Authorisation of organ procurement — is it influential factor for the identification of potential organ donors?

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Abstract

For many years, the authorisation of organ procurement has been discussed as a contributory factor to the number of potential organ donors. This paper presents different forms of authorisation and their influence on the decisions of both individuals and society. The general legal framework for the authorisation of organ procurement in Poland is described along with the solutions implemented by countries in which both implicit and explicit consent models are in effect. The presented arguments suggest that the form of authorisation does not directly influence the number of organs procured for transplantation.

Key words: brain death, presumed consent, authorisation of organ procurement

Neurological criteria for the determination of death were established in 1968 [1]. Their adoption did not introduce any changes to the definition of death but complemented the rules and regulations then in effect regarding the pronouncement of death. In the vast majority, death is still pronounced according to circulatory criteria. In 2012 in Poland, 384,000 people died, 786 of whom were referred as potential organ donors and were therefore pronounced dead by neurological criteria [2, 3]. Pronouncing brain death should be connect with withdrawal of life-sustaining measures, which results in the cessation of circulation. The other possible procedure is to support vital functions of the body to consider organs recovery [4].

The precisely specified conditions that must be met when determining death by neurological criteria make it impossible to applied these criteria to vegetative, locked-in syndrome patients or anencephaly. Prior to the establishment of neurological criteria, the legal regulations regarding death functioned only in the context of inheritance and crime. Establishing a legal framework for organ procurement put emphasis on the uniqueness of the situation to which the new criteria applied and lent them credence.

REASONS FOR THE AUTHORISATION OF ORGAN PROCUREMENT

An organ is the sine qua non condition for transplantation. In the 1950s and 1960s, when clinical transplantology was still in its early stages of development, main source of organs were donors after irreversible cessation of circulatory function. The establishment of neurological criteria for determining death resulted in an unprecedented situation wherein medical doctors became legally entitled to take organs from donors in whom circulation was maintained. This led transplantation medicine to become the main beneficiary of the new criteria.

Consequently, a new piece of legislation, the Uniform Anatomical Gift Act, was promulgated in the United States of America. The act provided adults the right to donate organs/body after death and that it was legally binding. The 1987 amendment to the original act specifies more precisely that authorisation is in effect even if the donor’s family wish to revoke the gift [5].

FORMS OF AUTHORISATION OF ORGAN PROCUREMENT

Medical activity in general is based on the informed consent of the patient for any medical related action. When translated into the language of the market economy, the consent becomes a type of contract between the doctor and the patient. The moment of determining whether to take organs from a potential donor is highly demanding with regard to the authorisation of medical staff activity. The necessary characteristics of ethically unquestionable con-
sent for organ donation include: self-awareness, freedom of will, processing in-depth information on becoming a donor, sufficient time for decision making, and the possibility to reconsider and change the previously taken decision. In the following, the word authorisation is substituted for the word consent. The word consent presupposes acceptance of a certain state of affairs. In the case of organ procurement, arriving at a decision is not always linked to giving consent for action.

Voluntary, explicit, express, informed, and opt-in consent are all terms that are used to refer to an active form of will for organ donation after death for transplantation purposes either through signing a formal declaration or registering in the organ donor registry. In the USA, the legislature assumed that the most appropriate form of authorisation of organ procurement would be explicit consent. This term, in Anglo-Saxon terminology, is also known as first-person consent.

In the USA, the legal requirements for obtaining authorisation stem from a high degree of respect for civil rights such as civil liberty and sovereignty. According to the Uniform Anatomical Gift Act, which was passed by all states of America, every citizen is entitled to be volunteer for organ donation. The authorisation for organ donation does not require obtaining affirmation from a third party. Depending on the place of residence (state), authorisation can be granted by potential donors in one of the three ways: completing the donation section on the application for a driver’s license, signing a donor card, or registering in the electronic organ donor registry. In the case of a lack of information regarding the deceased person’s wish to become a donor, the next of kin after death of individual is informed about possibility to donate organs for transplantation. According to US statistics, approximately 50% of interviewed families grant authorisation for organ procurement [6, 7].

CONSEQUENCES FOR THE INDIVIDUAL AND SOCIETY

Informed consent seems to be the most appropriate way of conveying information on what happens to the decedent’s body. Inherent to every individual, human dignity together with the right to self-determination and autonomy in the decision-making process grant the possibility to use those rights in active authorisation of organ donation (e.g., in the act of sign the donor card). The phrase used above, “seems to be”, was purposely chosen to reflect the experience of countries where explicit consent has been in effect and where it is deemed responsible for low procurement rates. The examples of the United States of America and Great Britain clearly show how difficult it is to make decisions with regard to the authorisation of organ recovery. Despite social education programmes, electronic organ donor registries and community campaigns targeted at various ethnic groups, the authorisation of organ procurement is still a less than popular act of self-determination. Only approximately 30% of American citizens have actively decided to donate organs for transplantation after death. Does this fact conclusively prove that there exists a lack of social approval of transplantation?

In the USA, approximately 40% of transplanted kidneys from a living donors. Such a high proportion of recipients receiving a kidney from related or unrelated persons signifies that this therapeutic procedure is commonly accepted and, more importantly, that there exist good human relationships. By comparison, this proportion is only approximately 5% in Poland [8]. The reasons behind this situation vary from prosaic ones (e.g., lack of time) through ignorance (e.g., authorisation of organ procurement does not apply to me), to the abstractness of the notion of death.

The necessity to reflect on the end of life is the main reason why organ donor declaration forms are not usually filled in and submitted. In the likely case of the lack of legally binding consent, it is the family who make the decision of whether to donate organs. Some families permit organ procurement and view this act as consistent with the beliefs and will of their next of kin. Holland is one example of a European country where voluntary, explicit consent is in effect. Dramatically different from the USA in terms of both territory and population, as a postcolonial country it is also multicultural. In Holland, exists an organ donor registry with opt-in and opt-out for organ donation or indicate relatives who are to make the decision for them. School education (targeted at high school students) and media campaigns are the two core elements used to promote transplant knowledge. The Dutch authorisation system has managed to achieve model solutions. However, despite all of the factors enumerated above that positively influence the process of decision making, the system still falls short of active authorisation. Since the establishment of the register in 1998, despite increased educational efforts, the number of submitted declarations has been decreasing.

A positive correlation between campaigns promoting organ donation and the number of procured organs has been demonstrated. The authors of a study analysing the lack of informed consent state that this tendency has been triggered by a factor that is difficult to define [9]. One possible explanation for the above-described situation may be found in the works of psychologists who examine human behaviour in the decision-making process. Researchers argue that crucial decisions made under pressure result in opting for the alternatives that provide a sense of security and psychological comfort. Such decisions are dictated by minimisation of psychological discomfort without having to state one’s. In the context of consent for organ donation and different forms of authorisation might lead to no choice option [10].
DEcision autonomy

The assumptions on which direct consent is based are correct in that they are consistent with the democratic tradition and ethical foundations of personalism. According to Beauchamp and Childress, the key representatives of this approach, authorisation should fulfil crucial requirements. The basis for the act of explicit choice is the respect for the decisions of the individual who has the necessary knowledge for making them in accordance with their moral values, beliefs and preferences. Acquiring knowledge about donation and transplantation purposes (by discussing and considering different options), understanding the differences between these options, freedom of choice (arriving at the decision without controlling influences), and the possibility to communicate one’s will are all necessary for autonomous expression of preference [11]. In social communication the term explicit choice should be used with regard to donating organs for transplantation. It stems from the fact that the disposition of one’s bodily remains goes beyond earthly life and that it is not in any way connected to the activities which influence our existence and its quality [12].

Individual choice and autonomous expression of will regarding the posthumous disposition of one’s organs made by the decedent before death are deemed especially significant when we realise the difficult situation of the decedent’s family when faced with loss of loved one and the decision of whether to give or withhold permission for donation. Cohen described good characteristic of this situation: “we ask the wrong persons, at the worst possible time, what they should never have been asked at all” [13].

implicit, presumed, opt-out consent

Theoretical assumptions underlying the definition of presumed consent are clear. After death, every individual becomes a potential tissue and/or organ donor unless he or she explicitly decided otherwise while alive. Assuming that in absence of refusal, decedent automatically become donor is the literal interpretation of this definition. Depending on the means of execution, the following forms of presumed consent have been identified:

“routine removal policy”

Presumption of this option means that appointed authorities are entitled by law to recover tissues and/or organs from every deceased person. It is based on the premise that, after death, the authority over the cadaver rests with society, which has every right to use it. Decisions made by individuals or their families are not taken into consideration, as the only appropriate conduct is to take action for society’s good.

“strong presumed consent”

This form is in accordance with the above-quoted definition of presumed consent. The decision to retrieve organs is announced but not consult with the family. Existence of refusal is tantamount to refraining from organ procurement, which does not rule out the pronouncement of death by neurological criteria. In Poland, the Central Registry of Refusals operates within Poltransplant, a government agency responsible for supervising organ procurement and transplantation.

“weak presumed consent”

In case of absent individual refusal, this form of authorisation involve consult with the family members whom may make decision to not donate. The decision is respected by medical staff. It is important to note that the families are not asked for consent but rather expected to reliably reflect the wishes of the decedents. This form of presuming is preferred in the majority of countries where presumed consent is active by law.

“tacit consent” [14]

A lack of express refusal may be interpreted as a form of silent consent for organ procurement and transplantation. Such an interpretation of missing authorisation was proposed by the authorities in charge of transplantation procedures in Holland. The regulation entailed double-checking with the potential donor whether he or she had any objections to the donation of organs. If the person does not send back a binding answer, one would be registered as a potential donor (the regulation was rejected by the Dutch Parliament in 2005).

consequences for the individual and society

Routine removal policy, in its simplicity and lack of respect for the fundamental values of the person, is out of the scope of what is currently considered acceptable. The remaining interpretations of this form of authorisation should be applied in no other circumstances than when a potential donor is aware of his or her right to register refusal. This means that every citizen should be informed about the available opportunity to sign in will in existed register. In sum, only when conditions such as having the knowledge necessary to make informed decisions as well as having opportunity to register and change those decision during life are met may it be assumed that a particular register contains data from people who do not wish to have their organs removed after death.

The proponents of presumed consent state that lack of refusal is permission for organ donation. Is this presumption
correct? Is it true that people who did not opt-out, granted permission? Is a lack of presumed consent equal to consent for organ procurement? The answer is yes but when the aforementioned conditions are fulfilled, it is justified to consider tacit consent.

In Poland, support for organ transplantation and willingness to donate were shown to be strong and widespread. Over the last ten years, the percentage of people expressing positive attitude towards organ donation has grown to more than 80% [15].

In the USA, proponents of presumed consent view this policy as the opportunity to most fully realise most persons wishes concerning the disposition after death in a less demanding manner than explicit consent [16]. However, an organ procurement system founded upon presumed consent poses serious moral questions such as: Is it fair to assume that “removing organs from the bodies of people who did not want them removed” and “not removing organs from the bodies of people who did want them removed” are equally morally bad? Those who oppose presumed consent argue that disregarding the right to bodily integrity violates the autonomy of people who have failed to indicate their will [17]. This discussion takes on a new significance in the context of healthcare in the USA. The current health insurance system provides approximately 50 million of American citizens without access to transplantation procedures [18]. Consequently, applying the principle of social equality for funds sufficient to cover highly specialised long-term treatment. At the same time, it allows for autonomous decisions on whether to register one's presumed consent. As a result, in 1996, citizens gained the opportunity to express their will by registering their refusal for organ donation. This situation does not apply to Poland or other European countries.

In Poland, every insured person, irrespective of material status, is entitled to receive a transplant in the case of organ failure as well as post-transplant treatment. However, it should be emphasised that undergoing a transplant surgery is just the beginning of treatment. To classify transplant as a good outcome we must ensure that, the recipient must have proper conditions for long life expectancy. In the United States, a potential transplant recipient is scanned for funds sufficient to cover highly specialised long-term care and treatment expenses.

**DECISION AUTONOMY**

Presuming consent can be considered the morally driven pattern of social behaviour based on solidarity, altruism, and social voluntarism. At the same time, it allows for autonomous decisions on whether to register one's presumed consent.

Opponents of implicit consent suggest that such presumption deprives person possibility for decisive gesture which is genuine act of love in the form of explicit consent [19]. Is opt-out less valuable in its generosity than opt-in? Dispelling all doubts regarding presumed consent and determining whether it really is the best realisation of human autonomy directs us towards an in-depth socio-philosophical discussion.

**AUTHORISATION OF ORGAN PROCUREMENT IN POLAND**

The first legal regulations concerning beneficent transplantation of organs in Poland date to 1949. At the beginning of the 1950s, organ transplants were considered as an experimental method of treatment. That is why medical records from that period only contain descriptions of tissue procurement procedures. Section from first act regulated organ/tissue recovery stated “the decedent’s family had no right to express or withhold permission for cadaveric tissue procurement for therapeutic or scientific purposes”.

The state was the only rightful owner of the cadaver entitled to granting permission for tissue/organ recovery. This regulation was in effect until 1994. At the beginning of the 1990s, when transplant procedures became the standard, the decision to procure organs was made by the head of the clinic no later than 12 hours after the determination of death. At that time, all ethical and legal issues were dealt with by doctors as no statutory regulations on the transplantation of organs existed. Death was pronounced in accordance with the *primum non nocere* concept and to the best of the doctors’ knowledge. The above-quoted article was consistent with both the criteria of utilitarian norms and the legislation adopted in Poland after 1945. The right of an individual to self-determination was not enforced. Ensuring legal amendments introduced the system of presumed consent. As a result, in 1996, citizens gained the opportunity to express their will by registering their refusal for organ donation in the Central Registry of Refusals [20]. The form of authorisation currently in effect in Poland is the strong form of presumed consent, however, the weak form is in practice. Although seeking the decedent’s family’s consent is not obligatory, without it organs are not procured. From the legislator’s perspective, adopting the system of presumed consent was the simplest way to introduce standards similar to those introduced in civilised countries. Nevertheless, up until 2007, this change was viewed as an example of legal positivism in the service of transplantology.

During the legislative process, before the new transplantation law was passed, lawyers emphasised that “in the face of relatively low legal consciousness of our society, the requirement for presumed consent seemed to remain largely fictional and as such it would have to provoke serious conflicts with the decedent’s family” [21]. Guided by intuition and legally bound by the Code of Medical Ethics to act with respect to human dignity, physicians routinely initiate a discuss with the relatives about organ donation.
**Table 1. Deceased donors per million population (pmp) in different regions of Poland**

<table>
<thead>
<tr>
<th>Region</th>
<th>2000</th>
<th>2007*</th>
<th>2008*</th>
<th>2013</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Północnopomorskie</td>
<td>27.7</td>
<td>31.9</td>
<td>40.8</td>
<td>25.9</td>
<td>31.5</td>
</tr>
<tr>
<td>Wielkopolskie</td>
<td>17.4</td>
<td>16.9</td>
<td>25.5</td>
<td>26</td>
<td>21.4</td>
</tr>
<tr>
<td>Pomorskie</td>
<td>11.5</td>
<td>13.1</td>
<td>13.6</td>
<td>25.2</td>
<td>15.8</td>
</tr>
<tr>
<td>Opolskie</td>
<td>22.9</td>
<td>2.5</td>
<td>15.4</td>
<td>19</td>
<td>14.9</td>
</tr>
<tr>
<td>Mazowieckie</td>
<td>15</td>
<td>8.7</td>
<td>10.5</td>
<td>13.4</td>
<td>11.9</td>
</tr>
<tr>
<td>Lubuskie</td>
<td>14.7</td>
<td>8</td>
<td>8</td>
<td>14</td>
<td>11.0</td>
</tr>
<tr>
<td>Dolnośląskie</td>
<td>18.1</td>
<td>6.5</td>
<td>10.6</td>
<td>9.3</td>
<td>11.0</td>
</tr>
<tr>
<td>Warmińsko-mazurskie</td>
<td>3</td>
<td>7.6</td>
<td>14.1</td>
<td>19.3</td>
<td>11</td>
</tr>
<tr>
<td>Śląskie</td>
<td>8.8</td>
<td>8.6</td>
<td>8.2</td>
<td>17</td>
<td>10.6</td>
</tr>
<tr>
<td>Łódzkie</td>
<td>11.2</td>
<td>7</td>
<td>9.4</td>
<td>11.6</td>
<td>9.8</td>
</tr>
<tr>
<td>Kujawsko-pomorskie</td>
<td>2.9</td>
<td>12.6</td>
<td>13.3</td>
<td>10</td>
<td>9.7</td>
</tr>
<tr>
<td>Podlaskie</td>
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<td>7.6</td>
<td>7.6</td>
<td>14.3</td>
<td>8.6</td>
</tr>
<tr>
<td>Lubelskie</td>
<td>2.2</td>
<td>4.6</td>
<td>8</td>
<td>10</td>
<td>6.2</td>
</tr>
<tr>
<td>Świętokrzyskie</td>
<td>0</td>
<td>0.8</td>
<td>4.7</td>
<td>12.3</td>
<td>4.45</td>
</tr>
<tr>
<td>Małopolskie</td>
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<td>0.9</td>
<td>0.6</td>
<td>11.8</td>
<td>4.1</td>
</tr>
<tr>
<td>Podkarpackie</td>
<td>1.9</td>
<td>0.9</td>
<td>2.4</td>
<td>9.5</td>
<td>3.7</td>
</tr>
<tr>
<td><strong>Poland</strong></td>
<td><strong>10.6</strong>*</td>
<td><strong>9.2</strong></td>
<td><strong>11.2</strong></td>
<td><strong>15.4</strong></td>
<td><strong>11.9</strong></td>
</tr>
</tbody>
</table>

*Junction points: 2007 is the lowest index point. 2008 brought the introduction of systemic solutions

**DOES THE FORM OF AUTHORISATION INFLUENCE THE NUMBER OF ORGANS PROCURED?**

Great Britain is a country where the introduction of presumed consent has been proposed for many years and is considered a way to reduce the disproportion between the number of those awaiting transplantation and the number of organ donors [22, 23]. The main assumption behind this demand is that, if presumed consent were operative, the lack of refusal would very probably lead to a situation in which people become donors more frequently than is the case with explicit consent. From a purely legal point of view, this is true; however, it does not translate into practice or affect the number of organs available for transplantation. A good example to support this claim is the situation in Poland. Despite legal solutions that allow organ recovery from any person who did not opt-out, for many years significant disparities between Poland’s provinces have been observed with regard to the number of donors per million population (pmp). Characteristic feature is the progressing decreasing index of donor identification from the west to the east of the country (Table 1). This pmp rate is not related to population density, the degree of industrialisation, the distribution of hospitals or the number of intensive care beds. A similar tendency is displayed by countries in which presumed consent is in effect [24]. The main differentiation factor is the degree of engagement of medical staff in the transplantation process and especially in organ donor identification. In West Pomeranian Province, ever since transplantation teams began to operate, that is, since the 1990s, medical staff working in anaesthesiology, intensive care, neurology, and neurosurgery departments have been supported in the pursuit of continuing education. Regularly organised courses in donor identification and care consolidated the standards of conduct in anaesthesiology and intensive care departments. The first transplant coordinator position was appointed in the Regional Hospital in Szczecin. An equally important factor was wherewithal that would be distributed to the donor’s hospital and the medical staff responsible for donor identification and care as remuneration for above-standard efforts.

The solutions described above have now been implemented throughout Poland. The decrease in the number of identified donors that began in the second half of the first decade of the 21st century and reached a historical lowest point in 2007 as a result of the “doctor G” case became a powerful trigger for the introduction of systemic changes. Thanks to the then national consultant for transplantology, professor Wojciech Rowiński, Transplantation Coordinators School was founded. It is currently responsible for educating future hospital transplant coordinators. The Ministry of Health initiated the National Program for the Development of Transplantation Medicine, with finance perspective 2020, to improve the organisational and logistic infrastructure for transplantation purposes as well as the equipment to be used in transplant centres in Poland. The “Partnership for Transplantation” project, which engages
local government administrations, has managed to stir to action hospitals that are directly subordinate to those structures. All of these activities have improved the rates of identification of actual donors, especially in those regions of Poland that used to have the lowest rates (Fig. 1). Four years ago, the Polish National Health Fund put organ donor identification in its refundable procedures catalogue, which means that financial resources are transferred from the payer directly to the donor’s hospital. Those hospitals where hospital transplantation coordinator positions were created are granted additional accreditation points. These activities have increased donor identification pmp rates from 9.2 in 2007 to 15.4 in 2013 [25].

In Great Britain, low rates of donor identification in 2006 led to the appointment of a committee that prepared an analysis of the transplantation process. The main reason for the inefficiency of the organ procurement system was identified as the lack of systemic solutions such as coordinating structures and an algorithm for identifying potential donors. The 14 suggested recommendations for remediying the situation were implemented between 2008 and 2011. These changes resulted in an increase in the rate of identified donors of 25% over a three-year period in comparison with the period between 2007 and 2008 [26]. The results of the implemented solutions failed to provide arguments in favour of changing the existing form of authorisation in Great Britain.

SUMMARY

Examples of mentioned above countries but also Austria and Singapore prove that the form of authorisation used for organ procurement does not significantly influence the process of identification of potential donors [27].

In Spain presumed consent established in 1979 did not make real improvement in donor identification. Ten years after that a national organisation for transplant supervision was appointed, which was crucial for systemic approach to organ donation [28, 29]. Irrespective of the form of authorisation or the country, one noteworthy feature of various initiatives increasing supply of organs for transplantation is their constant character. Systemic solutions are the basis for successful local/regional activities, which is essential for maintaining high rates of donor identification in national perspective.

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