrinal legal approaches to understanding transplantation in the context of civil law, as well as the interpretation of this concept in national and international transplantation legislation.

**Presenting main material.** Etymologically term ‘transplantation’ comes from the Latin ‘*transplantare*’ and is formed by adding the prefix ‘*trans*’, which means ‘across, beyond’ to the verb ‘*plantare*’ – to plant, derived from the noun ‘*planta*’ – seedling [8, p.620]. There is no doubt that the term ‘transplantation’ is medical and is obviously used in the sphere of medicine, mainly referring to organ, tissue or cell transplant surgery. M. Webster’s Medical Dictionary defines transplantation as an act or process that involves the removal of tissue from one part of the body or from one individual and its implantation or insertion in another especially by surgery [9]. It should be noted that the generally accepted use of the term ‘transplantation’ in the scope of medical and legal literature refers to:

- allotransplantation (allogenic transplantation, homotransplantation): transplantation occurs between organisms belonging to one species [10, p.443]. This type of transplantation is the most common. In particular, human-to-human organ transplantation refers to allogenic transplantation;
- autotransplantation: transplantation occurs within the same organism [10, p.443; 11 p.141; 12, p.6]. For example, the patient is transplanted his own tissue. The donor and the recipient are the same person in such a surgery. The legal regulation is distinct for this type of transplantation, therefore the transplant legislation is not applied to autotransplantation;
- xenotransplantation: transplantation of organs and tissues from one species representative to another species representative [13]. This includes animal-to-human organ transplantation. Currently this type of transplantation is in the clinical trials and is not sufficiently adapted to modern medicine possibilities;
- isotransplantation (isogenic transplantation): transplantation between identical twins or between animals that are in such a blood relationship that their genetic material is identical [10, p.443; 12, p.6].

Medical sources stipulate that transplantation is applied only on the basis of clinical cues [14, p.12]. Therefore, transplantation could be understood as life-saving medical technique on artificially transferring tissues, cells or organs of a living or posthumous donor to a specific recipient. An indication for transplantation is end-stage organ failure or another disease that cannot be cured with medication, intensive care, or surgery.

The definition of ‘transplantation’ in Ukrainian legislation is provided by the Law of Ukraine ‘On the application of anatomical materials transplantation to humans’ dating 17.05.2018 272427-VIII. In accordance with Art. 1 of this Law, transplantation is a special method of treatment, which consists of transferring human anatomical material from a donor to a recipient with the purpose of human health restoration [15].

Hence, in conformity with the Ukrainian legislator, the meaning of the term ‘transplantation’ is reflected by following features:

- transplantation is a method of treatment;
- it is performed by transferring anatomical material from a donor to a recipient;
- the ultimate goal of transplantation is human health restoration.

The above indicated legal definition has a tendency to the established medical terminology. Unfortunately, the norms of the honoured in this area international law documents tend to define transplantation as a medical issue as well. Thus, The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention) [16] does not contain a normative definition of ‘transplantation’. The Additional Protocol to the Convention on Transplantation, adopted on the 24-th January 2002 in Strasbourg, states that the term ‘transplantation’ covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage [17]. The concept is explained somewhat differently in the Explanatory Report to the Oviedo Convention, which consider organ transplants to be current medical techniques helping to save, prolong or greatly facilitate the lives of persons suffering from certain serious disorders [18]. Therefore, the concept of the Additional Protocol to the Convention on Human Rights and Biomedicine is reflected with an emphasis on the medical aspect, taking into account the description of the transplantation process itself. Instead, the Explanatory Report mostly emphasizes human rights (the concept is reflected with regard to the socio-humanitarian aspect) [19, p.10].

The European Union provides a similar interpretation of the considered term. Directive 2010/53/EU defines transplantation as a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient [20]. Consequently, it could be argued that the European Directive focuses

on two core aspects of transplantation: functional (transplantation is an organ replacement from a donor to a recipient) and targeted (transplantation is aimed at restoring certain functions of the human body).

Therefore, both national legislation and international one have a noticeable tendency to formalize medical terminology in regulations. This conclusion is facilitated by the fact that generally legal determination of the term ‘transplantation’ is reduced to its interpretation as a method of treatment and the process or act of organs and tissues transferring.

Moreover, legal doctrine definitions of transplantation are steadily mediated by the terms ‘medical care’ and ‘medical service’. Thereby, civil law studies provide thesis that transplantation is a type of medical care, which includes the provision of medical services and medical works aimed at a recipient health restoration by transferring an organ or a tissue to a donor [21, p. 8]. This position is justified by the fact that the issue of medical care is broader than the issues of ‘medical work’ and ‘medical service’ and is involved in the concept of ‘medical activity’.

This conclusion has not received general acceptance with the approach of I.R. Ptashnyk, who proposes transplantation to be defined as ‘a special type of medical service that promotes the constitutional right of citizens to protect their life and health and is performed by surgery of transferring organs and tissues in medical institutions on the basis of the recipient’s consent [22, p. 24]. The emphasis in this definition is that transplantation is a specific type of medical service by its legal nature. This component is fully compliant with the opinion of M.S. Bryukhovetska, as she substantiates that deceased donors’ organ transplantation is a specific medical service provided for free, which includes a set of actions aimed at transferring an organ or other anatomical material from the post-mortem donor to the recipient, with the purpose of treating the last one, and is the final stage of the right to posthumous donation. [23, p.21].

A systematic analysis of the above considerations allows us to identify the following approaches to understanding transplantation:

- transplantation as medical manipulation (medical intervention);
- transplantation as a process of organ or tissue replacement;
- transplantation as a method of treatment;
- transplantation as a medical care;
- transplantation as a medical service.

It is worth noting that such a variety of views on the interpretation of the studied issue is quite justified initially due to the multifaceted nature of the transplantation phenomenon. All the above approaches seem to be correct in one way or another, because they reveal it from different angles.

Functionally transplantation is the anatomical material replacement from a donor to a recipient. Thereby, it is a certain type of medical intervention, which obviously can be performed only by surgery.

As a medical intervention, transplantation is mediated by a set of processes that are performed in a certain sequence. These are primarily such stages as surgery, during which the organ is removed for transplantation (donor operation) and the actual replacement of the organ in the recipient’s body (implantation).

Regarding the understanding of transplantation as a medical care and medical service, it is worth noting the following. Fundamentals of the Legislation of Ukraine on Health Care define medical care as the practice of professionally trained medical workers aimed at prevention, diagnosis and treatment of diseases, injuries, poisonings and pathological conditions, as well as regarding pregnancy and childbirth [24]. Organ and tissue transplantation provides a highly specialized medical care. In turn, the European Commission notes that highly specialized medical care means medical care that involves high complexity of a particular disease or condition in its diagnosis or treatment or management and high cost of the treatment and resources involved. The provision of such medical care should be based on high-quality, accessible and cost-effective healthcare services [25].

Thus, it becomes clear that both medical service and medical care are the objects of civil law. However, our results are in complete agreement with the opinion that the very concept of ‘medical service’ could reflect the civil-law nature of the relationship for the medical care provision in the proper way, whereas the main basis for its provision is the medical services provision contract. The institute of medical care is interdisciplinary and it is mostly considered in the context of personal non-property rights of an individual in the civil law. At the same time, medical service is a separated object of civil rights (Article 177 of the Civil Code of Ukraine) [26, p.54].

The doctrine of law considers medical service to be a useful activity of the provider, which is aimed at meeting the health needs of the individual and is intangible [28]. A.A. Hertz highlights the features of medi-

cal service that determine its special legal phenomenon. These include (but are not limited to) the following: the transformative, useful role of activity; inability to guarantee a positive result; inseparability of the process of providing medical services from the actions of the medical worker, and the beneficial effect – from the patient; irreversibility, uniqueness, exclusivity; providing mainly through direct contact, etc. [26, p.75]. Transplantation is characterized by all of the above features. At the same time, the current transplantation legislation, in particular the Law of Ukraine ‘On the application of anatomical materials transplantation to humans’ [15] does not indicate that transplantation should be considered as a type of medical service. This creates a problem of fragmentation of special legislation and does not contribute to the formation of an integral idea of the transplantation legal nature.

**Conclusions.** An integrated approach is needed to reflect the precise meaning of the thought-about definition. The content of transplantation as a legal concept should be disclosed with regarding to both medical and legal aspects. The following features would best reflect the legal nature of this term:

- transplantation is a kind of medical service provided by specially authorized health care facilities on a professional basis;
- transplantation involves the provision of highly specialized medical care;
- medical transplant service is provided through the application of one of the most valuable techniques in medicine, which involves organ or tissue replacement;
- indication for transplantation is the loss of human body vital functions as a result of the organ failure or other disease, evidenced by clinical cues;
- humanistic orientation of transplantation (the purpose of transplantation is to save human lives);
- transplantation is provided on the basis of the informed consent of the donor and recipient.

Consequently, findings of this study consider the following definition of organ and tissue transplantation would be appropriate:

‘Organ and tissue transplantation is a medical service for the provision of highly specialized medical care by replacement of an organ and (or) tissue that has lost its vital functions, performed by a specially authorized medical institution on the basis of medical indications and the informed consent of the recipient and the donor (its next of kin – in the case provided by law) in the manner prescribed by law.’

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