
Correlation of Effective Organ Procurement Rates and the Role of Legislation in Individual European Countries

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Abstract:

Purpose: Clinical transplantation has proven to be a lifesaving method since the last century. The shortage of donors and organs pool for transplantation is a worldwide subject of discussion and legislation.

Design/Methodology/Approach: Authors did a critical review and identified actual donation models in individual European countries.

Findings: Critical revision of the distribution of donation models in individual European countries were presented: no country has chosen the model of strict consent, 18 countries adopted a model of opt-out, of which 13 were based on a strict model of opposition, and five decided to use an extended opposition system. The extended consent model was adopted in 1/3 of European countries (14 countries), three European countries adopted the information solution, Bulgaria is the only country adopting a higher necessity model. Authors identified in European countries opt-in to opt-out movement trend and "hard" presumed consent paradox.

Practical implications: Different models adopted in European countries and the shortage of organs for transplantation implicate some countries' transfer from opt-in to an opt-out model. It can benefit in increasing organ pool.

Originality/value: The article includes the first complex and critical analysis of effective organ procurement and legislation models in European countries.

Keywords: Opt-in, opt-out, donation, transplantation legislation, organ pool, presumed consent.

Paper Type: Research article.

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1. Introduction

Clinical transplantation has proven to be a lifesaving method since the last century (Linden, 2009). Data from the Global Observatory of Donation and Transplantation in 2018 proved 140,964 organ transplants globally (Summary, 2018), where kidney and liver were the most frequently transplanted organs. Unfortunately, local donation activity, contraindications to organ donation (i.e., infections, general conditions, reimbursement policies, etc.), and long waiting lists (e.g., 3-5 year waitlist for kidney transplants in Europe) determine challenging transplantation processes (Int. report, 2017; Dor *et al.*, 2011). In the European Union (EU), nearly 50,000 patients were waiting for a kidney transplant and over 63,000 were waiting for any organ (over 6,800 on the liver waiting lists; about 3,400 on the heart waiting lists; about 2,000 on the lung waiting lists; about 1,400 patients on the pancreas waiting lists). Estimates more than 4,000 patients died while on waiting lists in the EU every year. Statistics confirm that more than 10-30% of candidates failing to receive a transplant in Europe every year. The shortage of donors and organs for transplantation is a worldwide problem and subject of discussion and legislation (Gare *et al.*, 2017; Lennerling *et al.*, 2012; Merion, 2006; Youn, 2014).

2. Methodology

The publication is dedicated to the ex mortuo donation of cells, tissues, and organs actual legislation and transplantation mechanisms in Europe. First of all, the definitions of opt-in and opt-out donation were presented.

An analysis of individual models of consent authorization or donation objection in the 48 European countries legalization was performed, with an attempt to classify into commonly applicable models. The individual local transplant acts were analyzed.

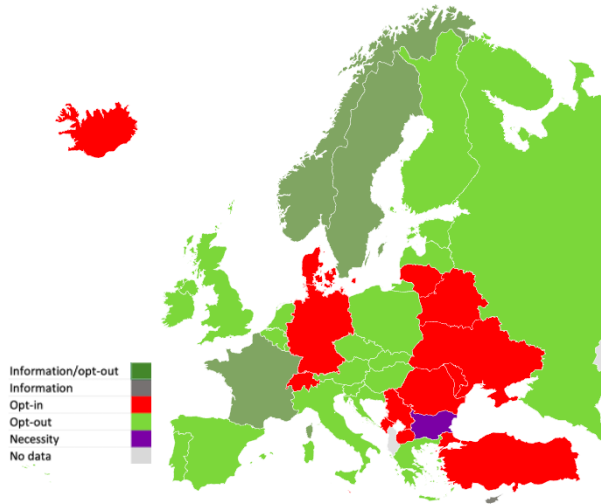
3. Findings

Legal acts of ex mortuo donation were identified in 43 of 48 European countries. Two general donation models were defined: US-Canadian model opt-in – the strict and extended consent solution, and the French opt-out – the strict and extended opposition resolution and information option in organ donation legislation. Summarizing the detailed analysis of the distribution of models in individual European countries, it can be stated in Figure 1:

- no country has chosen the model of hard consent;
- 18 countries (including Poland) adopted the opposition model, including eleven countries based on a hard opposition model, and five decided to use the soft, extended objection system;
- the soft extended consent model was adopted in 1/3 of European countries (14 countries);

- six European countries adopted the information solution;
- Bulgaria is the only country adopting the higher necessity model.

Figure 1. Donation consent and objection models in EU Member States and other countries in 2020.



Source: Own elaboration.

In last years UK, Ireland and Netherlands decided to change the legislation model opt-in to opt-out to increase potential donors and organs pool. Authors identified in European countries opt-in to opt-out movement trend: Netherlands - Active Donor Registration Law (in force from Summer 2020); England - Organ Donation (Deemed Consent) Act 2019 (in force from May 2020); Scotland - Human Tissue (Authorisation) (Scotland) Act 2019 (in force from Autumn 2020) and presumed consent paradox on Polish example.

4. Models of Objection or Consent to the Cells, Tissues and Organs Transplantation

4.1 Opt-in and Opt-out Donation Models

The legally permissible donation of cells and tissues, and human organs after death includes two models in the world. The first one is the American-Canadian model that requires consent in life – opt-in system – the model of extended and strict consent. The first, extended consent – soft consent, in the absence of the donor's explicit will, the only source of information about the presumed will of the deceased are eligible persons, most often the closest relatives of the deceased. The second, the strict consent model – hard consent, presupposes the donor's explicit consent expressed "pro-futuro" during his lifetime in oral or written form (Guzik-Makaruk, 2008).

The second, the French model, requiring an explicit exclusion of such consent and the presence of presumed consent – opt-out system – resolution of strict objection (hard), extended (soft) objection, and information option. Presumed consent may be lifted at any time by identifying whether a given person has objected to the prescribed form during his lifetime – "rebuttable presumption." Thus, no objection is tantamount to consenting to donation, but it is necessary to establish potential donor objection to organ donation after his death. This model assumes three forms of objection. We deal with the form of extended objection when, in the absence of an explicit objection by the donor, the presumed objection of the deceased must be expressed by authorized persons – most often the closest relatives.

A strict objection arose when a living person formulated an objection for organs donation in writing or witnessed oral. It is necessary to assume that there is compelling evidence that organ donation is excluded after death. The third form is the information solution, i.e., extended consent or extended objection, assuming that the potential donor and his relatives have been informed of the right to object. In the event of disagreement or objection of the deceased, which was expressed during his lifetime, a specific period is set within which it is possible to raise legally effective objections (Guzik-Makaruk, 2008).

The opt-in model applies, i.e., in Denmark and Germany. The solution in the opt-out form was adopted, among others in Poland, Finland, France, Austria, and Belgium (Arshad, 2019). In Poland and most European countries, transplant law does not require the consent of the donor's family, and under civil law, human corpses do not belong to anyone (Nestorowicz, 2019). The corpse does not constitute part of the estate, remains no property rights, and therefore there is no legal basis for the family to decide in this situation. The relatives of the deceased have only the right to bury the body.

Ex mortuo donation is independent of the consent of the deceased's family or the absence thereof. The common practice of obtaining the deceased's families' consent for organ donation is contrary to the applicable provisions of law. The main reason is in physicians respecting the principles of professional ethics and the emotional sphere of the deceased's relatives. This condition is exacerbated by social resistance related to organs donation after death, which results from insufficient knowledge of the issues of brain death, confirming the death of people treated in hospital, and often insufficient trust of the families of the deceased.

Guzik-Makaruk presents one more model, the priority rule – of the state of higher necessity – it is recognized that the life and health of the living person being rescued remain good of a higher value. Therefore it is allowed to sacrifice a natural good in the form of violation of the integrity of a human corpse, even if the donor denied the possibility of donation and opposed it during life (Guzik-Makaruk, 2008).

4.2 Stratifying Donation Models

The basic moral rule is the willingness to be a donor in exchange for eligibility to receive an organ. Consequently, it would be incorrect to allow organ recipients the right to refuse to donate upon their death.

Stratifying the above models, in terms of benefits for transplantology idea, the adoption of strict consent seems the least desirable. The only country in the world that has adopted the above model is Japan - probably for religious reasons resulting from a different Buddhist concept of death. The model with the most donation profits is a state of necessity, accepted only in Europe in Bulgaria – legally opt-out (Guzik-Makaruk, 2008). This model is the most controversial among human rights defenders and constitutionalists, as it threatens the full recognition of human subjectivity and guarantees the autonomy of his will. By denying a man the right to decide about himself and donate organs after death, it comes down human to the role of an object. Organ donation is beyond doubt in the case of consent, while the expressed objection has no specific legal consequences because, in saving health and life, there are always conditions of a state of higher necessity. If a person can be an organ recipient, they should also be able to give an organ, and vice versa.

The most important in the context of the negation of the model of higher necessity seems to be the uncompromising assumption that no medical law or state authority can take over the donation disposition over seemingly unowned organs, tissues and cells of the deceased. It also seems groundless to make the potential recipient's right to health and life dependent on this disposition. Guzik-Makaruk added that "a physician cannot invoke the state of necessity and, saving the patient's welfare, disregard the right to object to the donor or other authorized person" (Guzik-Makaruk, 2008).

A solution that promotes securing the potential donor's decision seems to be the strict consent model, but unfortunately, it also has a depressive influence on the development of postmortal transplantation. It is not easy to assume that every person will consent to organ donation in his lifetime. This model remains only a theoretical assumption (except for Japan). It should be suspected that this model would not also be accepted in most European countries because making an effort to submit consent would be excessive trouble and, above all, would not be in the direct interest of the person. Moreover, the donors are often young people for whom the concept of death, including their death, is so abstract that they do not make any disposition in case of death (Guzik-Makaruk, 2008; Nestorowicz, 2019).

Extended consent also seems to secure the donor's decision similarly, after whose death his family becomes the expression of his will. This ensures that organ donation is inadmissible if there is a suspicion that the deceased would not agree to a possible donation of organs, which will be confirmed by information from the deceased's closest relatives.

The strict objection can raise some questions, the lack of objections of a given person does not have to be the same as consent to transplant. The meaning of the no opposition intention does not mean that there is consent for donation. The soft objection model is much less controversial and much more protects the will of a potential donor. Discussing with the closest family allows one to know more about the person's position about the organ's donation. This model guarantees better protection against explanting activities inconsistent with the will of the deceased.

On the other hand, it is not entirely sure whether the closest family implements real donors' decisions. In this situation, it is also possible to put their beliefs ahead of the decision of the person they represent. In case of a lack of previous donor intention, the possible family choice is to object to donation (Delgado, 2019; Abadie, 2006).

The information solution - allows for a complete transfer of the decision made to the family in a situation where there is no consent or objection from the deceased. The family has the freedom to decide for the deceased at their discretion, guided by their convictions and conscience, and any decision they make, even the negative one, will be fully recognized (Arshad, 2019; Delgado, 2019; Abadie, 2006).

Each of the solutions presented above has its advantages and disadvantages. The existence of such a broad panel of models confirms that none of them are perfect. Some of them will polarize towards protecting the autonomy of the donor's will, and some towards saving the recipient's life and health and, at the same time, developing transplantology. Only the state of higher necessity's model finds broad support, mainly because it does not respect the right to decide about the donor's person. In order to rank the above models, two trends were identified: American-Canadian - informed consent (IC or opt-in) and French - presumed consent (PC or opt-out) (Abadie, 2006; Parsons, 2018).

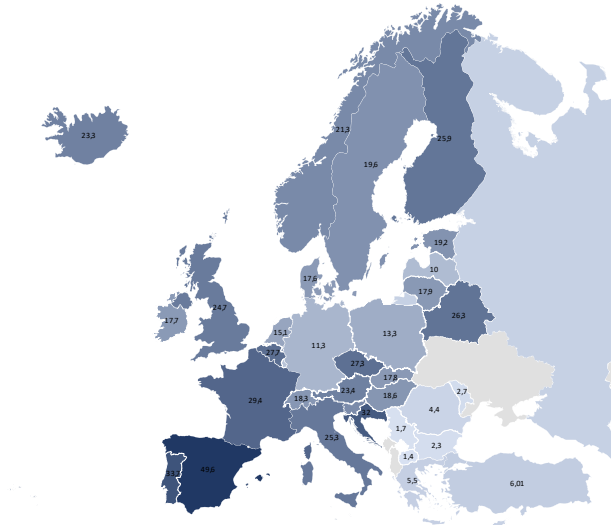
According to the analysis of the Annual Reports of the Global Observatory On Donation And Transplantation (GODT) in the period 2019, in terms of the number of ex mortuo transplants, the correctness of the dominance of the opposition model (e.g., Spain, Austria, and Belgium) [16]. In countries that have adopted such a solution, even the lowest rates of postmortem transplantation achieved are five points higher than the highest achieved in countries that have adopted the consent model (Germany) - Figure 2.

4.3 Reality

The most critical challenge in postmortal donation is donor family objection, often regardless of donors' decisions. Families express final decisions about donations. Although in soft opt-out it is accepted, in hard opt-out is, unfortunately, possible – Polish paradox. The impact of relatives' decisions about their relatives' organs on actual donation rates is not proved, but family plays a crucial role in the final donation decision (Delgado, 2019; Parsons, 2018). The UK family in 2018 in 48%

were opposed to donation in comparison with 20% in Spain. The Spanish organ donation system has long been regarded as the "gold standard" for after-death organ donation. In 1979, Spain introduced the current opt-out legislation, and between 1979 and 1986, the number of kidney transplants significantly increased (Willis, 2014).

Figure 2. Deceased donation (DBD and DCD donors) rates per million population in the EU Member States and other countries in 2019.



Note: DBD - donors after brain death, DCD - donors after circulatory death

Source: Own elaboration (Global Observatory On Donation And Transplantation (GODT)).

In the absence of written consent (opt-in), the family typically gets involved by default in the organ donation decision in two possible ways. First, if the family member has made no choice and families are allowed to veto opt-in decisions. Second, in some countries like Germany, the family can veto the opt-in decision if they provide good arguments for a change in the person's mind after the consent statement. Hence, family consent might explain why opt-in countries might well observe an attenuated effect on donations, which makes them similar to opt-out countries. More generally, the presence of family vetoes depends on individual family cultural characteristics alongside country-specific influences such as information system characteristics, hospital processes, and family support for the deceased (Delgado, 2019; Parsons, 2018; Willis, 2014).

4.4 Donation Model Switch

European countries show diversity in their organ donation laws (Arshad, 2019; Delgado, 2019). In countries with informed consent or opt-in legislation, such as Germany and Sweden, the donor's family must expressly consent to organ donation.

Countries with the presumption of consent, such as Spain, Portugal, and Austria, accept universal consent without expressly registering otherwise. These two systems have become a widely discussed political issue, and many countries have recently moved from opt-in to opt-out, such as Wales, the Netherlands, England, and Scotland, with the debate taking place in Denmark [Wales: Human Transplantation (Wales) Act, 2013. Netherlands: Active Donor Registration Law. In force from Summer 2020. England: Organ Donation (Deemed Consent) Act 2019. In force from May 2020. Scotland: Human Tissue (Authorisation) (Scotland) Act 2019. In force from Autumn 2020)] (Lewis *et al.*, 2020; Jensen, 2019; Glazier, 2019). A recent publication indicates that presumed consent policy impacts donation rates, and it was significant in a European country (Shepherd, 2014).

Evidence supports the association between presumed consent and increased donation rates and that countries with opt-out laws have rated 25 to 30% higher than those in countries requiring explicit consent (Shepherd, 2014). However, presumed consent appears to be only one of several influential factors. Other factors include potential donor availability, transplantation infrastructure, health care spending, and public attitudes, as well as familial consent and donor registries. It is not proved the correlation between effective organ procurement rates and the role of legislation, but the suggestion that switching to an opt-out system may increase organ donation rates (Arshad, 2019; Willis, 2014; Lewis *et al.*, 2020).

Switching to opt-out also improves donation as the standard and recommended choice (Murray, 2006; Keller, 2011; Fabre, 2014; Kessler, 2019). Likewise, the presumed consent seems less complicated, requires less physical effort (i.e., filling out forms), and requires less emotional effort for objection in that area (Murray, 2006). Kessler and Roth (Kessler, 2019) document that families support the donation in future decisions if the deceased did not 'opt in' rather than when directly opted out. It remains essential to explore the issue of family discussions in organ donation. Bill (Bilgel, 2012) reported that opt-out countries exhibit 18% higher donation rates on average compared with opt-in countries.

One of the main concerns against the opt-out system is ethical issues. For example, presumed consent to organ donation was approved in the United States in 1990 but was later rejected in 2006 because of fears that it conflicts with human rights. There is a conflict if presumed consent accurately reflects the patient's wishes, undermining the donor's autonomy if the potential donor does not wish to donate but has not registered for opt-out (Abadie, 2006). On the second side, recent evidence from the implementation of presumed consent in Wales shows a reduction in the number of organ donors (Abadie, 2006). There is a difference between the legal permissibility of opt-out and its implementation in practice. If the mere implementation of such legislation was enough to improve deceased organ donation rates, those countries with legal opt-out ought to respond to all display high donation rates. However, while opt-out countries such as Spain, Austria, and Belgium have

high donation rates, Luxemburg is legally opt-out with lower donation rate. The same Bulgaria with higher necessity model.

Moreover, Arshad comparing opt-out with opt-in countries observed no significant difference in total deceased donor rates (20.3 vs. 15.4, respectively; $P = 0.195$), but there were significant reductions in living donors (4.8 vs. 15.7, respectively; $P < 0.001$) among opt-out countries. Authors suggest that a simplistic switch to the "opt-out" model has unintended consequences for living organ donation. Unfortunately, it does not provide a "quick fix" to improve donor rates that have been previously suggested. The authors suggest the preferred way to increase in organ donation is education and informing the general population about the benefits of transplantation (Arshad, 2019).

4.5 Polish Paradox

In the soft objection model (relatives consent) - by definition, the family can manipulate the donor's decision, but in hard consent, in the author's opinion, if it contains various forms of objection authorization, such manipulation is also allowed (Costa-Font, 2020)

The provision, which is intended to strengthen the guarantee of respecting the will of the deceased, may paradoxically, in fact, constitute an attack on an autonomous decision, expressed implicitly during life. Although in Poland, with a strict presumed consent model, there is no legal obligation to ask the family for consent and family preferences for donation. In such a legal structure, information obtained from relatives may often distort the real will of the deceased person. Marking the existence of an objection in the form provided for in Art. 6 sec. 1 point 2 and 3 (2. a written declaration signed by author/potential donor; 3. an oral statement made in the presence of two witnesses, confirmed in writing by them), results in taking into account the beliefs and views regarding postmortal donation - not necessarily true. Then it works withdrawal from the collection of cells, tissues, and organs ex mortuo, and the presumed consent becomes only a theoretical interpretation, not applicable in reality (Polish Transplantation Act, 2005).

The *de lege ferenda* postulate that eliminates the above doubts seems to be the adoption of the formula of the extended (soft) objection, according to which, in the absence of a clear opposite position towards the transplantation of a potential donor, authorized persons (most often the closest relatives) would express the alleged will of the deceased. To a greater extent than strenuous objection, this model protects the will of a potential donor and, at the same time, guarantees respect for the right to decide about oneself – *pro-futuro*. It allows clarifying the position of a deceased potential donor by talking with family and eliminating unjustified explanation activities. According to this solution, when there is any suspicion that the deceased would not consent to donation during his lifetime, the collection of cells, tissues, and organs is impossible. In support of this postulate, it can be argued that the current

legislative solution in Poland meets the assumptions of the extended objection - soft presumed consent.

The Polish Transplantation Act reveals a peculiar paradox - this observation does not appear in any of the most critical studies - the strict objection model adopted in the Act, which, in a superficial interpretation of the lack of such objection equated with presumed consent, seems to limit the natural right to decide about oneself. Subsequent articles of that Act - not necessarily in the manner intended by the legislator - actually change this model, resembling an extended formula or an information solution. This change results from the statutory order to exclude other forms of objection than the one filed in the Central Register of Objections (Polish CRS) based on available information or documents.

The model of extended objection is implemented in Poland through the formally imposed need to talk to the relatives of the deceased potential donor, which takes the formula of obtaining consent from the family for a postmortal donation, where the family becomes the exponent of the presumed will of the deceased. Moreover, drawing attention to the existence of the contradiction mentioned above is an essential argument against opponents of presumed consent, a consequence of the strict objection model adopted in Poland. The comprehensive interpretation of the Transplant Act and the forms of guaranteed shows that presumed consent is merely a theoretical interpretation, not applicable in reality. Presumed consent is only applicable if the existence of an objection is ruled out in all the forms provided for in the Transplant Act.

However, while maintaining the individual's protection, the soft objection model adoption requires the state to conduct a large-scale information campaign on the concept of *ex mortuo* transplantation, the register of objections, and the consequences of failure to report it. Article 19 of the Protocol to the EBC recommends that "Parties shall take all appropriate measures to promote the donation of organs and tissues" as well as disseminating knowledge about the acceptability of posthumous organ donation for transplantation (Sheperd, 2014; Murray, 2006; Keller, 2011; Fabre, 2014; Kessler, 2019; Costa-Font, 2020; Prabhu, 2019).

5. Conclusions

For any organ donation system to be effective, an efficient procurement system is needed based on a well-organized infrastructure. It is necessary regardless of the regulations. As a result, a focus on the legislative change is unlikely to achieve the goal if more excellent benefits could arise from organizational and structural changes.

Spain is cited as an example of how the opt-out system can increase donation rates and record the highest number of organ donors for last year's record. Spain's success

is not only a result of a change in legislation to an opt-out system but rather due to the improvement of the organ donation model. They introduce early notification, identification/targeting of organ donors, broadening the eligibility criteria for usable organs, the DCD process (inclusion group of donors after circulatory death), organ donation promotion, and training in communication with potential donors' families.

There is no hard evidence that the opt-out system alone leads to an increase in donation rates. Statistical facts not prove higher deceased donor rates in opt-out countries, but confirm lower living donor rates. An opt-out system consists of "soft" and "hard" rules, with the "soft" version requiring families to refuse to postmortal donation to a relative; the results are likely to be influenced by familiar decisions. Legislation rules of the "hard" concept in paradox make it similar to the "soft" model.

List of abbreviations: DBD - donors after brain death, DCD - donors after circulatory death

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