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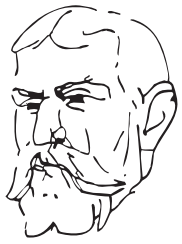

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REVIEW ARTICLE
PRACA POGLĄDOWA

PRESUMPTION OF CONSENT IN THE ECHR PRACTICE AND LEGAL SYSTEMS: LEGAL MODELS FOR ORGAN REMOVAL FOR TRANSPLANTATION

DOI: 10.36740/WLek201912224

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ABSTRACT

Introduction: Post-mortem organ donation is widely used and poses a problem for transplant specialists and lawyers, whose task is to provide legal support for the removal of organs of the deceased.
The aim: of the article is the scientific search for the optimal legal model of organ removal for transplantation.
Materials and methods: The theoretical base of the research consists of the works of Bonnie F., Dakhno I.N., Erin C., Evans R., Kevorkian J.A., Price D., Richardson R., Reriht A.A. The empirical base includes the results of the opinion poll and the analysis of the ECHR practice. Formal-logical (dogmatic) method, comparative legal method, logical-semantic method, generalization and modelling techniques are used.
Conclusions: To improve the legal regulation of transplantation it is necessary to improve the legal literacy; create effective mechanisms to protect the patients' and doctors' rights; increase the information and scientific support of transplantation.

KEYWORDS: transplantation, organ transplantation, «presumption of consent»

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INTRODUCTION

Post-mortem organ donation covers 90-95% of transplant services demands in different countries and thus poses a problem not only for transplant specialists but also for lawyers, whose task is to provide legal support for the removal of organs of the deceased. The development of the law governing posthumous organ donation puts the legislator in a difficult position. On the one hand, it is necessary to ensure human rights to the autonomy of the body and its respect after death, on the other – to create an effective legal model of the system of removal of cadaverous organs. Thus, the legislator must pass between the wall of the accusations of "pseudo-Democrats" and so-called "human rights" in the lack of respect for "universal values" and the sick, the dying an agonizing death from an incurable disease without a possibility to be saved by donors' organs [1, p. 21]. All the above-mentioned factors determine the relevance of the research topic.

THE AIM

The purpose of the article is the scientific search for the optimal legal model of organ removal for transplantation, considering the practice of the ECHR and the legislation of countries with different legal systems.

MATERIALS AND METHODS

Research methods are chosen according to the aim of the article. Both general and special scientific methods are used.

The formal-logical (dogmatic) method was used to interpret certain provisions of current Ukrainian legislation, foreign legislation and international legal acts. The comparative legal method was applied in foreign experience studying of the legal regulation in the field of transplantation. The logical-semantic method was applied to interpret and distinguish basic concepts and some scientific categories. Generalization and modelling techniques have been used to examine existing regulation practices in the field of transplantation.

The theoretical base of the research is papers of Bonnie F., Dakhno I.N., Dubovik O.L., Erin C., Evans R., Kevorkian J.A., Price D., Richardson R., Reriht A.A. The empirical base includes the results of the opinion poll and the analysis of the ECHR practice.

REVIEW AND DISCUSSION

A serious obstacle to postmortem organ donation is people's lack of confidence that death will be diagnosed accurately and will not be accelerated specifically to obtain the necessary organ.

Thus, one of the most important tasks faced by the legislators of many countries is to consolidate the rules of law to regulate the necessary actions and conditions for the accurate diagnosis of human death, taking into account the latest achievements in Biomedicine. In search of the optimal legal model it is necessary to refer to the existing

experience. The analysis gives us the basis to allocate four main approaches to removal of bodies of the dead for transplantation regulation:
1) routine transplantation;
2) forcible removal from persons sentenced to death;
3) the removal of organs based on "consent" (the "presumption of disagreement") of the deceased during his life (partial agreement – no doubt agreement) or his next of kin after the donor's death (full consent procured (simplified) consent»;
4) removal of organs based on the" presumption of consent " of the deceased, that is, his alleged consent.
So, what is the meaning of routine transplantation as a method of organ removal?
According to experts, this method is the most beneficial in terms of ensuring the needs of transplantology, but at the same time from a legal point of view has significant gaps, since the removal of the organs of the deceased only the permission of the medical administration and, in criminal cases, the forensic expert and the Prosecutor is required. This does not take into account the will of the deceased or his relatives, which grossly violates the human rights to autonomy and integrity of his body and respect for him after death. The basis of the ideology of this organs removal system is the belief that the corpse belongs to society. The legal basis of this system is usually not laws, but by-laws as it was, for example, in the USSR before its collapse and in several countries of the "socialist camp".

Advanced democracies have rejected the method of routine organ removal for transplantation purpose because a person has the right to express his or her will about his or her body after death, or the right is transferred to the relatives of the deceased (the so-called "next of kin").

Only in China, through the use of this method, there is a systematic removal of kidneys from sentenced criminals. However, the state authorities of China claim that the permission of the criminals themselves and their relatives for the removal of organs as compensation for the harm caused to people was obtained in advance.

In the Syrian Arab Republic according to the law this method is allows to take organs for transplantation from criminals that are convicted to the penalty. Similar approaches are used in Egypt and Taiwan [2, p. 83].

The author (A.O.) considers that this method should be legally prescribed for convicts, who have committed grave crimes in case of an them diagnosis of deadly disease, except for contraindications to this procedure.

At the same time, the review allows us to conclude that described approaches to the removal of deceased organs for transplantation are currently being used very limited and rejected by all democratic states, where there are two principal Legal models of "expressed consent" or "presumption of consent".

Each of these "models" from a legal point of view is both "strong" and "weak" depending on the will of deceased's relatives.

The "strong" model does not require any mandatory approvals of relatives of the potential donor, if there is a formal confirmation of the will of the deceased to donate their organs (for example, the so-called "donor card"), or none of the relatives of the deceased did not inform about the refusal to remove organs.

A "weak" model requires, in any case, the obligatory alignment of this procedure with of the deceased's relatives, even if there is a notarized volition of the deceased on the donation of organs.

The essence of the withdrawal system on the basis of "expressed" or "concerned" consent is that it is necessary to obtain a "pronounced" consent, issued by the deceased during the life, or the obligatory consent of relatives of the deceased on the removal of organs for transplantation (concerned consent). Under such approach one of the so-called "cards" of the donor could be used, where he expresses his willingness to donate of their organs for transplantation after the death (UK) or categorically abandon this (Denmark, Holland, Spain, Portugal, Sweden). In Belgium and Sweden these data are logged in the central computer database.

However, as a practice shows, the effectiveness of such consolidation volition was low. In particular, in 2013 in the United States the staff of the centre Gellop found that 69% of Americans are willing to donate their organs after death, but only a small part of them has a "card" of donor [3].

In the UK, 27% of the individuals has such a card, but only 1 of 5 carry it constantly with them, in the US – only 1 of 4 [4].

Even in the early 80s, many countries abandoned the system of "expressed consent" and switched to the "presumption of consent" system. For example, according to F. Stewart (1981) of 28 countries in 13 a legal model for the removal of organ transplants based on "presumption of consent" was introduced at that time. A review conducted by the Council of Europe in 1987 testified the implementation of a system based on "presumption of consent", in 21 states of the Council of Europe and also in Finland.

At the same time, it should be noted that in almost all countries with the legalized system of "expressed consent" its "strong" version implemented (Argentina, Australia, Denmark, Norway, the Philippines, Romania, Slovenia, Venezuela, Zimbabwe), "weak" version took place in United Kingdom, Japan, and Lebanon [5, p. 92].

Practically, as the literature review shows, the case went differently. According to the law in countries with a "strong" version of "expressed consent", relatives had no right to change the volition of the deceased, but the medical staff had such an opportunity (Great Britain, the USA, Australia). Thus, in most countries with the legalized "pronounced consent", the practice of the permission to relieve relative's authority, which was subsequently enshrined in the legislation of several states, was developed. Thus, for example, by the law of Germany in 1997 [6, p. 2363]. Seizure of the organ for transplantation is permitted provided that:
1) There is consent provided for life by the donor;
2) In case of absence of any written official volition of the deceased there is the consent of the close ("next kin") relative.

Similar provisions were enshrined in the legislation of Venezuela, Algeria, Sri Lanka and Turkey.

It should be noted that although the law was supposed to get the consent of relatives, but in most regulations there are no any clear instructions that would oblige someone to purposefully seek these relatives. Therefore, in some countries, these requirements have appeared in the laws much later.

The additions made to these laws partially eliminated this gap by putting the responsibility of the medical official to allow the removal of organs in the absence of volition of the deceased and the consent of relatives only in cases when they are convinced that necessary, and provided reasonable efforts of the staff were made to establish a valid will of the deceased and to search for his relatives.

Under Danish and Dutch law, the lack of direct consent of relatives prohibits the removal of organs for transplantation.

Of great interest is the law of Germany "on donation, withdrawal and transplantation of organs." The essence of this law is manifested in the fact that, acting on the basis of the model of "Express consent" doctors, in the absence of an express will of the deceased, will agree to the request of relatives, who have a certain period of time to decide whether they agree to the removal of organs of the deceased for transplantation. Relatives in such cases are formally warned that the absence of any response will be regarded as consent (although this reservation is characteristic of the presumption of the consent). Therefore, relatives, by law, must confirm their awareness. In this case, the following is of interest:" silence "of relatives can be considered as a consent by prior agreement of the parties since without a preliminary explanatory conversation, the assessment of" silence" as consent is contrary to the general rule of law.

The differentiated approach to the consideration of the above systems leads to the disclosure of the legal nature of the model of withdrawal based on the "presumption of consent".

In foreign literature, it is noted that the "presumption of the consent" approach is the "weakest link" in the legislation on transplantation of human organs of many States and serves as an occasion for discussion and well-reasoned objections. Systems based on the "presumption of consent" are often compared to routine organ removal. John. Kevorkian even expressed the view that the removal of organs based on "presumption of consent" is simply a state system of organ theft [7, p. 48].

Some authors and, in particular prof. Richardson believe that society paid dearly for failing to recognize the need of consent and that the "presumption of consent" is essentially a denial of this necessity [8, p. 78].

Erinn S., Harris J. (1999) consider the "presumption of consent" to be a legal fiction, and that without "Express" consent can be considered that it does not exist at all [9, p. 366].

At the same time, many supporters of the "presumption of consent" believe that a significant number of medical manipulations are based on the "presumption of consent" and therefore it is not a fiction, but a real consent.

Despite the revealed differences among specialists, it can be concluded that with "expressed consent" there is a real consent to the removal of organs for transplantation, and with "presumption of consent" – there are simply no identified objections.

"Strong "versions of legal models based on the "presumption of consent" legalized in Austria, France, Luxembourg, Poland, Portugal, Slovak Republic, Spain, Peru, Brazil, Singapore," weak " – in Belgium, Finland, Russia.

To date, there has been some debate as to which system of "expressed" or "implied" consent is better. No one doubts the superiority of the first in terms of moral and ethical and the second in terms of much greater opportunities to provide patients with donor organs.

Only a few authors believe that there is no correlation between the legal model of organ removal in the country and the number of organs seized.

It is very interesting that recently there has been a clear trend towards convergence of both legal models due to the fact that although "de jure" medical personnel should not actively "ask" for the consent of relatives in the presence of a "strong" version of the "presumption of consent", "de facto" this happens in almost all cases.

For example, in Spain, which has the world's most effective post-mortem organ donation system, there has been provided more than 1,500 kidney transplants in 2017.

The same trend can be seen by comparing transplantation legislation in the UK ("expressed consent") and Norway ("presumption of consent"). In the legislation of both countries for the removal of the organs of the deceased the requirements are: the "express consent" of the deceased; the absence of objections of relatives, subject to the expression of consent of the deceased.

None of these laws contain a provision on the mandatory receipt of the consent of the deceased after his death – his relatives, and in Croatia, Sweden, Norway need a mandatory family permit for transplantation. Rules for the harmonization of medical manipulation with the family or other community are adopted by States within the framework of the so-called "principle of family autonomy".

It should be noted that there are cases where both criteria are applied at the same time to establish death. For example, in accordance with Art. 2 and 15 of the Venezuelan Law "on transplantation of organs and anatomical materials of the person" receiving of donor's organs is possible from a person whose death is established on the basis of traditional criteria of clinical death (cardiac and respiratory arrest, lack of reactions to external stimuli) or complete cessation of electrical activity of the brain within 30 minutes (in persons whose vital functions are maintained artificially). You should pay attention to the fact that the Law expressly stipulates the condition that should be equated with death: it is reversible toxic, and metabolic changes caused by hypothermia [10, p. 73].

The European Convention on Human Rights (ECHR) (formally the Convention for the Protection of Human Rights and Fundamental Freedoms) is one of the basic European legal acts in many spheres, including transplantation.

Thanks to the European Court of Human Rights the Convention [11] is a "living document". The European Court in its case law concretizes, clarifies and expands the normative content of the ECHR. Examples of such solutions are used in the field of transplantation and organ donation. The study of the practice of the European Court in the field of transplantation and donation is limited to two cases.

The judgment in the first case "Petrov against the Republic of Latvia" (Petrov v. Latvia, complaint No. 4605/05) was issued in June 2014 [12]. The judgment in the second case "Alberta (Elberte v. Latvia, complaint No. 61243/08) against the Republic of Latvia" was issued in January 2015 [13]. The plots of these cases are similar in factual circumstances.

In Petrov v. Republic of Latvia, the applicant's son suffered serious injuries as a result of a traffic accident, after which he was taken to the hospital, where he underwent a craniotomy, and it was decided by doctors to remove the kidney and spleen for further organ transplantation.

The Complainant was reported to have deteriorated in her son's condition but was not approached with the consent of an organ transplant. About what happened, the applicant learned nine months later during the consideration of the criminal case on the fact of a traffic accident. Following the Complainant's complaint, the police concluded that the transplantation of her son's organs was legal under the national law and refused to initiate criminal proceedings [12].

According to the Law of the Republic of Latvia "On the protection of the body of a deceased person and use of human organs and tissues in medicine" (as of January 1, 2002), it was assumed that every person in life has the right to inform the institution in writing that he/she agrees to further removal of their organs after death. Such information is entered in the internal passport of a particular person on his consent or disagreement to the removal of organs during transplantation, this information is as well recorded in special registers. Article 11 of this Law provided that "the removal of organs and tissues from the deceased donor for further transplantation is allowed if during his lifetime he did not object to this and if his next of kin did not prohibit this removal" [14].

In her application to the European Court of justice, the applicant claimed that the case involved a violation of article 8 of the Convention concerning the removal of organs from her son without his prior consent and the prior consent of the applicant herself. The European Court concluded that in the applicant's situation there had been a violation of the right to private and family life (article 8 of the Convention). That is, the European Court recognized that interference with the right to respect for private life was not provided by law, as required by article 8 of the Convention, because Latvian law, formally granting close relatives of the deceased the right to object to the removal of his organs, which were not formulated clearly and did not provide effective protection against arbitrariness [12].

The legislation of Latvia does not provide proper notification of relatives of the deceased on the transplantation of its organs so that they could argue against it, as well as did not forbid the removal of organs without obtaining consent from the relatives if the deceased had not expressed their will. The applicant, formally having the right to object to the removal of her son's organs, was not informed of how and when she could implement it, let alone to obtain proper explanations [12].

It should be noted that in response to this situation, the Law of the Republic of Latvia "on the protection of the body of a deceased person and the use of human organs and tissues in medicine" was amended. The amendments were aimed at a clearer definition of "consent", including by close relatives. Thus, article 11 this Law establishes that "the Removal of organs and tissues from the body of a deceased person for transplantation is allowed in cases when the register of citizens of the Republic of Latvia has no information concerning the refusal of the deceased person from the post-mortem use of organs or tissues, or its consent to the procedure, and the nearest relatives of the deceased before the transplant not reported medical institution in writing of its objections to post-mortem use of organs and tissues of his body made during his lifetime. The removal of organs and tissues from a deceased child for further transplantation is prohibited unless one of his parents or his legal representative has given written consent to it" [15].

In the second case, Elberte v. Latvia, the applicant's man died in a car accident. During the autopsy at the forensic center his tissues were seized and transferred to a pharmaceutical company in Germany for the manufacture of bio implants under an approved state contract.

The Complainant alleged, inter alia, that without her consent and notification, tissue samples were taken from her deceased husband and that her husband was buried with his legs tied. The applicant learned about the seizure of tissues two years later during the consideration of the criminal case on the fact of large-scale illegal seizure of organs and tissues from the corpses [13].

The Complainant claimed that there had been a violation of article 8 of the Convention in the case, in particular, that the removal of her husband's tissues had conducted without his and her consent. She complained that in the absence of such consent his dignity his individual integrity had been violated and his body had been treated with disrespect. The Complainant also claimed that there had been a violation of article 3 of the Convention in this situation because the removal of tissue from the man's body had been carried out without her prior consent or notice, and that she had been forced to bury him with his legs tied.

Violation of the Law "on the protection of the body of a deceased person and the use of human organs and tissues in medicine" in two ECHR cases are the same.

The European Court found that the Latvian authorities had not created the legal and practical conditions that would have allowed the applicant to Express her opinion on the removal of her deceased husband's tissue and thus allowed interference in the exercise of her right to respect for private life [13].

The Latvian authorities differed on the significance of the applicable domestic legislation. The forensic medical

examination center and the Latvian police assumed that there was a system of "presumed consent", whereas the investigators believed that the Latvian legal system was based on the principle of "informed consent", and the removal of organs and tissues was possible only with the consent of the donor (during his lifetime) or his relatives. At the time when the Latvian police agreed with the interpretation proposed by the Prosecutor's office and decided that it was necessary to obtain the consent of the applicant, the Statute of limitations for criminal prosecution had already expired. Such disagreements between the authority's point to the lack of clarity of the provisions of the legislation of Latvia [13].

Concerning to compliance with article 3 of the Convention, the European Court found that apart from the grief caused by the death of a close family member, the applicant suffered without knowing why the man's legs were tied when the body was returned to her for burial. In fact, she became aware of what fabrics were seized and in what quantity only during the proceedings in the European Court.

Thus, the applicant was denied the negative consequences of the violation of her personal rights, concerning a very painful aspect of her private life, namely the right to consent to or object to the removal of her deceased husband's tissues.

Although in the highly specialized field of organ and tissue transplantation, it is generally accepted that the human body should be treated with respect even after death. Indeed, there are many international treaties, including the Convention on human rights and Biomedicine and its Additional Protocol, aimed at protecting the rights of living or dead organ and tissue donors. Moreover, respect for human dignity is one of the " trunks" of the Convention [13].

Analyzing the Ukrainian legislation in our opinion there is a substitution of "presumption of disagreement" of "presumption of consent". Currently, Ukraine has a presumption of disagreement, which is reflected in article 17 of the Law of Ukraine "on the use of transplantation of human anatomical materials" 2018 (hereinafter – the Law) [16]. " It is forbidden to remove anatomical materials for transplantation and / or production of bioimplants from a deceased person in the case of: the existence in the Unified State Information System of Transplantation of the information about the life-giving written consent for the death donation provided by such person". A logical question arises: "The absence of written disagreement is the basis for the transplantation of human anatomical materials?". The subparagraphs of this article are contradictory and may lead to conflict and abuse of law. For example, another case of a ban on the removal of anatomical materials for transplantation and/or the manufacture of bio-implants from a deceased person is the lack of consent of relatives.

If the donor-corpse has no legal representatives the deceased may be a subject of law, but not of legal relations. In this case, in our opinion, it would be logical if the interests of such a subject of law would be represented by the state, provided that there is no expressed disagreement on organ transplantation.

In case of formation in the future of judicial practice in part of Art. 17 p. 3 PP.1 of the Law there should be a mandatory procedure for informing relatives about their right to informed consent.

As for the recipients, that in article 13 [16] the Law clearly stipulates that the withdrawal of anatomic materials for transplantation and/or manufacture of bio implantation is carried out with the consent objectively proposed by capable person. In the absence of consent to the operation, the specified medical intervention is prohibited. But article 13 p. 5 of the Law provides for the case of a real threat to life (but what is meant by a real threat to life is not clear, because medical practice knows many "journal" cases of patients coming out of conditions that threaten their lives), which implies the lack of consent of the recipient to medical intervention.

It is necessary to pay attention to one more issue which will lead to the inhibition of the development of transplantation. This contradiction between the Law "fundamentals of legislation of Ukraine on health protection (article 47, 52) [17], where for the first time the definition of the concept "the moment of irreversible death" – the moment of brain death or biological death, and the Order of the MOH of Ukraine No. 821 dated 23.09.2013 "About establishment of the diagnostic criteria of brain death and the procedure of finding the death of the person" [18], changes to which had not been made. The reference rules of the order are based on the old law on transplantation and contain outdated provisions, which is unacceptable. This in turn leads to the incorrect execution of procedural actions during transplantation.

The law did not provide specifics about the order of obtaining consent from relatives and family members of the donor in case there is a list of persons defined by law or in the case of radically different views on the removal of anatomical materials. The main task of the Ukrainian legislator is to solve these conflicts. In our opinion, this is especially aggravated in cases that concern the future recipient. Regarding this, we consider it appropriate to conduct the procedure of listening to both sides in terms of validity, objectivity, the impartiality of the judge in the field of the main question: "what would be better for the life and health of the recipient?"

CONCLUSIONS

Taking into account the practice of the ECHR and the experience of other legal systems, it is necessary first of all to focus on improving the legal literacy of the population and on the peculiarities of accepting consent to the removal of human anatomical materials. This is the first point. The second point is that the improvement of legal culture is not possible without the creation of effective mechanisms to protect the rights of patients and doctors. The third one is the necessity to increase the information and scientific support of this sphere.

Despite the mixed nature of the system of removal of anatomical materials, the Ukrainian legislator prefers the

presumption of disagreement. This system requires a complex process of debugging. And the presumption of consent may be the next stage when the pyramid "Transplantation in Ukraine" will be competently and harmoniously built, will be based on the trust and law.

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