Ethical Dilemmas Related to Presumed Consent (opt-out)

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Abstract

In recent years, the demand for organ and human tissue transplants has increased, but the number of donors is still insufficient. Different legislative reforms have been proposed to increase the number of donors, but this has not necessarily caused a significant increase [1]. Among the different legal provisions, Presumed Consent (opt-out) has stood out as a legal mechanism for reducing the gap between demand and availability of human organs. The experience of Spain shows that the impact of this law together with other amendments led years later to an important increase of donors, but this did not happen in other countries in the area. Therefore, there may not be a direct relation between the introduction of the presumed consent law and increased donor rate [2]. From the viewpoint of some bioethicists, it is stated that presumed consent violates the spirit of voluntary charity and individual autonomy, and this would contradict the spirit of informed consent and would be ethically unjustified [3]. Many people would still not be aware of the law and therefore presumed consent may be equivalent to organ conscription.

Keywords: presumed consent (opt-out), ethics, ethical dilemmas

WHAT IS PRESUMED CONSENT (OPT-OUT)

All persons are considered organ donors, and it is enough not to have expressed a refusal to confirm them as such. In other words, it is necessary to express that one does not desire to be a donor to get out of the potential donor pool. This model has two versions, a strong one and a weak one. The former implies that if a person was not opposed during life to donating his organs, the procedure will take place regardless of the opinion of family members [4]. This is the case of countries like Austria (1982 Law), Finland (1985 Law), Portugal (1993 Law), Poland (1990 Law), Singapur (1997 Law), Republic of China (1984 Law), Turkey (1979 Law), among others. The latter, on the other hand, assumes that if during their life the persons were not opposed to being donors, the procedure will be carried out, but the opinion of the family will always be considered. This is the case of countries like Spain (1979 Law), France (1972 Law), Norway (1973 Law), Sweden (1996 Law), Italy (1999 Law), among others [4].
AVAILABILITY OF ORGANS FOR TRANSPLANTS

The standard donor potential of a country is a rate between 30 and 40 donors per million inhabitants (p.m.p). Based on this, the donor availability for some countries/regions can be assessed; for example, in the United States there are 25.8 donors (p.m.p). During 2013, the European Union reached 19.2 donors (p.m.p), while in 2011, it was 19 donors (p.m.p), and in Oceania, it reached 16.8 donors (p.m.p). The lowest rates are reported for Africa and Asia, with 2.6 and 1.1 donors (p.m.p), respectively. Latin America and the Caribbean have rates of around 4.5 donors (p.m.p), while the countries of the Southern Cone approach 7 donors (p.m.p). The exception is Uruguay, which reached an average rate of 17.1 donors (p.m.p) [5].

In Chile, according to the data of the Corporation del Transplant and the Ministry of Health, 2013 registered the lowest donor rate, with 5.9 donors (p.m.p), in contrast with 1998, when it was 7.7 donors (p.m.p), showing a negative growth of -23.3 during that period [6].

IS THERE A CAUSAL RELATION BETWEEN THE INTRODUCTION OF THE PRESUMED CONSENT LAW AND THE LATER INCREASE OF DONOR RATES?

Although several countries have a presumed consent system, this does not seem to be compulsory nor with an immediate effect on donor rates. For example, in Spain presumed consent had no effect on the donor rate until ten years later, while the USA does not have a legislation supporting presumed consent, yet both have high donor rates compared to other countries. Another example is Sweden, which adopted presumed consent in 1996, but (still) maintains a low-level 10 donors p.m.p rate afterwards [7]. In contrast, a studying 22 countries over a ten-year period showed that presumed consent legislation had positive and considerable effects on the rate of organ donation compared to later periods [7]. However, other studies state that the results are not definitive because there are methodological limitations that produce variations in them. In this relation, a systematic review published in 2009 showed that out of 13 chosen studies, only eight could compare the periods before and after the introduction of presumed consent, and only four of those studies were of sufficient methodological quality to give reliable results [8]. All of them assessed the impact of other factors such as mortality due to traffic accidents, cerebrovascular stroke, the country's transplant capacity, the per capita gross internal product (GIP), the per capita health expenditure, religion (Catholicism), education, public access to information, and a common law juridical system. The same study showed that in Austria the donation rates increased from 4.6 donors (p.m.p) to 27.2 p.m.p over a five-year period. However, it should be noted that this study did not consider other relevant changes that occurred at the same time that the presumed consent law was introduced, involving a limitation for the comparisons [8].

In 2012 a study analyzed the causality relation between presumed consent and increased donation in 13 European countries, showing that there were no substantial differences between the countries that applied the law and those that did not. Furthermore, it is stated that from the methodological standpoint there is high heterogeneity in the transplant systems to support the inferences that were made [9].

On the other hand, in Australia, the population has developed a positive feeling toward organ donation, but the donation rates are the lowest in the Western World. A telephone survey made in Central Queensland with (n = 1289) analyzed the trust of the people in terms of their decision to donate organs and on their support of presumed consent. Each of the predictors involved predicted independently the desire of those surveyed in favor of donating their own organs. However, this is in contradiction with the country's donor rate [10].

Another study used secondary data from Eurobarometer 2010 (n = 29,288) and compared the willingness to donate organs through a representative sample composed of 19 countries
with approved presumed consent (opt-out) laws versus 10 countries with prior consent (opt-in) laws, all of them European. Most of the participants (66%) declared that they were willing to donate their organs for transplants. The proportion of persons willing to donate their organs were not different between countries with opt-in (65.97%) and countries with opt-out (66.37%). When the people were aware of their country’s legislation, the proportion of persons willing to donate their organs was greater in countries with opt-out (85.26%) than in those with opt-in (80.72%). On the contrary, when the persons were not aware of their country’s legislation, there was no difference between the attitude of personas willing to donate their organs in opt-in (58.63 %) and opt-out (59.23 %) [11]. This suggests that the role of keeping the population informed on legal processes and other aspects related to organ donation is important.

RELATED ETHICAL CONFLICTS

Consent is the ethical cornerstone of all kinds of medical interventions. Without going deeply into the ethical issue, the problem faced by presumed consent is whether it is possible to consider it an authentic consent and in that way, from the legal standpoint, interpret it as a desire of an individual to donate his organs [12]. Therefore, from a philosophical approach of the law and of human rights, it can be argued that the right to dispose of one’s own body, even when it is a corpse, continues to be a highly personal human right. This concept belongs to civil law, and it states that some rights are inalienable and imprescriptible, that they only admit their enjoyment by their owners, who are born with them and cannot be separated even after their death. Those rights are defined as ”subjective private, innate and lifelong rights whose object is the inner manifestation of the person, and because they are inherent, nonproprietary and necessary, they cannot be transmitted or disposed of in an absolute and radical manner (as a law does it imposing a rule for everybody)” [13].

The right to donate is a right to decide freely and the right to express solidarity, recognizing the act as free choice, decision-making and generosity that people assume for themselves and share with their families. Therefore, it cannot be an act that is imposed, obliged, required, or manipulated by others. Donating organs must be an act of free and voluntary consent and adhesion, sustained by Article I of the Universal Declaration of Human Rights, which states that “All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood” [14].

From the characterization as a sui generis highly personal right and from the subjective right that represents the juridical powers or authorities inherent to man as a result of nature, contract or other legally admissible cause, with respect to the attention of the corpse, the following reasons appear as obstacles for the implementation of the presumed consent: first, disposing of the corpse is a power integrated in the core of essential human rights, and man himself is the only subject that can resolve on the final fate of his body; second, because of its highly personal nature, the right to dispose of one's own body has the qualities that typify these kinds of powers, among them intransmissibility, since nobody can decide better the fate of one's own body than the owner of that body [15].

Based on the above, it can be stated that presumed consent by law in case of silence would affect the aforementioned very personal right because the subject's will cannot be substituted, not even by legislators. Therefore, the argument of presumption would not be valid, not only because the intention of renouncing a very personal right “cannot be presumed”, it is a characteristic that is one's due of an “innate” nature that requires that the acts for which one
exerts those rights to be reputed as “voluntary,” that is, executed with discernment, intention and freedom [15].

From the standpoint of bioethics, the main problem is focused on the autonomy of individuals. The fact of not stating an objection can be a signal of the will to donate, but it can also be the result of ignorance or lack of interest. If that is true, removing a person’s organs when he actually did not want to would be an unacceptable action.

In this respect, there is much discussion on what is understood by consent and presumed consent, since from its definition, consent cannot be presumed, and at most, it would be hypothetical. For example, it can be said that a potential donor is actually a donor or whether a faked bill is actually a bill. It is therefore true that a presumption would be an assumption, but conditioned by various factors [16, 17].

According to the Merriam-Webster Unabridged dictionary, “presumed” comes from Latin praesumptus, praesumere (suppose), and the sense of the verb is to presume or suppose, anticipate. For example, it can be presumed that a group of colleagues will second a motion aimed at improving a procedure. A secondary sense of the term connotes the idea of a reasonable supposition or probability, so that the expectations of some are not necessarily the expectations of the others. However, a third sense of “presume” is “to take without adequate authority,” and it is closely related to “presumptuous”, which means, “to take liberties, to dare (do something).” In this context, it can be mentioned that the juridical sense of "presume" as "it is imminent to take as a result until the opposite is shown," which is very similar to presumed consent [18].

Currently there is an unresolved argument with respect to the concept of presumption, its scope in pragmatics and the theory of argumentation, stating that the nature of presumption is still under development [19]. In this respect, the following logical reasoning is stated: “all F cases are G”. From probabilistic or statistical viewpoints, it may be said that we have a percentage of property and property G in every case. On the other hand, presumption is a reasoning based on a challengeable general premise. If something owns “F” it can or cannot also own property “G” since this is challengeable. Another example is the problem of generalization of the presumption. “There is clear presumption that a person missing for seven years is dead”. Therefore, we can contrast the following: A universal generalization “The presumption that a missing person is dead” and the factual generalization “People missing for seven years are always dead.” The presumption is valid but the generalization is incorrect [20].

On the other hand, in the juridical sphere presumption has five dimensions: ontological, conceptual, epistemic, justificative, and logical. All of them allow challenging the applicability of presumption, because it is fallible and subject to revision, and allows challenging the manifestation of the presumptions when they are presented as conditional expressions in the argumentative discourse [21]. In the context of a policy of consent presumption, the State takes it for granted that for those who do not opt to express their refusal to be donors, their organs can be taken after their death if they are required and viable. But the question is: if the individual has not expressed that he wants to be a donor, is there consent for using his organs after his death? Regardless of what is established and from the argumentative standpoint, a relative may appeal simply because there is no evidence, since it is not clear that what is presumed is true.

From the perspective of bioethics, presumed consent would be backed by a utilitarian ethics. In this respect, Jeremy Bentham (1748-1832) proposed that any moral obligation is ultimately derived from the principle of utility, which considers that among the group of alternative actions we would be obliged to choose the one that provides greater benefit to the largest number of persons. On the other hand, John Stuart Mill (1806-1873) developed two other utilitarian postures; the first considers that a given action is correct if there is no great
difference between its good and bad consequences; the second considers that a given action is compulsory if the rest of the possible actions generate a smaller difference between its good and bad consequences [22, 23, 24]. However, the above brings up conflicts with principles such as autonomy and solidarity, but it is thought that a morality with a utilitarian or protectionist character is tolerable faced with the need for organs and tissues for transplants. Presumed consent is justified when subjecting individual autonomy to the needs of the collective (sanitary justification prevails over individual autonomy). However, it is not possible to ignore that the autonomy principle requires all the participants to consent to the action in an informed and voluntary manner.

The juridical-political organization of great part of present western societies, as well as their normative and institutional moral foundations are supported implicitly by personal autonomy, which conceives human beings as craftsmen of their own thoughts, decisions and actions. The autonomy does not only factually belong to the person and is not granted by others, it is a possession. This allows achieving one's own ideals through decisions and actions, made responsibly and worthy of moral merit. An intersubjective reason is that the recognition of autonomy leads to the reciprocal respect and recognition of others as moral agents. Autonomy can be understood from three dimensions. Decision-making autonomy, centered on the freedom of choice in view of the ability to deliberate and decide on a course of action among a range of valuable options through communication processes (information, willingness, and ability). Informative autonomy, consisting of the ability to dispose of and control information so that we can decide by ourselves when and under what conditions we will proceed with respect to our life and health. Functional or executive autonomy, referred to the freedom of action, acting, or abstaining [25].

As to the solidarity principle, it assumes that individuals that belong to a social group would be involved mutually with one another. From the ontological standpoint, this refers to the fact that the social whole is indissolubly involved in the fate of each of its members. This in turn leads to another additional principle responsibility, where every member of the community would be responsible for the good of the others. A fragmentation of this society makes it more vulnerable because it gets fewer benefits or goods in common. In turn, the solidarity principle is related to the principle of justice, which with respect to health must translate into a benefit to its members in a differential manner, favoring the more vulnerable sectors. This implies a system applied to transparent processes and adequate technical criteria, as ingredients for making decisions on the distribution of resources [26]. In matters of transplants, the principle of justice would seek to be able to establish equality and transparency conditions for all the individuals of the society that may be potential beneficiaries or donors.

**CONCLUSIONS**

From the standpoint of bioethics, presumed consent is in conflict mainly with individual autonomy due to the possible lack of information that does not allow making individual and conscious decisions. Therefore, would a utilitarian policy be acceptable without adequate information, stating that "silence means consent"? Does it make sense to talk about "consent" when what we are dealing with is to attribute to one person a non-opposition? Furthermore, the principles of protection and solidarity are reduced, since they are not stimulated in the individual but in a rather a contradictory imposition they are transferred to the State. So it can be stated that we are faced with an authentic paradigm that increases greatly the role of the State in the face of the citizens, and in this way the models of a transparent society, without privacy and without ontological autonomy.
On the other hand, the studies on the effect of the presumption of consent on donor rate do not explain by themselves the variations seen in the rates of organ donation among the countries. Legislation, donor availability, the organization and infrastructure of the transplant service, investments in health care, public attitudes, and sensitization to organ donation can play a role, but their relative importance is not clear due to the great heterogeneity found in most of these studies.

There is also an unresolved issue on the concept of presumption. This brings up the question of whether presumption of consent is real or it is a fiction from the argumentative standpoint. So it would not be ethically acceptable to extract organs from people who have not given their consent and would have been opposed to it, but did not leave written or verbal evidence of their opposition?

Finally, we must recognize the existence of a highly personal right that is intransmissible. So the right of disposal by some relatives to be the successors of the intestate is discarded. A presumed consent law can be understood as a well-meaning act aimed at social solidarity, but it looks a mistaken road that violates human decisions. We must insist that the act of donating an organ should be authorized expressly by the person, and it must be achieved promoting education, information, organization of a communication system that assures human beings of a free determination and a deep conviction that they are deciding on it according to a social solidarity principle, otherwise it is only a weak mechanism that generates uncertainty.

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REFERENCES


