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**DONOR ANONYMITY: NATIONAL  
LEGAL REGULATION  
AND INTERNATIONAL EXPERIENCE**

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**Цитування:** *Медичні перспективи. 2020. Т. 25, № 3. С. 198-204*

**Cited:** *Medicni perspektivi. 2020;25(3):198-204*

**Key words:** *principle of anonymity, anatomical material transplantation, donor, recipient, confidential information*

**Ключові слова:** *принцип анонімності, трансплантація анатомічних матеріалів, донор, реципієнт, конфіденційна інформація*

**Ключевые слова:** *принцип анонимности, трансплантация анатомических материалов, донор, реципиент, конфиденциальная информация*

**Abstract. Donor anonymity: national legal regulation and international experience. Shpuhanych I.I., Diukarieva-Berzhanina K.Yu., Yavorska O.S.** *The article is devoted to the analysis of legal, medical, moral and ethical aspects of the principle of donor anonymity. The principle of anonymity has a legal framework and appropriate regulation in international documents. These are: Directive on standards of quality and safety of human organs intended for transplantation, WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 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 and the Additional Protocol etc. This principle is the basis of the legislative regulation of donation in many countries, including Ukraine. The normative approaches to the legal regulation of donation and the principle of anonymity in accordance with national legislation are investigated. The Law of Ukraine "On the Application of Transplantation of Anatomical Materials to Man" bylaws and the application of the principle of anonymity depending on the type of donation: posthumous and lifetime are analyzed. The international experience of applying the principle of anonymity is characterized. The principle of absolute anonymity is enshrined, in particular, in the legislation of the Netherlands, Sweden. Accordingly, such regulatory approaches exclude any contact between the donor and the recipient. According to the principle of conditional anonymity (in particular, the United States and the United Kingdom), the exchange of information between the donor and the recipient is permitted, surely at the will. The advantages and disadvantages of direct communication between the donor and the recipient are described. The expediency of applying the principle of conditional anonymity in national practice is substantiated regarding moral, ethical, and psychological aspects. In order to implement this, it is proposed to consolidate the right of the donor and the recipient to approve or deny the data exchange at the legislative level. It is suggested to assign the appropriate functions aimed at facilitating the parties' interaction to the transplant coordinator.*

**Реферат. Анонимность донорства: национальное правовое регулирование и международный опыт. Шпуганьч И.И., Дюкарева-Бержанина К.Ю., Яворская А.С.** *Статья посвящена анализу правовых, медицинских, морально-этических аспектов принципа анонимности донорства. Принцип анонимности имеет нормативное закрепление и соответствующую регламентацию в международных актах: Директива о стандартах качества и безопасности человеческих органов, предназначенных для трансплантации, Руководящие принципы ВОЗ по трансплантации человеческих клеток, тканей и органов, Конвенция о защите прав и достоинства человека в связи с применением достижений биологии и медицины: Конвенция о правах человека и биомедицине и Дополнительный протокол к ней и т.п. Такой принцип положен в основу законодательного регулирования донорства многих стран, включая и Украину. Исследованы нормативные подходы правового регулирования донорства и принципа анонимности в соответствии с национальным законодательством: Закон Украины «О применении трансплантации анатомических материалов человеку» и*

подзаконные акты. Проанализировано применение принципа анонимности в зависимости от вида донорства: посмертное и прижизненное. Проанализирован зарубежный опыт применения принципа анонимности. Принцип абсолютной анонимности закреплён, в частности, в законодательстве Нидерландов, Швеции. Соответственно такие нормативные подходы исключают любой контакт между донором и реципиентом. В соответствии с принципом условной анонимности (в частности США и Великобритании) разрешено обмен данными между донором и реципиентом при наличии их волеизъявления. Охарактеризованы преимущества и недостатки прямого общения донора и реципиента. С учётом морально-этических и психологических аспектов обоснована целесообразность применения принципа условной анонимности в отечественной практике. С этой целью предлагается закрепить на законодательном уровне право донора и реципиента давать согласие или несогласие на обмен данными. Для налаживания взаимодействия сторон соответствующие функции предложено возложить на трансплант-координатора.

Health secrecy, confidential information, patient anonymity, medical secrecy - these and other similar terms are used both in Ukrainian legislation and in medical practice. At the same time, confidentiality is an established legal, medical, ethical and social norm in the patient's relationship with the doctor. Prohibiting health professionals from disclosing information that they become aware of in the course of their official duties is a solid basis for building confidence in a particular physician and the health care system in general.

In this aspect, the norms of the Law of Ukraine "On the use of transplantation of anatomical materials to humans" [4] (hereinafter – the Law on Transplantation) of May 17, 2018 were not an exception. Among the basic principles in this act is the principle of anonymity (Article 4). Such approaches are used by many countries around the world, which use it, taking into account the legitimate interests and wishes of donors and recipients.

Therefore, the purpose of this article is to study the current state of legal support for the secrecy of donation and the formation of proposals for its improvement based on foreign experience. To achieve this goal, dialectical, analytical, systemic, formal-legal and comparative-legal methods were used.

The right to anonymity of both the donor and the recipient is a common practice of the vast majority of countries in the world where transplantation is allowed at the legislative level. The same position is set out in Directive N 2010/45/EC on standards of quality and safety of human organs intended for transplantation [7]. Its provisions do not allow the disclosure of personal data of the recipient to the donor or his family members, and vice versa.

The WHO Guidelines for Transplantation of Human Cells, Tissues and Organs also emphasize the need to respect the principle of anonymity and confidentiality of donors and recipients (Ex. 11) [2]. Also important are the provisions of the Convention for the Protection of Human Rights and Dignity on the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine of 4 April 1997 [3] and its Additional Protocol of 24

January 2002 [1]. They enshrine the right to respect for one's private life; regarding information on health, it is stated that all personal data of the donor and recipient are confidential and must be protected.

The principle of anonymity enshrined in the Law on Transplantation should be considered in combination with a whole set of norms and rules that "remind" of the need to comply with it. Ensuring the anonymity of the donor and recipient should be facilitated by the Unified State Transplant Information System (hereinafter – USTIS). At present, such a system has not been created, which makes it almost impossible to transplant anatomical materials. However, the system is planned to be launched in 2021, and until then the transplant is proposed to be carried out on the basis of information on paper. After the creation and launch of USTIS, it will include a set of minimum data – information about donors, recipients, characteristics of anatomical materials that are collected, processed and protected in the manner prescribed by law. These data are information with limited access (confidential) within the meaning of the Law of Ukraine "On Information". Based on the provisions of this act, such information may be disseminated at the request (consent) of the person concerned in the manner prescribed by him/her in accordance with the conditions specified by the latter [5].

In our opinion, the study of the principle of anonymity in the analyzed area should be carried out in view of the two main types of donation enshrined in the domestic Law, depending on the donor: 1) lifelong donation, when the donor is a living person; 2) posthumous donation, when transplantation of anatomical materials is performed from a deceased person (corpse donor).

Lifetime donation, in turn, is divided into the following types: 1) *family donation*: a living donor is a close relative or family member of the recipient; 2) *cross-donation* (exchange of living immunologically compatible donors between recipients); 3) *donation of anatomical materials capable of regeneration (self-reproduction), including hematopoietic stem cells*, which can be carried out by a

living donor who is not a close relative or family member of the recipient.

As a general rule, a living donor of anatomical material, other than those capable of regeneration, may be a close relative or family member. The list of such persons is defined in Art. 1 of the Law on Transplantation and which was even amended in February 2019. Instead, the legislation of foreign countries (for example, the United States) does not limit the number of people who want to be donors of anatomical materials, only close relatives or family members. Any person, in accordance with medical indicators, can become a donor for a complete stranger. This approach seems progressive.

Instead, if transplantation in Ukraine from a close relative or family member is not possible, given the results of determining the immunological compatibility of the donor and recipient, the medical council may decide to use cross-donation. In this case, another recipient included in the USTIS is searched for and donors are inter changed. However, the requirements for cross-donation are not detailed at the legislative level. The relevant Procedure for the use of cross-donation is approved by the Cabinet of Ministers of Ukraine. However, such an act has not been adopted yet. Therefore, the use of this type of donation is currently almost impossible. Due to the fact that the principle of anonymity is the same for all types of donation, its application to cross-donation is mandatory.

As for the donation of anatomical materials capable of regeneration (self-reproduction), including hematopoietic stem cells, this is the only type of donation that can be performed by a living donor who is not a close relative or family member of the recipient. Hematopoietic stem cell donation is also not subject to the principle of gratuitousness, which is mandatory for other types of donation.

Postmortem donation is characterized by the possibility of removing for further transplantation of the recipient anatomical materials of the deceased, in respect of which in the manner prescribed by law, consent was obtained to remove from his body anatomical materials for transplantation. A donor can be any able-bodied adult who has given his or her consent to posthumous donation, or such consent has been obtained from an authorized representative appointed by the donor, or in some cases from the other spouse or one of the person's close relatives (children, parents, siblings).

The application of the principle of anonymity in practice differs slightly depending on the type of donation. When transplanting anatomical materials from a living donor – a close relative or family members of the recipient, anonymity should be

considered through the prism of the obligation not to disclose medical secrets. Keeping the secret of donation in a close (family) circle of close acquaintances is quite difficult and hardly necessary. Interestingly, the Order of the Ministry of Health of Ukraine of April 10, 2012 "On providing a living family donor with homotransplant for transplantation", which was adopted in accordance with the Law of Ukraine "On transplantation of organs and other anatomical materials to man" (lost validity). This act entitles the probable donor and recipient and/or his/her parents/legal guardians to access any information concerning the donor-recipient pair [6]. In our opinion, the application of the norms of this, albeit current Order of the Ministry of Health of Ukraine, contradicts the norms of the newly adopted Law in the field of transplantation, as well as the provisions of the Central Committee of Ukraine and a number of international acts on fundamental human rights and freedoms. Persons who have received confidential information about the identity of a donor or recipient, in connection with the performance of official duties or from other sources, have an obligation not to disclose it, except as provided by law. On the other hand, in the presence of the will of the donor and the recipient, the secrecy of family donation, and hence the observance of the principle of anonymity, is in fact quite conditional.

Ensuring a person's right to privacy, including health secrets, in other types of donation is a rather complex and debatable issue. The issue of possible disclosure of information about the donor and recipient has been repeatedly the subject of research and lively discussions among physicians, psychologists, sociologists and lawyers around the world [8, 10, 13, 22].

The provisions of the current Law on Transplantation are formulated in such a way that in fact exclude the possibility for a donor or his family members to receive information about the recipient and vice versa (except for family donation). However, it seems that such a position is too categorical. After all, the recipient, like the donor (his/her close relatives or family members at the postmortem donation), may equally express a desire to obtain information about each other. As a general rule, the legislation of Ukraine allows a person to dispose his/her personal data and information about the state of his/her health at his/her own discretion, deciding who should disclose them and who should not. However, on the other hand, there are no practical ways to implement this right in the field of transplantation of anatomical materials. After all, the principle of anonymity, as well as the obligation to

comply with the legal regime of confidential information contained in USTIS, comprehensively exclude the possibility of exchanging data on the identity of the donor and recipient, even with the mutual consent of both parties.

Thus, as of today, the legislation of Ukraine enshrines the principle of absolute anonymity, which excludes the possibility of the donor receiving information about the recipient and vice versa. This approach is used, for example, in the Netherlands [15] and Sweden [24]. The laws of these countries are designed to protect the families of the donor and recipient from the public and from each other. They provide for the possibility of contact between subjects only through the exchange of depersonalized correspondence through donor or transplant organizations [17, 23]. However, recently there have been active discussions about the expediency of enshrining the possibility of establishing direct contact between the donor and the recipient in the regulations of these countries [12, 21]. Instead, the principle of conditional anonymity has been introduced in the practice of a number of other foreign states. For example, in the United States [8], the United Kingdom [19], and Australia [18], postoperative contact between a donor (his family member) and a recipient is allowed, provided that both parties agree. According to researchers, contact should occur only after a certain period of time after transplantation, as well as with the support of medical professionals in a controlled environment [11, 14].

The European Society for Organ Transplantation (ESOT) conducted a comprehensive study of the positions of donors and recipients on the issue of their anonymity, both before and after transplantation of anatomical materials. The obtained results gave grounds to conclude that the principle of conditional anonymity in the postoperative period is the most acceptable for both the donor and the recipient [9].

It seems that such results are not unfounded. Disclosure of information to the donor about the recipient and vice versa before the transplant is quite a risky decision. However, contact between donors (their close relatives) and recipients in the postoperative period has a number of advantages. The main positive moments from the acquaintance and communication of donors (or their close relatives or family members) and recipients are the following:

- the opportunity for recipients to personally thank the donor or his/her close relatives. Sociological surveys of donors, recipients and their families in different parts of the world suggest that words of gratitude for the provided anatomical

materials, which were so necessary to the recipient, are invaluable experience and an important psychological relief for the recipient and at the same time support donor or his family. This issue becomes especially relevant in posthumous donation. In this case, the pain of losing a loved one is easier to accept [20] and rethink;

- the ability of the donor personally or his/her close relatives to observe the positive results of the transplant [16]. The lack of donor organs and tissues in the world is a common problem, the solution of which lies in the formation of a positive attitude in society to transplantation as a method of treatment, encouragement to donate their own anatomical materials;

- the opportunity to get answers to questions that concern both sides of the transplant process. Often both donors and recipients want more information about each other, about the person's well-being after the transplant, lifestyle, and so on. Such a desire can be satisfied only by giving the donor and recipient or their family members the opportunity to communicate directly.

Undoubtedly, there are certain risks when meeting a donor (his/her close relatives) and recipients. The main ones include the guilt that arises in the recipient in front of the donor's family members (in case of postmortem donation), the probability of violating the principle of gratuitousness by demanding compensation for transplanted anatomical materials (except for hematopoietic stem cell transplantation), frustration associated with the idealization of the other party, and unfulfilled expectations from communication. It is important to emphasize once again that the disclosure of personal data of the donor or recipient is possible only with their consent. Similarly, in the case of post-mortem donation, close relatives or family members of the donor cannot be forced into contact, and thus the disclosure of information about themselves and the deceased donor to the recipient or his family.

In view of the above, we propose to introduce the legal basis for the disclosure of information to the donor (his close relatives or family members) about the recipient and vice versa at the legislative level. We believe that an important condition is the consent of both parties to the exchange of personal data. It seems that the authority to ensure the disclosure of information about the personality of the donor and recipient, with their consent, it is advisable to put the authority on the transplant coordinator. He/she, as a person with a higher medical education could advise the parties on the possible advantages and disadvantages of direct contact. Our

proposed approach balances the legal rights and interests of each participant in the process of transplantation of anatomical materials, including the right to privacy and secrecy of health, as well as

the right to information about another person with his consent.

Conflict of interest. The authors declare no conflict of interest.

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The article was received  
2019.12.23

