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PRESUMED CONSENT IN ORGAN DONATION – LIMITATIONS OF CONSENT MODEL REGARDING TRANSPLANTOLOGY IN POLAND

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Purpose: Organ transplantation is a treatment for patients with end-stage organ failure limited by the number of organs. The aims of this article are: to compare the relevance of the indicated systems for the number of donated organs, to analyze the status of organ donation, to identify current issues and possible measures in order to increase the number of donations from deceased donors in Poland.
Design/methodology/approach: The paper refers to theories from behavioral economics: status quo bias, human tendency to procrastinate, aversion to changes. It also analyzes statistical data of donated organs and the number of objections raised in Poland.
Findings: There is a widespread public approval for organ donation in Poland, however most people do not state their decisions. Countries with an opt-out system have a higher rate of organ donations. In Poland in 2020 less than 0,1% of population objected to donate organs, yet 12% of potential donors were disqualified due to record in the Central Register of Objections or family's statement. In 2016 only 20% of population was aware that presumed consent is legally binding. Moreover, 75% have never talked with their relatives about donating their organs.
Research limitations/implications: The article relies on general data from statistical databases and population-based survey studies, which do not include detailed information on the subject described, and thus do not provide data for reliable in-depth statistical analysis. Due to unavailability of numeric data on the reasons for abandoning the organ procurement, the article relied on the available general statistical classification. The authors find an qualitative research to be worth considering in the studied area in order to identify profound causes of the problem and to find a target group for future experimental research.
Practical implications: As majority of Polish population is pro-donation the presumed consent for organ donation is preferable to increase the number of donors.
Social implications: Profound ignorance of the legislations and broad unawareness of the family's preference is the foundation of public fear and uncertainty towards organ donation.
Originality/value: As the social factor appears to be the limiting factor for organ procurement it is fundamental to educate the society about transplantation in a relevant way in order to increase the number of donations in Poland.

Keywords: Organ Transplantation, Tissue and Organ Procurement, Presumed Consent.
Category of the paper: Research paper/General review.

1. Introduction

For end-stage organ failure, transplantation is the best and most cost-effective clinical solution (Lewis et al., 2020). For decades, organ transplantation has reduced suffering of patients with end stage disease, allowed restoring of organ function and provided a possibility to survive, preventing premature death (Bezinover, Saner, 2019; Reese et al., 2020; Vanholder et al., 2021). Existing organ shortage is the fundamental challenge in transplantology field which results in high numbers of patients signed on waiting lists (European Parliament, 2020). In United States of America (USA) each day 17 people die waiting for an organ transplant and 106 287 people are signed on a waiting list (Health Resources & Service Administration, 2022). In the European countries covered by Eurotransplant, 13 460 people were registered on the waiting list in 2021, of whom 5 622 received organs from deceased donors (Eurotransplant, 2022a). This data demonstrates a growing disproportion between the demand and the number of procedures performed, and indicate an insufficient scope of organ transplantation.

For all types of organs, there is a disparity between the need and availability (Bezinover, Saner, 2019). The most frequently transplanted organs are kidneys (European Parliament, 2020). In 2021 in the USA 24 670 kidney transplantations were performed, simultaneously including 90 483 patients on a waiting list (Health Resources & Service Administration, 2022). Other common transplantations include liver, heart, lung, and pancreas. It is worth underlining those new types of transplants are being developed at all times (European Parliament, 2020). In the Netherlands, Belgium, Luxemburg, Germany, Austria, Hungary, Croatia and Slovenia the number of transplanted organs from deceased people are shown in the Figure 1.

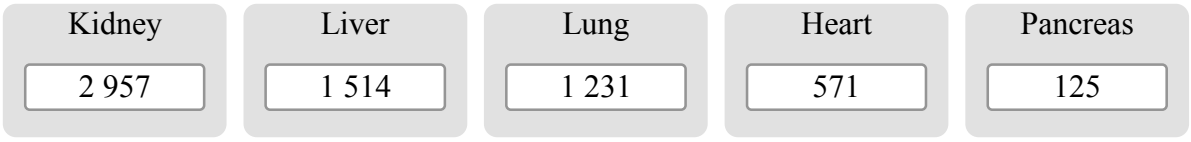

Figure 1. Number of organs transplanted from deceased people in 2021 in Eurotransplant area.
Source: own elaboration based on (Eurotransplant, 2022a, factsheet, reference date: 10.01.2021).

In 2010, the European Union legislation was adopted to encourage the optimal distribution of organs between member countries. Most EU member countries are already involved in cross-border exchange of donated organs either through bilateral agreements or other arrangements (Eurotransplant, 2022b).

Organ exchange carries three main objectives:

- Reducing the loss of donated organs due to mismatch of the donor and the recipient when there are no eligible recipients on the waiting list.
- Increasing the chances for certain groups of patients to receive organs from a compatible donor.
- Enabling optimal donor and recipient matching by expanding the donor and recipient pool (Weiss, Kocher, Immer, 2015).

International organ exchange increases the number of organs available for transplantation in the European Union by offering the possibility to transfer organs to a compatible recipient in another country in cases where there is no suitable recipient on the national waiting list (Eurotransplant, 2022b).

The organ donor recruitment process is based on neurological and circulatory criteria. Respectively, they diversify Donation after Circulatory Death (DCD) and Donation after Brainstem Death (DBD). The path from potential donor to an actual use is multi-step (Poltransplant, 2021). Actual deceased donor is an eligible DCD or DBD donor who had a surgical incision made with the intent to obtain an organ for transplantation or from whom at least one organ has been obtained for transplantation. A utilized donor is an actual donor from whom at least one organ has been transplanted (ODEQUS, 2013).

Transplantation carries an important role in preserving the lives of people with organ defects. Therefore, it is crucial to debate possible measures to increase organ donation. In Europe overall organ donation and transplantation activity is higher than on the other continents. However, differences in European countries are noticeable (Vanholder et al., 2021). In the next section of the work, the differences between the number of organ donations from deceased people in European union countries based on the type of consent are described. One of the purposes of the article is to compare two types of agreement systems for organ donation, specifically presumed consent and explicit consent to indicate the importance of both options for organ donation. Considerations were supplemented with behavioral economics theories including the status quo bias, people's tendency to procrastinate in case of making decisions and general aversion to changes (Halpern, Ubel, Asch, 2007; Beraldo, Karpus, 2021).

2. Methods

The paper refers to theories from behavioral economics, particularly status quo bias, the human tendency to procrastinate and aversion to changes. An analyzis of statistical data illustrating the number of donated organs in certain European countries in relation to the form of consent and an analyzis of the number of objections raised in Poland were performed. Moreover, the authors compared the results of public opinion studies on organ donations.

3. Results

Explicit consent and presumed consent in organ donation – background and implications

While there is a widespread public approval for organ donation, it has no reflection in actual donor registrations (Howard et al., 2016). In different countries, the number of potential deceased organ donors depends greatly on how the option of becoming or not becoming a donor is perceived and how the corresponding option is chosen (Beraldo, Karpus, 2021). The Figure 2 shows the number of organ donations per 1 million of inhabitants from deceased people in European countries.

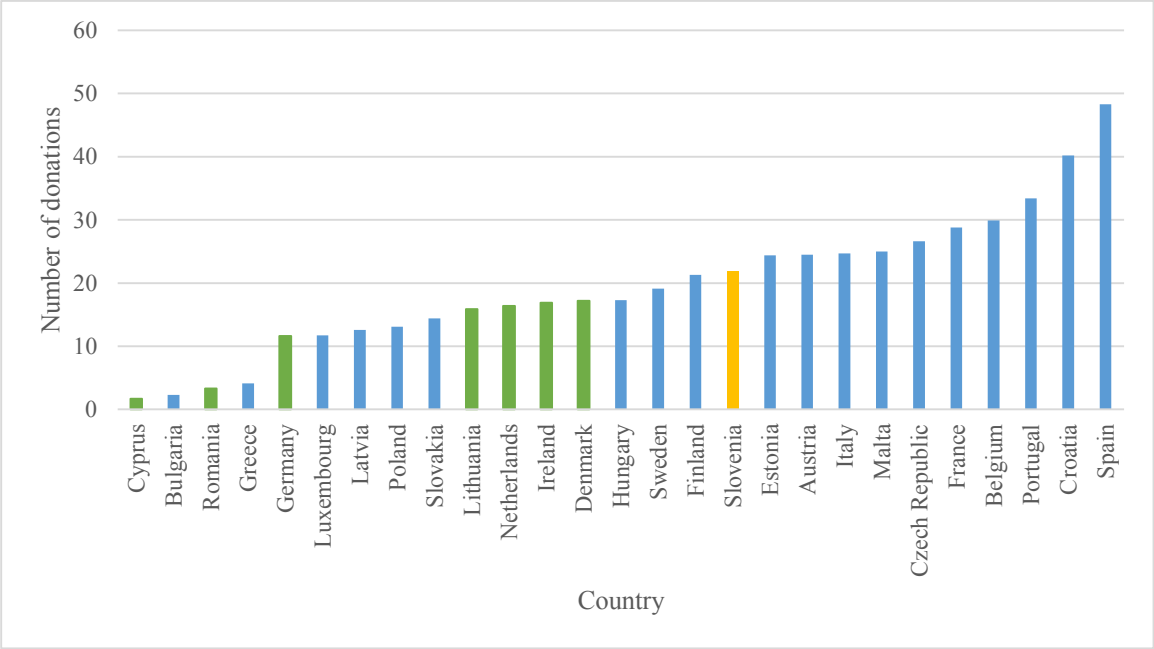

Figure 2. Number of organ donations per 1 million of population from deceased people in the European counties in 2018 (opt-in system – green, opt-out system – blue, mixed system – yellow).

Source: European Parliament (2020, p. 5).

In annual ratio both donors, DBD and DCD were included. In the Figure 2, it can be seen that the differences in deceased donation rates vary considerably between European countries. In all of the indicated countries, one of two strategies related to organ donation is in place. Exceptionally, in Slovenia the system is a mix of both systems previously mentioned.

In Cyprus, Romania, Germany, Lithuania, the Netherlands, Ireland and Denmark, the system is opt-in, which means that someone is not a potential organ donor unless that person registers as a donor, for example by obtaining a donor registration card (Beraldo, Karpus, 2021). In explicit consent countries, nobody is an organ donor without registering (Johnson, Goldstein, 2003). Opt-in is otherwise known as explicit (informed) consent. This is a legally valid permission to remove organs for transplantation according to a person's voluntary consent (ODEQUS, 2013).

Among other countries shown in the figure, system of organ donation is classified as opt-out, which assumes that people are donors by default unless they declare otherwise during their lifetime (Johnson, Goldstein, 2003; Beraldo, Karpus, 2021). This means that in the absence of an explicit refusal, by definition people are willing to donate tissues and organs after death (Williams, O'Donovan, Wilkinson, 2022). Presumed consent is a legally valid presumption of acceptance for the removal of organs for transplantation purposes whenever there was no individual and previously declared refusal of permission (ODEQUS, 2013). The policy of presumed consent assumes that, on principle, all citizens agree to donate organs, but have freedom to easily register their disagreement to become donors (Thaler, Sunstein, 2008).

It is noticeable that countries with an opt-out system generally have a higher rate of organ donations than countries with a predominantly opt-in system. The type of system adapted plays an important role because it is common that in an opt-in system undeclared people do not register as donors, while in an opt-out system they do not provide a declaration to be non-donors. In general, most people do not state their decisions, regardless of being for or against donation and independently from the system in place (Beraldo, Karpus, 2021). Most choices in public policy feature default inaction (Johnson, Goldstein, 2003). This issue of explicit consent (opt-in) and presumed consent (opt-out) is an extremely interesting aspect of behavioral economics. Based on evidence from social sciences and psychology regarding default effects (Williams, O'Donovan, Wilkinson, 2022), whether people are urged to choose what they believe to be the best choice depends largely on what causes them to stay with the default option. Causes of the effectiveness of defaults are following:

- the status quo bias,
- people's tendency to procrastinate (Beraldo, Karpus, 2021),
- aversion to changes (Halpern, Ubel, Asch, 2007).

The classic model of human decision making is the rational choice model, which concerns the highest chance of satisfying one's preferences. Making a decision that is inconsistent with one's preferences is therefore considered irrational (Breslin, 2018). An important assumption of the rational choice model is that an individual's decision under certainty or uncertainty is influenced by important preference characteristics. It means, neither labels nor the sequence in which alternatives are presented should affect the individual's choice. In real world conditions the alternatives are often connected with influential labels. One alternative inevitably connects the label status quo, indeed. An option to maintain one's previous or current decision is always an attractive option for not taking an action (Samuelson, Zeckhauser, 1998). Status quo bias, involves an increased attractiveness of choosing the default option by preferring the presumably worse option under the condition that better option requires abandoning the status quo, even if the costs of change are negligible (Karl et al., 2019). While considering to make a decision, it is often impossible to remain utterly passive, because even refraining from an active choice is *de facto* a certain kind of choice. In conclusion, preserving the status quo is also an option. This means that if a passive decision maker is presented with a choice, the effect of his

indecisiveness will be to automatically select the base option, which is the answer predicted by the choice architect (Baszczak, 2020).

This theory is grounded in economic psychology, public health and marketing. The status quo bias shows behavioral tendency to choose status quo option incommensurably often (Burmeister, Schade, 2007). The preference for one's present status also influences health decisions. A preference for the easiest path may explain some habits like physical inactivity, difficulty with quitting smoking and unwise daily eating habits, which are often a default choice (Karl et al., 2019). People are psychologically uncomfortable with changes and might adhere to the status quo, even if it directly conflicts with their preferences (Breslin, 2018). Because of this tendency to avoid decisions and the intention to preserve the status quo, default values are very effective in guiding choices even in important areas of life such as organ donation (Samson, Gigerenzer, 2016).

Procrastination involves unwanted and unnecessary delay to deadline realization, solution implementation and decision making. When a person is confronted with a choice situation and with liberally available alternatives, the preference for delay is a consequence of the "later" dictum (Svartdal, Granmo, Færevaag, 2018). The opt-out approach links to reduce effects of peoples' procrastination and inertia in willing donors who fail to take the necessary time or effort to communicate a positive preference in organ donor registry. Opt-out clauses eliminate the possibility that eager individuals will "fail" to register a positive choice to donate an organ through the donor registry (Williams, O'Donovan, Wilkinson, 2022). Behavioral economics shows how the manner in which a choice is presented can influence different decisions. This is described in the assumptions of choice architecture (Reese et al., 2020). An alternative to mentioned two models which are by Thaler and Sunstein believed to be the best architecture of choice regarding organs donation is statutorily mandated choice (Thaler, Sunstein, 2008). The policy of a mandated choice requires that each person decides whether or not they want to be considered as a potential organ donor. This implies that instead of assuming one option to be the default choice, it requires everyone to actively decide and make a choice at some point in their lives. This is certainly a forced policy, but it is nevertheless being discussed as a viable option to overcome a number of problems associated with default rule nudging (Beraldo, Karpus, 2021).

In summary, the three fundamental solutions that can be implemented for organ donation are presumed consent, explicit consent and mandated choice.

Presumed consent or family's decision – issues with presumed acceptance of organ donation in Poland

Poland uses an opt-out system. This means that all citizens are classified as potential donors, but have a possibility to freely change their option by expressing their objection. Citizens of Poland may refuse to donate organs in 3 ways during their lifetime: by registration in the Central Register of Objections kept by Poltransplant, by a written declaration, provided with

a handwritten signature, and by an oral declaration of choice made in the presence of at least two witnesses, supported with their written confirmation (Dz.U. 2005, nr 169, poz. 1411, art. 6.1). According to Poltransplant (2016), when a potential deceased organ donor is reported, organ procurement may be discontinued if:

- there is no evidence of brain death (for BDB) or no irreversible cardiac arrest within the designated time frame (for DCD),
- there is no authorization by existing index to the register of objections or by donor's family statement,
- a medical contraindication is present,
- no suitable recipient can be found.

In order to illustrate the situation of organ donation in Poland, the number of potential and qualified deceased organ donors was analyzed in Figure 3, as well as the number of registered statements declaring opposition to organ donation after death in Figure 4.

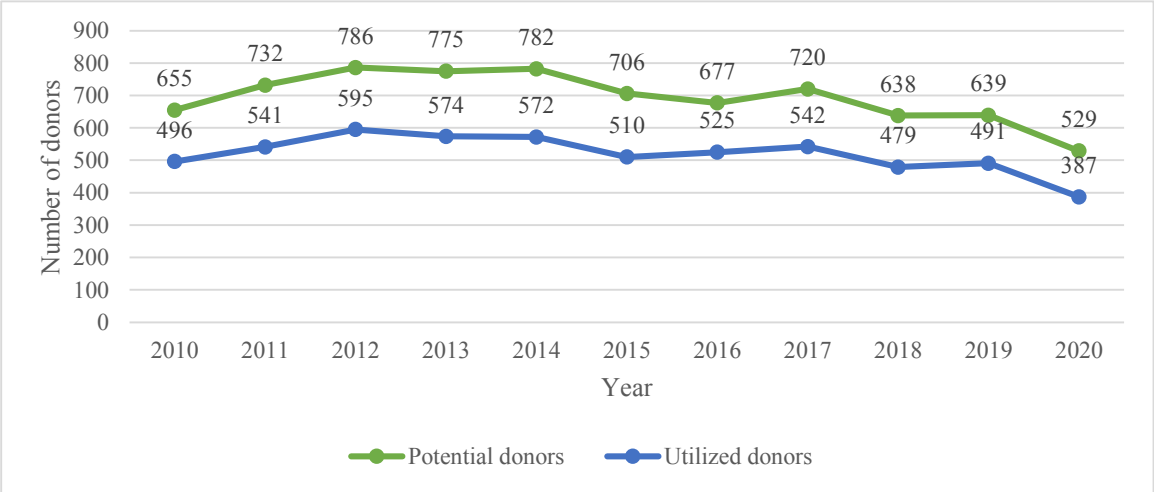

Figure 3. Number of deceased organ donors in 2010-2020 in Poland.

Source: own elaboration based on Poltransplant 2021, p. 6 and Poltransplant 2016, p. 14.

When analyzing the number of potential and utilized donors since 2012-2014, there is a negative linear trend in both. Considering the importance of every single organ transplantation and the constantly growing trend of patients waiting for this procedure, the situation presented is extremely unfavorable. What is more, approximately 38% of all disqualifications of potential donors are due to denial of authorization which is second only to medical contraindications (46%) (Poltransplant, 2021). Clinical practice suggests an unexplored issue which is the lack of registration process for deceased people who could become potential organ donors which is directly dependent on the activity of hospitals that theoretically have the capacity to procure organs but refrain to do so due to financial and organizational reasons (Paulo, 2010)

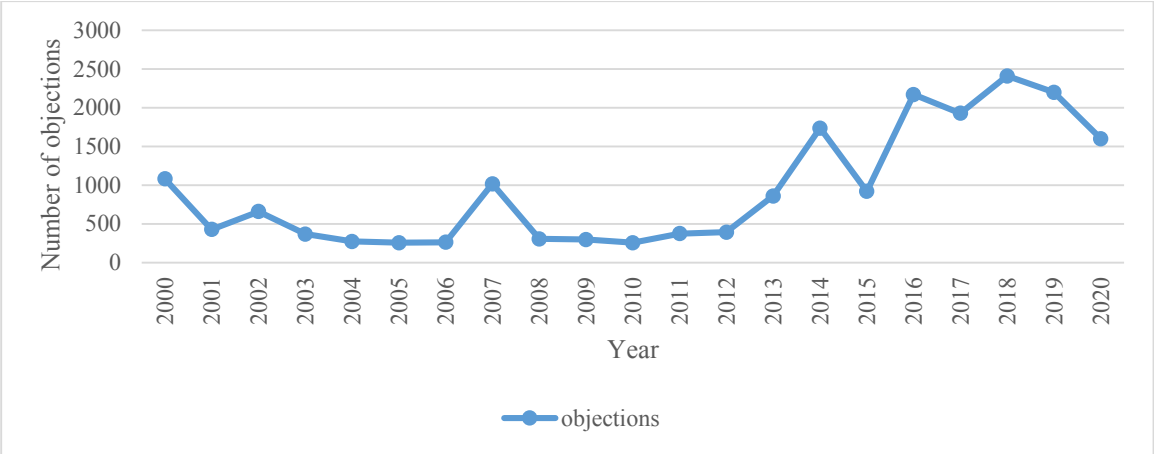

Figure 4. Number of declared objections registered in the Central Register of Objections in 2000-2020.

Source: own elaboration based on Poltransplant 2021, p. 60.

The number of registered declarations in the Central Register of Objections has an upward trend, which is also a major disadvantage for organ donation. On the other hand, at the end of 2020 there were 38 265 013 citizens in Poland (GUS, 2020) with 37 056 of them registered to the Central Register of Objections (Poltransplant, 2021). This would mean that less than 0,1% of referred Poland population objected to donate organs, yet approximately 12% of potential donors are disqualified due to lack of authorization resulting from existing record in the Central Register of Objections and potential donor's family statement (Poltransplant, 2021). Unfortunately, the report did not indicate the reasons why people chose to sign up for the registry nor the statistics of the mentioned 3 basis for disqualification due to lack of authorization. However, clinical practice may suggest an explanation for this phenomenon. Despite the fact that physicians are not required to obtain family's approval neither inform about ongoing organ procurement, the transplant community has come to the conclusion that the family's objection causes organ procurement to be abandoned (Nesterowicz, 2010, as cited in Woderska, 2018). Cause of that may lay in insecurity of presumed consent for organ procurement as the physician will not risk the procedure when the family may later testify in court that their close one categorically objected before death (Paulo, 2010).

The following consider the level of knowledge of current legislations and attitude towards organ donation in Poland. Figure 5 represents public awareness of current transplant law.

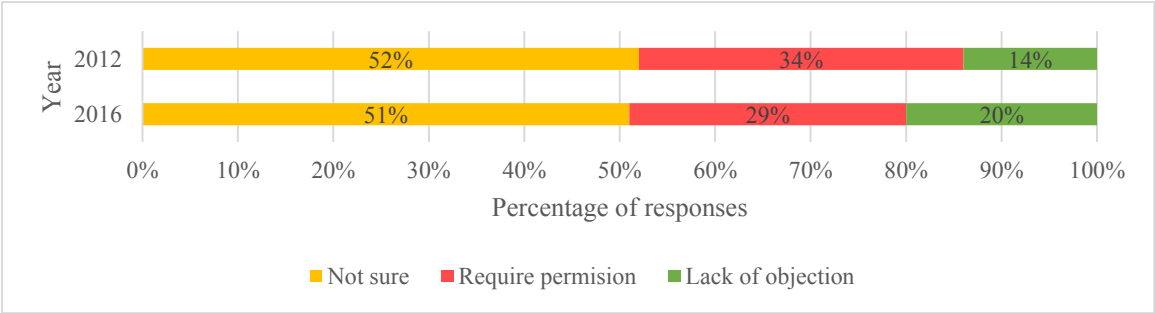

Figure 5. What society considers to be the terms of consent system for organ donation in Poland.

Source: own elaboration based on CBOS, 2016, p. 13.

Another ongoing and persistent issue is the level of awareness of Polish population in transplantation area. On the basis of CBOS research (CBOS, 2016) repeated every couple of years, it appears that only 20% of examined population is aware that presumed consent for organ donation is legally binding in Poland. Even more people (29%) indicate incorrectly that Poland uses an opt-in system of consent and requires their active declaration for them to be considered as potential donors. Public opinions regarding the law governing the procurement of organs from deceased donors are divided. The concept of positive declaration given during one's lifetime is supported by 43% (with a downward trend) and essentially the same 42% (with an upward trend) consider the principle of presumed consent to be more appropriate. 5% say that neither of these solutions is sufficiently good. The direction of changes should be considered favorable for transplantology. The belief that presumed consent is a better solution, to some extent, is related to the favorable attitude towards being an organ donor after death and the approval for possible donation from a close relative. On the other hand, support for providing informed consent - with more frequent opposition to it.

Family communication patterns

Figure 6 shows how many people discuss their decisions about organ donation with their families.

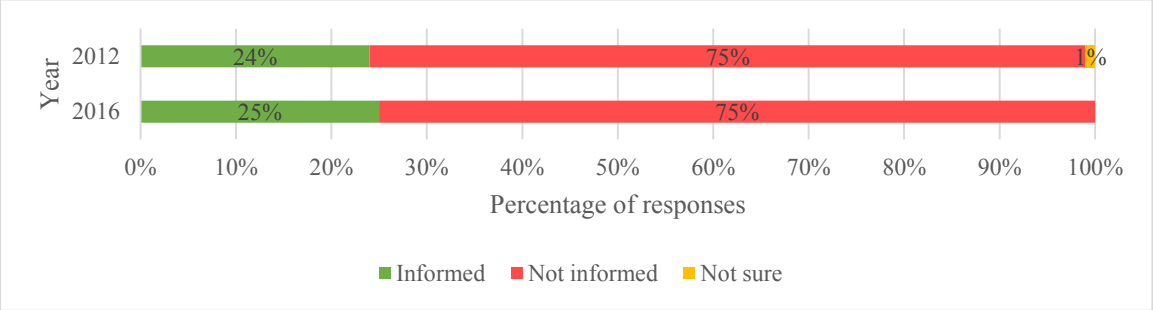

Figure 6. What part of the population has informed their family about their decision on organ donation. Source: own elaboration based on CBOS, 2016, p. 4.

According to the survey, three of four (75%) have never talked with their families about donating their organs after death and only one in four (25%) have shared their decision with their relatives. These were more often people with the best education, young people, residents of large cities, in good socioeconomical situation, and rarely the oldest people and respondents with primary education (CBOS, 2016). This conclusion may be supported with results of the study conducted among university students as within this group the number of respondents indicating that they have discussed this topic with their family is 67.7%. What is more, medical students were significantly more likely to engage in conversation than non-medical students (75,9% vs 52,2%) (Mazur et al., 2018). Basing on another study in a question concerning the source of knowledge gained in the field of transplantology we can learn that formal source of knowledge was indicated by 71% of medical students while only 17% of non-medical students pointed out this source with a prevalence for extracurricular and informal sources (Woderska,

2018). Considering that knowledge about the family's preferences in the field of organ donation aspires to be the most important factor responsible for donation rates increase (Koźlik et al., 2014), it is foremost important to formally educate society in the field of health sciences.

The connection between knowledge of the deceased's decision and family's reaction to organ procurement

Figures 7-9 indicate how knowledge of the deceased's decision regarding organ donation affects the family's consent.

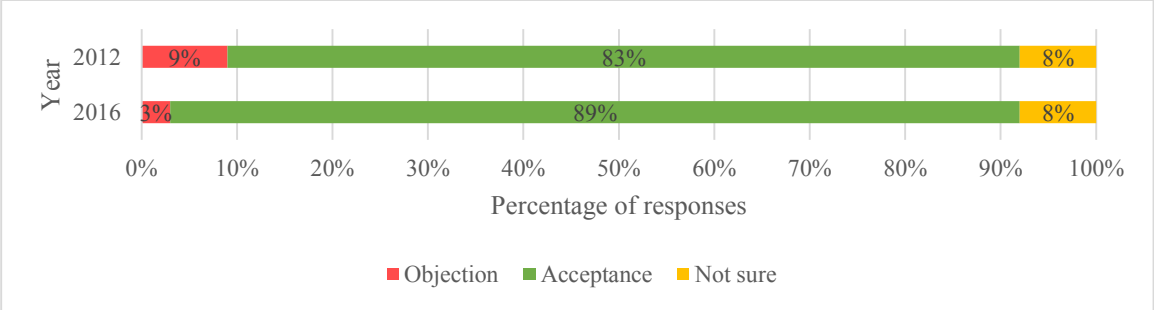

Figure 7. Acceptance for organ procurance from a related donor who had nothing against organ donation.

Source: own elaboration based on CBOS, 2016, p. 7.

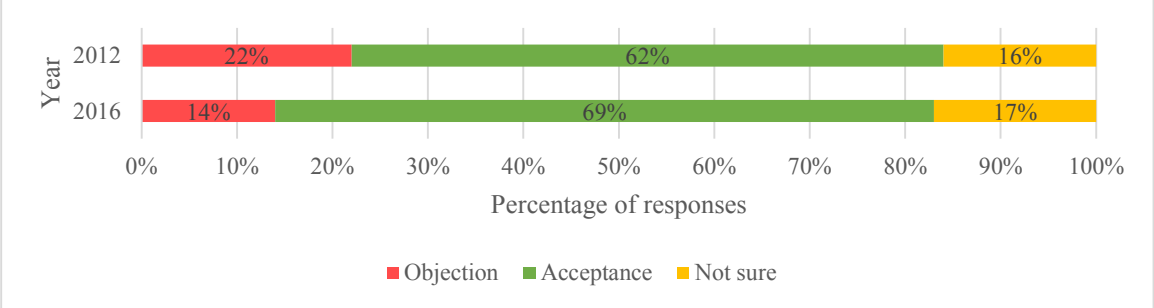

Figure 8. Acceptance for organ procurance from a related donor who said nothing or was unsure about organ donation.

Source: own elaboration based on CBOS, 2016, p. 7.

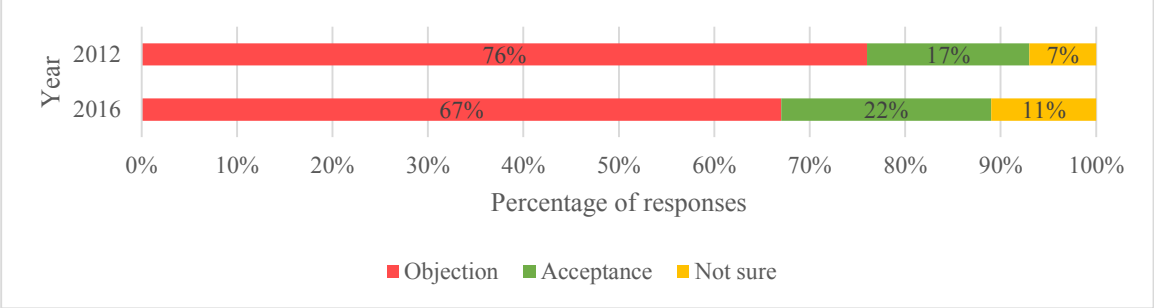

Figure 9. Acceptance for organ procurance from a related donor who was against organ donation.

Source: own elaboration based on CBOS, 2016, p. 7.

When examining the graphs, it appears that the majority of respondents declare their willingness to respect the wish of the deceased and in the case of their consent to organ donation, 89% of respondents would not oppose organ procurement. In the case of unfamiliarity with the deceased person's view on organ donation, 69% of respondents would not oppose organ procurement, while rest of respondents are unsure how they would act or would express their objection (17% and 14% respectively). A similar study conducted in 2020 among citizens of Gdańsk presented comparable results and is also worth mentioning (Ruszkowski et al., 2020). Due to the broad unawareness of the family's preference for organ donation and the general public's support for donation, the difference in responses between results obtained when we know that the deceased wanted to donate organs after death and not knowing about their decision is an area of potential donor loss.

While exploring the main reasons of families' objections to organ procurement from related donors we can find reluctance and fear of invading the body of the deceased, inability to accept the death of a close family member and to decide in such a crisis, lack of knowledge of the deceased's declaration for organ donation and a general reluctance to make decisions on someone else's behalf to be the main one's (Groot et al., 2015; CBOS, 2016; Woderska, 2018).

4. Discussion

Transplantation is a treatment option for patients who have developed organ failure (Howard et al., 2016). There are many challenges in the field of transplantation, and its main limiting factor is the shortage of available organs (Van Dalen, Henkens, 2014; European Comission, 2022). Due to the persistent imbalance between supply and demand for organs, maximizing the use of available organs is extremely important (Sharif, 2022).

Basing on evidence of default effects from social sciences and psychology, people's postponement of decisions and inertia among willing but unregistered donors, leads to conclusion that changing the consent system from opt-in to opt-out in European countries would contribute to increasing the number of organs from deceased donors and closing the transplantation gap (Williams, O'Donovan, Wilkinson, 2022). People by nature exhibit an aversion to changes, a fear of making mistakes, or a desire to maintain the status quo. Therefore, a valid default option is crucial (Halpern, Ubel, Asch, 2007).

Despite all mentioned issues, the direction of changes in peoples' acceptance towards organ donation and awareness of factual and legal terms are positive but slow-growing. Currently prevailing model of consent supports organ donation in many of the European countries, nevertheless it still requires active and thoughtful support. Unawareness of the Polish society concerning current transplantation law and unwillingness to discuss organ donation within families strongly suggest that the subject of transplantology is perceived as taboo, which as

a phenomenon frequently results from lack of factual knowledge. Continuing this point, it appears that the low level of knowledge about organ donation and transplantation or the principle of presumed consent might mean that fear and insecurity around organ donation still remains prevalent (CBOS, 2016).

The current number of recorded objections in the Central Register of Objections has an upward trend. It is critical to recognize the reasons why individuals choose to make this decision as it may provide a basis for qualitative research with Ethical Committee approval due to the sensitivity of the topic. The nonverbal message encased in the question concerning the deceased's family consent to organ donation is also not without significance, as it assumes that lack of consent on behalf of mentioned behavioral theories is the default option. Theoretically, the family of the deceased should not be asked to declare their choice, but to consider whether the patient has ever made a decision or declaration that they do not wish to donate organs after death, and if possible, to find their declaration in order to place it into the records. Practically, in situation where family is not aware of presence of the presumed consent policy and is unaware of the approach of the deceased to organ donation, odds for the acceptance for organ procurement are considerably lower regardless of their legal insignificance. At this point some findings (Groot et al., 2015; Molina-Pérez et al., 2022) emphasize the model of expressed informed consent as it seem more difficult for families to question or overrule, thus prevent some of the dilemmas and make burdening decisions easier.

In the scope of medical law and professional ethics (Dz.U. z 2009 r. Nr 52, poz. 417; Dz.U. z 2008 r. Nr 136, poz. 857), non-life-saving surgical procedures require informed and voluntary permission. Concept of presumed consent is capable to fulfill these requirements only when the subject is aware of regulations in force. It is worrisome that according to the data from CBOS (CBOS, 2016) 80% of population does not know that they are considered as potential donor thus, by definition, are unable to give the required informed consent for organ donation. Even though *,ignorantia iuris nocet* (lat. not knowing the law is harmful), for 80% of population a presumed blanket consent for organ donation seems far from sufficient. In everyday practice physicians have no instruments to pursue organ procurement if the family, not without justification, fiercely resist it as it is morally questionable in case of potential absence of the deceased's approval. According to Biały (2016 as cited in Woderska, 2018), when considering the lack of evidence for organ donation approvement, it does not appear that the only possible answer will always be yes. The deceased, while still alive, may have been unaware of the applicable legal principles. Moreover, they may also have postponed the decision to announce the wishes for another time. This causes that organ procurement limited to the basis of implied consent is always an action in the presence of doubt.

5. Summary

The positive aspect of presumed consent is that the majority of Polish population is pro-donation which is supported by numerous studies (CBOS, 2016; Ruszkowski et al., 2020; Woderska, 2018). This means that the essence of presumed consent is met. Still, majority of people, wish to be taken into account as potential donors as they believe in the life saving aspect of this gift regardless of lack of factual knowledge in the field of transplantology and law. But in order to ensure voluntariness and liberty of decision as well as to prevent violation of one's right to self-determine it is fundamental to undertake activities such as public awareness campaigns and to inform patients about their rights in order to educate the society about transplantation in a relevant way. Some authors suggest (Molina-Pérez et al., 2022) that in an ideal model of consent to organ donation, aimed at increasing the number of donors and respecting their decisions, family should be prevented from questioning the consent of the deceased and be moved away from decision made under the influence of extreme emotions. As for now, family's acceptance of organ donation impacts greatly on the possibility to donate organs in Poland.

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