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Consent to Deceased Donation in the American Transplant System

Abstract: According to the data, the deceased and living donor rates cannot keep pace with the growing need for organs in the United States. In three decades, the national waiting list has grown 8-fold. It is estimated that every 10 minutes another name is added to the national transplant waiting list. Approximately 22 people die every day waiting for a transplant. Most organs for transplants are recovered from deceased donors. The United States use the “donation model”, a consent model for deceased organ recovery that prioritizes the rights of the individual (or the surrogate decision maker) over the needs of society, by requiring authorization or explicit consent prior to deceased organ recovery. Some transplant community members have advocated for shifting the current donation model of deceased donor organ recovery to a model that permits deceased organ recovery without explicit consent or authorization, in order to increase the number of organs available for transplant. This article aims at answering a question whether shifting to such a model in the United States could solve systemic problems, organs shortage in particular, and whether it would be ethically justified. The paper describes models of deceased organ recovery and presents the model currently used by the United States. It presents, from the American perspective, the analysis of the model of deceased organ recovery without explicit consent or authorization, as well as proposes alternative opportunities to increase deceased organ supply.

Keywords: transplantation, donation, deceased donor

1. Introduction

In the USA, a number of donors has increased over 2.5¹ times since 1988². From 1 January 1988 to 31 March 2017, a total number of donors amounted to 341 033³. During this time, 695 096 transplantations⁴ were performed.

1 From 5 909 in 1988 to 15 943 in 2016.

2 Data of the Organ Procurement and Transplantation Network – OPTN, collected from the 1 of October 1987, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

3 Including 193 723 deceased donors and 147 310 active donors.

4 Including 548 002 *ex mortuo* i 147 094 *ex vivo*.

Most organs for transplantation come from the deceased. In the USA, a number of deceased donors has more than doubled since 1988 (from 4 080 donors in 1988 to 9 970 donors in 2016)⁵; apart from a few exceptions⁶, the number has increased each year. From 1 January 1988 to 31 March 2017, a total number of deceased donors amounted to 193 723⁷. During this time, 548 002 *ex mortuo* transplants were performed. A number of *ex mortuo* transplants increased from 10 794 in 1988 to 27 630 in 2016⁸.

Despite progress in medicine and the growth of technology and actions aimed at an increase of public awareness of donation of organs and transplantation, the relevant data imply that the number of *ex mortuo* and *ex vivo* donors is not sufficient to satisfy a growing demand for organs.

A list of individuals awaiting transplantation is continually increasing, in the past 30 years it has increased nearly eight times⁹. A total number of candidates for a recipient entered into the waiting list amounts to 118 173¹⁰, including 75 952 active candidates¹¹. Every ten minutes, a next candidate for a recipient is added to the above list. On average, 22 people die every day awaiting transplantation. In 2015 122 071 individuals¹² awaited transplantation; 30 975 transplantations were performed while organs were recovered from 15 068 donors¹³.

Currently, the USA has implemented “a donation model”, i.e. a consent model for deceased organ recovery that prioritizes the rights of the individual (or the surrogate decision maker) over the needs of society, by requiring authorization or explicit consent prior to deceased organ recovery. In order to increase the number of organs available for transplantation, some transplant community members have advocated for shifting the current donation model of deceased donor organ recovery to a model that permits deceased organ recovery without explicit consent or authorization.

5 The number was respectively: 4 080 (1988), 4 011 (1989), 4 509 (1990), 4 526 (1991), 4 520 (1992), 4 861 (1993), 5 099 (1994), 5 363 (1995), 5 418 (1996), 5 479 (1997), 5 793 (1998), 5 824 (1999), 5 985 (2000), 6 080 (2001), 6 190 (2002), 6 457 (2003), 7 150 (2004), 7 593 (2005), 8 017 (2006), 8 085 (2007), 7 989 (2008), 8 022 (2009), 7 943 (2010), 8 126 (2011), 8 143 (2012), 8 268 (2013), 8 596 (2014), 9 079 (2015), 9 970 (2016.).

6 In 1989, 1992, 2008 and 2010.

7 Between the 1st of January 2017 and the 31st March 2017, the number of deceased donors was 2 547.

8 In other years: 11 222 (1989), 12 878 (1990), 13 329 (1991), 13 563 (1992), 14 732 (1993), 15 211 (1994), 15 921 (1995), 15 983 (1996), 16 266 (1997), 16 979 (1998), 17 010 (1999), 17 335 (2000), 17 641 (2001), 18 292 (2002), 18 659 (2003), 20 049 (2004), 21 213 (2005), 22 207 (2006), 22 053 (2007), 21 746 (2008), 21 850 (2009), 22 101 (2010), 22 518 (2011), 22 187 (2012), 22 967 (2013), 23 720 (2014), 24 985 (2015), 27 630 (2016).

9 From 15 029 people in 1988 to over 118 000 currently.

10 As of 15 April 2017, at 18:28 (the list is updated on an ongoing basis).

11 Candidates who are currently eligible for a transplant and are entitled to receive the organ.

12 As at the end of the year.

13 Data of the OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

This article aims at answering a question whether the introduction of the above-mentioned model of organ recovery in the USA would solve systemic problems, and whether it would be ethically justified.

2. *Ex mortuo* organ donation models

Largely, legally binding solutions worldwide distinguish two general models of legally admissible *ex mortuo* organ recovery. The first one assumes that society has a legitimate interest in recovering organs from the deceased and may recover them without any form of permission or authorization from the interested individual (or the surrogate decision maker). In this model, social needs prevail over the rights of individuals¹⁴. It is defined as “deceased organ recovery without explicit consent or authorization”¹⁵, “presumed consent”¹⁶, or “opt-out”¹⁷. The Polish literature sometimes defines this model as the French one – requiring explicit exclusion of consent for organ recovery¹⁸.

The second model assumes that organs belong to an individual and cannot be appropriated without his or her explicit consent or authorization (or authorization of the surrogate decision maker). This model, defined as “the donation model”¹⁹, is currently binding in the USA. The domestic literature calls it the American-Canadian model²⁰ whereas the consent for organ recovery may be expressed in a written or spoken form in the presence of witnesses (opting in system) while presumed consent

14 Ethics..., *op. cit.*

15 In the opinion of the Ethics Committee OPTN / UNOS, this is the most appropriate term, see: Ethics of deceased organ donor recovery without requirement of explicit consent or authorization, White Paper, OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

16 E.g. A. Rithalia, C. McDaid, S. Suekarran, Impact of presumed consent for organ donation on donation rates: a systematic review, “BMJ” 2009, No. 338, a3162; R. Veatch, L. Ross, Chapter 10: Routine Salvaging and Presumed Consent (in:) Transplantation Ethic, 2nd ed., Washington DC: Georgetown University Press 2015, p. 147 and following; A. Abadie, S. Gray, The impact of presumed consent legislation on cadaveric organ donation: A cross-country study, “Journal of Health Economics” 2006, No. 25 (4), p. 599 and following.

17 Eg. L. Shepherd, R. O'Carroll, E. Ferguson, An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study, “BMC Medicine” 2014, No. 12 (131), p. 1 and following; C. Rudge, E. Buggins, How to increase organ donation: Does opting out have a role?, “Transplantation” 2012, No. 93 (2), p. 141 and following.

18 See eg.: E. Guzik-Makaruk, Transplantacja organów tkanek i komórek w ujęciu prawnym i kryminologicznym. Studium prawnoporównawcze, Białystok 2008, p. 34; G. Rejman, Zgoda na pobranie organu, narządu lub tkanek ze zwłok jako okoliczność uchylająca bezprawność czynu, “Studia Iuridica” 1991, t. 19, p. 167.

19 Ethics..., *op. cit.*

20 See eg.: E. Guzik-Makaruk, Transplantacja..., *op. cit.*, p. 34.

for organ recovery (opting out system) may be abolished determining that the deceased person objected to it before death²¹.

3. *Ex mortuo* organ donation model in the USA

The US “donation model” is based on the moral priority of an individual²² and a legal assumption according to which individuals have a “quasi-property right” to their bodies (including their organs). It gives them a right of certain kinds of control, without implying an ownership right to buy or sell body parts²³. The society must respect the right of an individual to dispose of their own organs. An individual (or in some case their authorized agents) may donate (as a gift) their body or parts thereof²⁴.

Ex mortuo organ recovery is regulated by the Uniform Anatomical Gift Act – UAGA, amended in 2006²⁵. The Act aims, among others, at establishing a system that honours and respects the right of an individual to donate their organs and strengthen the right of an individual to refuse to donate their organs by prohibiting others from overriding an individual’s wish not to donate organs. The substantive and objective scope of the Act is limited to the recovery of tissue and organs from the deceased donors, consent for donation, changing a relevant declaration of will, and withholding or refusing donation.

Pursuant to Art. 4 of the Act, an anatomical gift of a donor’s body or part²⁶ may be made during the life of the donor for the purpose of transplantation, therapy, research, or education. Such consent can be made by the donor (if he or she is an adult, emancipated minor²⁷, or a minor authorized under state law to apply for a driver’s license), an agent of the donor (unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift), a parent of the donor (if the donor is an unemancipated minor) and the donor’s guardian.

21 *Ibidem*, p. 34; E. Zielińska, Transplantacja w świetle prawa w Polsce i na świecie, “Państwo i Prawo” 1995, No. 6, p. 24.

22 P. Ramsey, *The Patient as Person: Explorations in medical ethics*, New Haven, Connecticut 1970.

23 Organ trade is forbidden by the National Organ Transplant Act – NOTA of 1984. According to. 301(a) it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. According to art. 301(b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both. Organ trade is also forbidden according to art. 16 Uniform Anatomical Gift Act – UAGA of 2006.

24 Ethics..., *op. cit.*

25 See more: Anatomical Gift Act (2006) Summary, available at the web page of the *Uniform Law Commission* at: www.uniformlaws.org (accessed: 26 April 2017).

26 “Part” means an organ, an eye, or tissue of a human being (art. 2(18)).

27 Minors who are self-dependent and not under parental control; usually pursuant to a court order, B. Garner (ed.), *Black’s Law Dictionary*, 10th ed., Thomson Reuters, 2014, p. 1147.

A donor may make an anatomical gift: by authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor's driver's license or identification card; in a will; during a terminal illness or injury of the donor, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness. A donor (or other person authorized to make an anatomical gift) may make a gift by a donor card or other record signed by the donor (or other person making the gift); or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry (Art. 5). A donor (or other person authorized to make an anatomical gift) may amend or revoke an anatomical gift (Art. 6). An individual may refuse to make an anatomical gift of the individual's body or part by: a record signed by the individual (or another individual acting at the direction of the individual if the individual is physically unable to sign); the individual's will, whether or not the will is admitted to probate or invalidated after the individual's death; or any form of communication made by the individual during the individual's terminal illness or injury addressed to at least two adults, at least one of whom is a disinterested witness (Art. 7).

The Act envisages preclusive effect of anatomical gift, amendment, or revocation (Art. 8). In the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor's body or part if the donor

made an anatomical gift of the donor's body or part or an amendment to an anatomical gift of the donor's body or part. In the absence of an express, contrary indication by the donor (or other person authorized to make an anatomical gift), an anatomical gift of a part is neither a refusal to give another part nor a limitation on the making of an anatomical gift of another part at a later time by the donor or another person. However, if a donor who is an unemancipated minor dies, a parent of the donor who is reasonably available²⁸ may revoke or amend an anatomical gift of the donor's body or part. Similar to this, if an unemancipated minor who signed a refusal dies, a parent of the minor who is reasonably available may revoke the minor's refusal.

An anatomical gift of a decedent's body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons (who is reasonably available), in the order of priority listed: an agent of the decedent at the time of death; the spouse of the decedent; adult children of the decedent; parents of the decedent; an adult who exhibited special care and concern for the decedent; the persons who were acting as the guardians of the person of the decedent at the time of death; and any other person having the authority to dispose

28 "Reasonably available" means able to be contacted by a procurement organization without undue effort and willing and able to act in a timely manner consistent with existing medical criteria necessary for giving a whole or a part of a human body (anatomical gift), Legal Glossary, available at: www.oregonlaws.org (accessed: 26 April 2017).

of the decedent's body (Art. 9). A person authorized to make an anatomical gift may make an anatomical gift by a document of gift signed by the person making the gift or by that person's oral communication that is electronically recorded or is contemporaneously reduced to a record and signed by the individual receiving the oral communication (Art. 10).

4. The postulate to introduce the model of *ex mortuo* organ recovery without explicit consent or authorization

Dukeminier and Sanders first proposed the model of "deceased organ recovery without explicit consent or authorization" in the US as early as in 1968²⁹, and it currently remains under debate³⁰. Some members of the transplant community are for the adoption of this model as it could increase a number of *ex mortuo* organs available for transplantation. In June 1993, Presumed Consent Sub-Committee of OPTN³¹ Ethics Committee/UNOS³² drafted White Paper containing ethical evaluation of presumed consent for organ recovery³³. It expressed an opinion saying that the reform of the process of organ donation should not be based on the model of presumed consent because from the ethical perspective, presumed consent does not sufficiently protect individual autonomy of potential donors. However, in effect of the White Papers' revision commenced in 2014, the document of 1993 was found outdated. For this reason, in December 2016 a new White Paper was drafted titled Ethics of *Ex Mortuo* Organ Recovery without Required Explicit Consent or Authorization³⁴, which analyzed this model of organ donation and a potential possibility of its adoption in the USA.

29 J. Dukeminier, D. Sanders, Organ transplantation: a proposal for routine salvaging of cadaver organs, "The New England Journal of Medicine" 1968, No. 279 (8), p. 413 and following.

30 See e.g.: R. Veatch, L. Ross, *op. cit.*; K. Healy, Do presumed consent laws raise organ procurement rates?, "De-Paul Law Review" 2005-2006, No. 55, p. 1017 and following.

31 Organ Procurement and Transplantation Network – OPTN – established under NOTA of 1984; supports and monitors a fair organ allocation system for transplants; keeps a list of candidates for the recipient; combines candidates for the recipient with organ donors; enables effective and efficient placement of organs for transplantation; takes measures to increase organ donation; see more on the official web page at: www.optn.transplant.hrsa.gov (accessed: 26 April 2017).

32 United Network for Organ Sharing – UNOS – a private non-profit organization that manages the national transplant system on the basis of an agreement with the federal government; connects patients, donor families and transplant professionals to create a fair organ allocation system; see more on the official web page at: www.unos.org (accessed: 26 April 2017).

33 An Evaluation of the Ethics of Presumed Consent, A Report of the Presumed Consent Subcommittee of the Ethics Committee (June 1993), document available on the official web page of the OPTN at: www.optn.transplant.hrsa.gov (accessed: 26 April 2017).

34 Ethics, *op. cit.*

This model is usually justified either by supreme public interest (defined as common good) in relation to the individual's choice, or "presumed" consent of the deceased. Its proponents assume that the needs and rights of an individual are subordinated to public needs and interests (common good). The State is authorized to recover organs from the deceased without explicit consent or authorization just to benefit the overall needs of society and to prevent additional deaths due to organ failure. The law in many countries of South Europe, Scandinavia and Asia allow for the recovery of organs from the deceased that generally stand in this tradition.

In the USA, although this model is not allowed for deceased organ recovery, the ethical justification is applied to other practices in health care, e.g. medical examiners are authorized to carry out autopsy of the deceased who died in unexplained circumstances without requiring consent or permission by the deceased person's family. This practice is justified by the prevalence of public health and safety over the interests of a deceased individual.

The law of some countries, mainly South American, including Argentina, Chile, Ecuador, Uruguay, Panama and Venezuela as well as Wales, explicitly refers to a "presumption of consent" and allow *ex mortuo* organ recovery without explicit consent or authorization. Presumed consent means that the deceased would consent if asked. Ethical justification for this model is placed on respecting the rights of the individual while prioritizing public health.

Although many scholarly work and the laws in some of these countries use the terminology of "presumed consent" to represent the model of *ex mortuo* organ recovery, several members of the OPTN/UNOS Ethics Committee argue that this terminology is inaccurate³⁵. Presuming consent rests on the moral premise that consent justifies an invasion of an individual to support the public's health that would otherwise be a violation of a moral right of the individual not to be touched. The ethical justification for this model requires empirical evidence demonstrating that most citizens of the particular country would consent if they were asked and had the ability to do so.

However, most countries with the presumed consent model have a significant minority of citizens who would not consent if asked³⁴. The national rate of authorization for eligible donors in the United States is approximately 75%³⁶. Therefore, justifying deceased organ and tissue recovery based on the "presumption of consent" appears to be flawed.

Furthermore, presumed consent is justified in other clinical contexts in the USA because some medical procedures rely on the presumption of informed consent, e.g. unconscious patients brought to an emergency room are treated without explicit

35 See: R. Veatch, L. Ross, *op. cit.*, p. 147 and following.

36 Data on Donation and Transplantation, Association of Organ Procurement Organizations, available at: www.aopo.org (accessed: 26 April 2017).

consent by relying on the legal notion of presuming consent, acknowledging that virtually everyone would consent to life saving treatment if they could be asked. Nevertheless, the concept of presumption remains morally controversial because if the presumption is wrong, an essential right of the patient is violated. In practice, however, only in rare cases patients brought to an emergency department would refuse treatment if only they could do so. This raises the question of how confident society must be in believing that the patient would consent if he or she could do so. Since a mistaken presumed consent involves violating an essential right of the patient, the ethical claim is that we must be very confident that the great majority of patients would consent. This is not empirically demonstrated when considering consent rates to organ donation³⁷.

Ex mortuo organ recovery without explicit consent or authorization may or may not include an opt-out option. The hard approach excludes an opt-out option, whereas the “soft” approach allows an individual (or the surrogate decision maker) to explicitly prohibit the state from recovering the individual’s organs³⁸. The majority of countries that have laws permitting deceased organ recovery without explicit consent or authorization allow the individual (or the surrogate decision maker) to opt-out in practice, even if the law does not explicitly describe the “opt-out” option³⁹.

Arguments contained in the White Paper supporting the adoption of the model without explicit consent or authorization *inter alia* depict that the USA adopt many regulations that restrict the rights of individuals in order to protect public health and safety (e.g. seatbelts and helmets laws). Furthermore, due to the fact that end-stage organ disease has become an epidemic (at least for kidneys), the rights of the individual could be restricted to fight this epidemic by increasing the number of organs for transplantation.

The literature demonstrates an association between higher organ recovery rates among countries that allow deceased organ recovery without explicit consent (by app. 25%-30%⁴⁰) when compared with countries that require explicit consent or authorization⁴¹. However, the above data must be interpreted within the broader socio-cultural context of the transplant system as each country’s government devotes

37 2012 National Survey of Organ Donation Attitudes and Behaviors, September 2013, U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Rockville, Maryland: U.S. Department of Health and Human Services.

38 C. Simillis, Do we need to change the legislation to a system of presumed consent to address organ shortage?, “Medicine, Science and the Law” 2010, No. 50 (2), p. 84 and following.

39 J. Fabre, Presumed consent for organ donation: a clinically unnecessary and corrupting influence in medicine and politics, “Clinical Medicine” 2014, No. 14 (6), p. 567 and following.

40 B. Boyarsky, E. Hall, N. Deshpande, Potential limitations of presumed consent legislation, “Transplantation” 2012, No. 93 (2), p. 136 and following.

41 See e.g.: A. Rithalia, C. McDaid, S. Suekarran, *op. cit.*, a3162; L. Shepherd, R. O’Carroll, E. Ferguson, *op. cit.*, p. 1 and following.

different resources and holds different cultural expectations of its citizens toward donation initiatives. Both models of *ex mortuo* organ recovery differ considerably in the practice of individual countries (e.g. some countries that do not require explicit consent or authorization require surrogate consent or allow for opt-out options while others do not)⁴².

Arguments against the adoption of the model of organ recovery without explicit consent or authorization in the USA *inter alia* depict the existence of many barriers (including legal, empirical and cultural) as well as factors connected with the transplant system due to which it would be extremely difficult to change the present model of donation. Such a process would require legislative initiative in a federal level, which could lead to legal (or even constitutional) torts. What is more, from a US cultural perspective, individual rights are deeply embedded in values and beliefs. Individualism is a key feature of American culture. The model of *ex mortuo* organ recovery that does not require explicit consent would not gain sufficient support to justify its adoption⁴³. Thus, in the USA, where individual rights are treated as a priority, organ recovery without explicit consent or authorization is unlikely to be embraced by the entire society.

Furthermore, it has been argued that if the adoption of the model of *ex mortuo* organ recovery without explicit consent or authorization causes a negative social attitude to organ donation (especially among individuals who would have previously agreed to donation), a number of organs recovered from the deceased might have increased only insignificantly (if at all).

It is argued that the introduction of an opt-out provision may reduce the risk of erroneously presumed consent. At the same time, any opt-out system that does not adequately inform US citizens of their right to opt out would be subject to legal challenge. It is alleged that the opt-out provision would not be sufficient to justify presumed consent. It would violate the rights of citizens to an unacceptable degree.

Ethnic minorities and socioeconomic groups that are underserved or marginalized have disproportionally lower rates of transplantation for all types of organs⁴⁴. At the same time, many of those groups have higher rates of risk factors that generate the need for organ transplantation. Various factors contribute to this, which can be divided into three broad groups: biological (such as higher prevalence of obesity or of immunological factors common to them but less common in the majority population⁴⁵); issues of the health care system (such as delayed average time before assessment for kidney transplantation for some minority patients or disparate

42 J. Fabre, *op. cit.*, p. 567 and following.

43 2012 National Survey of Organ Donation Attitudes and Behaviors, *op. cit.*

44 Data of the OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

45 G. Switzer, J. Bruce, L. Myaskovsky, Race and ethnicity in decisions about unrelated hematopoietic stem cell donation, "Blood" 2013, No. 121 (8), p. 1469 and following.

rates of living kidney donation⁴⁶); and issues related to lack of sufficient knowledge, and cultural values and behaviours of the groups themselves (such as a lower willingness to do living or deceased organ donation⁴⁷).

Studies devoted to *ex mortuo* donation among ethnic minorities and marginalized socioeconomic groups revealed a high level of distrust of the health care system and organ donation itself⁴⁸. Respondents of qualitative research frequently feared that if presumed consent existed, doctors will not do all they can to save them while donated organs will not be used to benefit them (e.g. people in the same minority group)⁴⁹. Such beliefs are the effect of long histories of discrimination of those groups in the healthcare system whereas the adoption of a model not requiring explicit consent would most likely only strengthen the above convictions.

For this reason, instead of feeding mistrust in the transplant system by focusing on the adoption of a model of *ex mortuo* organs recovery without explicit consent, it is postulated to intensify informative actions targeted at diverse ethnic and socioeconomic groups, and highlight the value of donation and transplantation. Such actions may eventually decrease disparities and increase donation rates in these populations.

Even though it has been emphasized that an increase of a total number of organ transplantations remains a priority, it is uncertain whether a change of the current US donation model to a model that does not require explicit consent or authorization would actually improve rates of organ recovery and transplantation.

46 C. Norris, L. Agodoa, Reducing Disparities in Assessment for Kidney Transplantation, "Clinical Journal of the American Society of Nephrology" 2012, No. 7 (9), p. 1378 and following; P. Reese, M. Nair, R. Bloom, Eliminating racial disparities in access to living donor kidney transplantation; how can centers do better?, "American Journal of Kidney Diseases" 2012, No. 59 (6), p. 751 and following.

47 See e.g.: C. Breitkopf, Attitudes, beliefs and behaviors surrounding organ donation among Hispanic women, "Current Opinion in Organ Transplantation" 2009, No. 14 (2), p. 191-195; E. Gordon, Patients' decisions for treatment of end-stage renal disease and their implications for access to transplantation, "Social Science & Medicine" 2001, No. 53 (8), p. 971 and following; E. Gordon, J. Mullee, D. Ramirez, U.S. Hispanic/Latino concerns about living kidney donation: a focus group study, "Progress in Transplantation" 2014, No. 24 (2), p. 152 and following.

48 M. Irving, A. Tong, S. Jan, Factors that influence the decision to be an organ donor: a systematic review of the qualitative literature, "Nephrology Dialysis Transplantation" 2012, No. 27 (6), p. 2526 and following.

49 See more: S. Davison, S. Jhangri, Knowledge and attitudes of Canadian First Nations people toward organ donation and transplantation: a quantitative and qualitative analysis, "American Journal of Kidney Diseases" 2014, No. 64 (5) p. 781 and following; M. Morgan, C. Kenten, P. Deedat, Donate Programme Team. Attitudes to deceased organ donation and registration as a donor among minority ethnic groups in North America and the UK: a synthesis of quantitative and qualitative research, "Ethnicity & Health" 2013, No. 18 (4), p. 367 and following.

5. Alternative opportunities to increase deceased organ supply for transplantation

The OPTN/UNOS Ethics Committee⁵⁰ believes that there are alternative opportunities to increase number of organs recovered from the deceased. An actual number of recovered organs and successful transplantations could be increased by, e.g., the implementation of comprehensive strategies to improve the system of organ recovery and transplantation. It is postulated to increase public awareness and education, expand federal support, or develop advanced technologies and expertise in the field of organ recovery, preservation and transplantation.

It has been pointed out that strategies that may increase the rates of *ex mortuo* organ recovery encompass, among others, improvement of organizational aspects. People object to organ donation often in result of a lack of understanding, lack of trust, or concerns raised by the families about the process of organ recovery and transplantation. Currently in the USA 26 donors/million give their consent. Educational efforts targeted at specific populations (such as people in minority and lower socioeconomic status) brought ambiguous (mixed) results in increasing donation. While studies have shown the donation rate is not related to socioeconomic indicators, donation rates correlate with organizational improvements using culturally congruent in-hospital coordinators⁵¹.

As pointed out, it is necessary to develop methods (techniques) of securing and preserving organs as well as resuscitation techniques in order to increase survival of organs coming from expanded criteria donors.

Since Spain has the highest rate of deceased organ donation in the world (33-35 donors per million population)⁵², it is postulated to adopt some organizational factors of the Spanish system that could result in the increase of *ex mortuo* organ donation in the USA. They encompass, *inter alia*, increased political and legal support of transplant and organ procurement professionals, implementation of a comprehensive programme of education, improvement of public relations, and development of hospital reimbursement⁵³.

50 Ethics..., *op. cit.*

51 L. Siminoff, C. Saunders Sturm, African-American reluctance to donate: beliefs and attitudes about organ donation and implications for policy, "Kennedy Institute of Ethics Journal" 2000, No. 10 (1), p. 59 and following.

52 R. Metasanz, B. Domínguez-Gil, E. Coll, Spanish experience as a leading country: what kind of measures were taken?, "Transplant International" 2011, No. 24 (4), p. 333 and following; B. Borro-Escribano, I. Martínez-Alpuente, A. Blanco, Application of game-like simulations in the Spanish Transplant National Organization, "Transplantation Proceedings" 2013, No. 45 (1), p. 3564 and following.

53 D. Rodríguez Arias, L. Wright, D. Paredes, Success factors and ethical challenges of the Spanish Model of organ donation, "Lancet" 2010, No. 376, p. 1109 and following.

The Committee believes that transplantation medicine should invest in social education connected with the prevention of chronic illnesses and a decrease of end-stage organ disease.

Furthermore, attention has been drawn to the possibility of using social media to create a donor registry and increase communication with friends or families. Yet such efforts must be undertaken in a long-term perspective and they should be complementary to other promotional activities.

Some claim that financial and non-financial incentives for *ex mortuo* donation may significantly increase the rates of organ donation from the deceased. However, due to, e.g., a ban on organ trafficking, such a possibility remains ethically controversial⁵⁴.

6. Conclusion

The number of *ex vivo* and *ex mortuo* donors cannot keep pace with continuous growth of demand for organs in the USA. It is necessary to introduce changes in the current system of organ recovery and transplantation. Some members of the transplant community claim that a number of organs for transplantation may only increase in effect of the changed model of donation into the model of *ex mortuo* organ recovery without explicit consent or authorization. However, for many reasons, this argument is extensively debated.

According to the OPTN/UNOS Ethics Committee, shifting to a model of *ex mortuo* organ recovery without explicit consent or authorization in the USA is not ethically justified for the following reasons:

- 1) the donation model in the US is current public policy, embedded in a culture of individualism. Shifting this model would require extensive legal changes (and potentially constitutional) which would challenge fundamental deep-seated American cultural values;
- 2) it is highly probable that the change of a model into organ recovery without explicit consent would adversely affect the public's trust in the healthcare system, particularly by marginalized populations, potentially resulting in lower rates of organ recovery;
- 3) authorization rates for *ex mortuo* organ recovery in the USA are already high (75%). Particularly if an opt-out option is included, shifting the model would not necessarily increase the rates;

54 See e.g.: S. Satal, D. Cronin, Time to test incentives to increase organ donation, "JAMA Internal Medicine" 2015, No. 175 (8), pp.1329-1330; E. Gordon, C. Patel, M. Sohn, Does financial compensation for living kidney donation change willingness to donate?, "American Journal of Transplantation" 2015, No. 15 (1), p. 265 and following.

- 4) although empirical data suggest an association between the rates of *ex mortuo* organ recovery and models that do not require explicit consent or authorization, as far as the increase of organ recovery rates is concerned, a substantial role therein may also be played by additional factors such as public education, federal support, or efficiencies in the organ preservation and transplantation system.

As pointed out, there are many alternative opportunities to increase the rates of *ex mortuo* organ recovery which do not violate individual rights and current public policy. They include, among others, the improvement of organizational aspects, increased efficiency and efficacy of organ recovery and transplantation system, increased public awareness of organ donation through mass media campaigns, social media and national donor registries and, finally, promoting scientific advancement in the area organ recovery, preservation and transplantation techniques.

BIBLIOGRAPHY

- 2012 National Survey of Organ Donation Attitudes and Behaviors, September 2013, U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Rockville, Maryland: U.S. Department of Health and Human Services.
- Abadie A., Gray S., The impact of presumed consent legislation on cadaveric organ donation: A crosscountry study, "Journal of Health Economics" 2006, No. 25 (4).
- An Evaluation of the Ethics of Presumed Consent, A Report of the Presumed Consent Subcommittee of the Ethics Committee (June 1993), dokument dostępny na oficjalnej stronie OPTN pod adresem: www.optn.transplant.hrsa.gov (accessed: 26 April 2017).
- Anatomical Gift Act (2006) Summary, dostępne na stronie Komisji ds. Uniformizacji Prawa (Uniform Law Commission) pod adresem: www.uniformlaws.org (accessed: 26 April 2017).
- Borro-Escribano B., Martinez-Alpuente I., Blanco A., Application of game-like simulations in the Spanish Transplant National Organization, "Transplantation Proceedings" 2013, No. 45 (1).
- Boyarsky B., Hall E., Deshpande N., Potential limitations of presumed consent legislation, "Transplantation" 2012, No. 93 (2).
- Breitkopf C., Attitudes, beliefs and behaviors surrounding organ donation among Hispanic women, "Current Opinion in Organ Transplantation" 2009, No. 14 (2).
- Data on Donation and Transplantation, Association of Organ Procurement Organizations, dostępne pod adresem: www.aopo.org (accessed: 26 April 2017).
- Davison S., Jhangri S., Knowledge and attitudes of Canadian First Nations people toward organ donation and transplantation: a quantitative and qualitative analysis, "American Journal of Kidney Diseases" 2014, No. 64 (5).
- Dukeminier J., Sanders D., Organ transplantation: a proposal for routine salvaging of cadaver organs, "The New England Journal of Medicine" 1968, No. 279 (8).

- Ethics of deceased organ donor recovery without requirement of explicit consent or authorization, White Paper, OPTN, dostępna pod adresem: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).
- Fabre J., Presumed consent for organ donation: a clinically unnecessary and corrupting influence in medicine and politics, "Clinical Medicine" 2014, No. 14 (6).
- Garner B. (ed.), Black's Law Dictionary, 10th ed., Thomson Reuters, 2014.
- Gordon E., Mullee J., Ramirez D., U.S. Hispanic/Latino concerns about living kidney donation: a focus group study, "Progress in Transplantation" 2014, No. 24 (2).
- Gordon E., Patel C., Sohn M., Does financial compensation for living kidney donation change willingness to donate?, "American Journal of Transplantation" 2015, No. 15 (1).
- Gordon E., Patients' decisions for treatment of end-stage renal disease and their implications for access to transplantation, "Social Science & Medicine" 2001, No. 53 (8).
- Guzik-Makaruk E., Transplantacja organów tkanek i komórek w ujęciu prawnym i kryminologicznym. Studium prawnoporównawcze, Białystok 2008.
- Healy K., Do presumed consent laws raise organ procurement rates?, "DePaul Law Review" 2005-2006, No. 55.
- Irving M., Tong A., Jan S., Factors that influence the decision to be an organ donor: a systematic review of the qualitative literature, "Nephrology Dialysis Transplantation" 2012, No. 27 (6).
- Metasanz R., Domínguez-Gil B., Coll E., Spanish experience as a leading country: what kind of measures were taken?, "Transplant International" 2011, No. 24 (4).
- Morgan M., Kenten C., Deedat S., Donate Programme Team. Attitudes to deceased organ donation and registration as a donor among minority ethnic groups in North America and the UK: a synthesis of quantitative and qualitative research, "Ethnicity & Health" 2013, No. 18 (4).
- National Organ Transplant Act, Public Law 98-507-OCT. 19, 1984.
- Norris C., Agodoa L., Reducing Disparities in Assessment for Kidney Transplantation, "Clinical Journal of the American Society of Nephrology" 2012, No. 7 (9).
- Ramsey P., The Patient as Person: Explorations in medical ethics, New Haven, Connecticut 1970.
- Reese P., Nair M., Bloom R., Eliminating racial disparities in access to living donor kidney transplantation; how can centers do better?, "American Journal of Kidney Diseases" 2012, No. 59 (6).
- Rejman G., Zgoda na pobranie organu, narządu lub tkanek ze zwłok jako okoliczność uchylająca bezprawność czynu, "Studia Iuridica" 1991, vol. 19.
- Revised Uniform Anatomical Gift Act (2006).
- Rithalia A., McDaid C., Suekarran S., Impact of presumed consent for organ donation on donation rates: a systematic review, "BMJ" 2009, No. 338, a3162.
- Rodriguez Arias D., Wright L., Paredes D., Success factors and ethical challenges of the Spanish Model of organ donation, "Lancet" 2010, No. 376.
- Rudge C., Buggins E., How to increase organ donation: Does opting out have a role?, "Transplantation" 2012, No. 93 (2).

- Satal S., Cronin D., Time to test incentives to increase organ donation, "JAMA Internal Medicine" 2015, No. 175 (8).
- Shepherd L., O'Carroll R., Ferguson E., An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study, "BMC Medicine" 2014, No. 12(131).
- Simillis C., Do we need to change the legislation to a system of presumed consent to address organ shortage?, "Medicine, Science and the Law" 2010, No. 50 (2).
- Siminoff L., Saunders Sturm C., African-American reluctance to donate: beliefs and attitudes about organ donation and implications for policy, "Kennedy Institute of Ethics Journal" 2000, No. 10(1).
- Switzer G., Bruce J., Myaskovsky L., Race and ethnicity in decisions about unrelated hematopoietic stem cell donation, "Blood" 2013, No. 121 (8).
- Veatch R., Ross L., Chapter 10: Routine Salvaging and Presumed Consent, (in:) Transplantation Ethic, 2nd ed., Washington 2015.
- Zielińska E., Transplantacja w świetle prawa w Polsce i na świecie, "Państwo i Prawo" 1995, No. 6.