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Presumed Consent for Organ  
Donation

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Aos meus pais

# Presumed Consent For Organ Donation

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## Abstract

The difference between supply and demand of transplantable organs is a global problem and one of the most discussed measures aiming to solve it is the implementation of a presumed consent (opt-out) policy in cadaveric organ donation. This kind of system is controversial both when it comes to its direct effects on organ donation rates and its ethical base. We aim to present the latest perspectives concerning the ethical implications of the policy, specially regarding consent: its need, the coherence of presuming it and the policy's capacity to fulfill its requirements. Regarding the issue at hand, a community perspective, the effects of defaults, *post-mortem* rights and the potential rights to family objection are also approached as well as the differences between theoretical discussion and concrete application of public policy.

Keywords: presumed consent; opt-out; organ procurement; transplantation.

## Introduction/Background

The revolutionary technique of organ transplantation appeared as an answer to a considerable and growing number of patients suffering from specific organ failures. This answer, as all therapeutic innovative procedures, brought with it a series of questions, particularly in the ethics and legislative fields – precisely the themes discussed in this paper.

When it comes to these issues the discussion arised not only in the same context as any other new medical-surgical intervention but also in one that is intrinsically dependent on the concept of transplantation – one had to consider not only the two usual perspectives– carer and patient- but also a new dimension or position – the donor’s. When considering the latter in addition to all legal necessities to guarantee his protection, when it comes to an ethical dimension never before has a procedure given rise to such questions – the invasion of someone’s (or his cadaver’s) physical limits (physical integrity) in such an extensive manner for sole clinical benefit of others.

This procedure uses two types of sources for transferable organic substrates - living and deceased donors – and while, when it comes to authorization and consent, the former can be asked about their willingness or not to donate and discuss their concerns and motivations, the same cannot be said of the latter, hence the fundamental need to create specific regulations for deceased donors.

In this last group, this decision and its respective statement will obviously have to be made *pre-mortem*, so that if the individual becomes a potential donor, agents can proceed accordingly. There are several different legislative schemes for this regulation:

- Explicit consent/opt-in: Only individuals that have officially registered their will to donate are considered *post-mortem* donors [1];
- Presumed consent/opt-out<sup>1</sup>: All individuals are considered donors after death unless they have officially registered their dissent [1];

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<sup>1</sup> In this introductory section these terms are used synonymously for mere simplification in the analysis of the policy’s empirical results. Later, the differences between both concepts will be explained and explored.

- Mandated choice, routine harvesting and programs involving incentives are other options - although their debate may be of great importance, they will not be discussed in this paper.

In both opt-in and opt-out systems the family may have a part to play in the decision (in some cases even full decisive power). When it comes to legislation if a "soft" mode is adopted, the family will be consulted and may reverse the official donation status of the deceased, but if a "hard" mode is adopted the law does not give them the right to have their opinion considered, let alone be entitled to a final say [2]. However, what is legislated is not always applied in clinical practice, as a matter of fact most practitioners consult the family and include them in the decision-making, regardless of the system in place[1, 3-9].

The increase in transplant waiting lists is currently a global problem, with a constantly increasing need for organs but very low numbers of available donors. That being, more and more patients are accumulating in a list that many believe underestimates the real need for organs [10] (for example: the knowledge of organ shortage may discourage physicians from enrolling their patients on the waiting list / patients that, after a long period of time on the waiting list become too debilitated to undergo major surgery and are excluded from it [8]).

This presents a very complicated situation for patients with organ failure, since in their case a transplant could vastly improve their quality of life, cure them or even save their lives. Aside from the obvious individual benefits for these patients one must also consider a positive financial impact for the health system itself [2], for example savings in chronic treatments such as dialysis in potential renal transplant recipients.

There are several different approaches when it comes to tackling the problematic difference between supply and demand that affects organ donation, being that the most discussed and debated is an increase in supply. Other suggested options (not necessarily less important) would be to implement measures to reduce the demand, prevent the waste of available organs or promote the development of new techniques and improvement of existing ones.

One particular measure that may play an important role in solving this issue, particularly regarding an increased supply of available organs, would be the implementation of a



presumed consent policy in cadaveric donation<sup>2</sup>[17], a legislation already in place in most European countries (21 of the 25 European Union member states)[1]. This measure will be the main focus of discussion in this paper.

There are different perspectives when it comes to the direct results of an opt-out policy in the number of *post-mortem* organ donations, but in fact almost all authors agree that donation rates are higher in countries where it is in place [3, 7, 18, 19].

Many argue that these results are not a direct consequence of legislation differences, but are instead the resulting effect of other confounding factors [11, 15, 18]. Among others it is mentioned that a switch to this type of system (only) demonstrates a more serious commitment towards increasing transplantable organs – the change in policy may have been just one of many measures applied with this goal in mind, being that the rest can act as confounders when evaluating the legislation's direct consequences [3, 18]. It is also discussed that other factors influence the effect of this policy on donation rates, in particular the consultation of next-of-kin [1, 18] and the registration system used (registration of consent/dissent/both) [7, 18], among others. The international discrepancies concerning these and other factors make conclusions about the data even more difficult [1, 11].

Two noteworthy facts are that despite the overall results described above not all countries have increased their donation rates after implementing this policy [15, 20, 21] and also that a considerable decrease in transplantation from living donors seems to affect countries where it is in place [3, 19].

As stated above the family is in most cases consulted regardless of the donation policy in place, and the fact that they, more often than not, have a final decision about the donation[4, 10, 16, 22] coupled with the fact that family consent varies according to the degree of explicitness of consent[22] (the more explicit the consent the more probable is

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<sup>2</sup> Several authors consider it unlikely that the isolated implementation of such a policy is able to solve donation problems by itself [5, 11, 12]. According to these an integrated and multidisciplinary approach (which does not necessarily need to include a change in legislation) is needed if the goal is to increase the number of donations [2, 13]. It is also said that an exclusive approach of this kind will have the risk (among others) of diverting attention from other measures that could be easier to apply and perhaps even more effective [1, 10, 14, 15], particularly ones aiming to decrease organ necessity/demand such as primary, secondary and tertiary prevention programs that can potentially reduce the incidence of terminal organ failures[16].

the acceptance[6, 7]<sup>3</sup>) may end up diluting to some extent the direct effects of consent legislation change.

Despite these facts there is a study stating that countries where family consent is not legally required exhibit roughly double the average donation rates when compared to countries where consent is required[7]. According to the authors a possible explanation is that different family approaches are used in each case, being that in the first case the family is simply informed that the donation will occur and that they have the possibility to object while in the second they are directly asked for permission to proceed [7].

In line with what was described the family ends up having a vital role when it comes to donation, affecting its results as much or more than the legal system in place[13]. That being so it represents a very important factor on which to intervene in an attempt to increase the number of actual donors [5-7, 17].

With this review we aim to organize, compare and present the different perspectives approached in the most recent literature concerning the ethical and social implications that the establishment of presumed consent for organ donation may bring.

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<sup>3</sup> In a presumed consent system we may have a larger pool of potential donors but families with less certainty of the deceased's will. In contrast, under a system of explicit consent we have a smaller donor pool but a family with more assurance of the deceased's will to donate because that intent has been registered. However, one must consider that that this can be countered if the change to presumed consent provokes a paradigm shift that turns donation into something natural and expected[8] - defaults may change perspectives - as will be discussed later on.

## **Methods**

To obtain a literary base for this review concerning the ethics of a presumed consent (opt-out) system applied to organ donation, a search was conducted in the MEDLINE®/PubMed® database using the following query (MeSH terms): “(tissue procurement) AND (presumed consent)”. The search was limited to papers published in the last five years so as to obtain the latest perspectives regarding the issue at hand. The following filters were also applied to the search: full text availability and Portuguese, English or Spanish language. The final result was 78 papers. All articles that after reading the title, abstract or full text were considered to be out of the scope of this project (34) were excluded. 2 articles could not be accessed.

## Results/Discussion

Autonomy is a fundamental principle in medical care [10, 23]. The concept of choice and consent takes a central role on modern societies and in what defines us as individual beings capable of reasoning, therefore such decisions (if voluntary and based on adequate information) must be respected, giving the individual the resources to defend his own values, goals and aspirations[12].

As stated earlier, while on almost every scenario the individual can reflect and make a decision to authorize or refuse when the situation presents itself, deceased organ donation presents a very particular case since it concerns procedures that are performed *post-mortem* and logically decisions and eventual actions to allow or refuse it must be performed *pre-mortem*.

It is not infrequent the opinion that people have interests even after their passing and these may be valued because they were significant to them while they were alive, to promote a socially desirable behavior or even as a way of familial psychological protection [24]. Accordingly, the premise commonly used is that a person has the right to decide what others may or may not do to her own body both during life and after their death[24, 25] which will mean that the removal of her organs without consent is wrong [10, 16, 25].

The core ethical discussion concerning this theme therefore consists of comparing two forces at play: the shortage of transplantable organs and concerns about autonomy, choice and consent [12]. Actually what is being discussed is whether or not it is possible to base an opt-out policy in an ethically acceptable type of consent or even if, to some extent, this policy would not be ethically justified even if it did not fulfill all conventional parameters of consent.

The term "presumed consent" is often used as a synonym for an opt-out system as it was in the introductory section but these terms, actually, do not have the same meaning.

“Presumed consent” in its purest and most basic meaning applied to organ donation is used as follows: it is presumed that someone consented to the removal of their organs when, during their life, they have not registered their dissent.

Another widely used approach is to use this term as a synonym for an opt-out policy when in reality it is just an example of a possible justification for this type of system.

The main practical component of an opt-out policy is that the default position becomes the removal of the individual's organs, being that in the case of an official registration of dissent, it is not performed. As stated earlier the contrary happens under opt-in systems in which non-donation is the default procedure and donation requires registration.

In the following section the main topics of discussion concerning the adoption of an opt-out system will be approached, starting with the discussion of presumed consent itself as a possible justification for this type of policy. We chose a topic organized structure not because the themes are unrelated but simply to facilitate their analyses.

## **1. May consent really be presumed?**

Within the consulted literature there isn't a single article that supports presumption of consent as a plausible justification for implementing an opt-out system. Several authors even question the real validity of the concept, defending that consent consists of an action and not a mental attitude or decision and one can't presume that an action has taken place if one knows for a fact it hasn't [13, 25, 26].

One situation when it is generally accepted to apply a presumption of consent is the requirement of an invasive procedure in a medical emergency with an unconscious patient, but even in this situation it may be argued that it is not presumed that consent has been given, it is presumed that the patient in question would consent if he had the capacity to do so, being that the justification for such presumption lies on acting in the patient's best interests[13]. The same can't be said when considering organ donation, it is not legitimate to appeal that it was in the individual's best interest to have his organs removed[13].

## **2. Implicit/tacit consent**

Instead of basing an opt-out system in a presumption of consent it may be argued that, if certain conditions are met, when an individual fails to register an objection consent has been given, although implicitly – the inaction in itself can be a sign of consent - making

presumptions unnecessary [22, 25, 26]. The aforementioned conditions are as follows: the meaning of inaction must be a matter of general knowledge[25]; dissent registration must be practically effortless[25, 26]; all information about the procedure and its consequences must be easily accessible<sup>4</sup> [25]. In this situation those that register their dissent will not be submitted to the procedure and only the ones that have not done so (those that have implicitly consented) will, so according to the authors, this justification respects the premise that the removal of organs is wrong if performed absent consent [25, 26].

In regard to the mental attitude that underpins the action of consenting (in this case implicitly) different opinions arise:

Some consider that by not recording his objection the individual is consenting regardless of his true feelings about the procedure, arguing that the mental attitude or intention is irrelevant if he actually consents - “no different from... someone who signs a consent form without intending to consent”[26].

Others strongly disagree : if a consent procedure doesn't accurately reflect the real opinion / will / mental decision of the subject won't it mean that we are using some kind of manipulation and therefore isn't the procurement of the consenting individual's organs immoral [22]? Although agreeing that in an ideal situation implicit consent could determine with good accuracy the exact will of the individual, this author considers that in this case an opt-out system gives few guarantees of approval-tracking [22]. This author's ideas are in line with others' when they state that approval or willingness to donate is something that is essential to the whole process[27]. It may however be argued that, in truth, there is no way to understand the desires and opinions of others if not by their actions, consequently (if certain conditions are met) one may say that an opt-out system is sufficiently approval tracking because people who disagree will have registered their dissent [28].

Although these last ideas may seem conflicting, even some authors who advocate intent as an essential part of donation agree that opt-out remains a voluntary system of donation

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<sup>4</sup> Regarding the need for informed consent in organ donation (in which the potential donors are well informed about the procedure's consequences, benefits and other details) opinions differ: some authors defend that guarantees that the individual is adequately informed are fundamental to the validity of the consent given [16] while others argue that easy access to such information already validates their consent - the individual can choose whether or not to inform himself of the details regarding the procedure [25, 27].

since there is a right to refuse even though, when it comes to donors, it may not be as accurately approval tracking as an opt-in system[27].

Various authors disagree, believing that just as it cannot be presumed one cannot accurately infer consent from inaction since it may happen for various reasons (ignorance or inertia towards official registration among others<sup>5</sup>) other than a purposeful act of implicit consent [9, 10, 16, 29]. Some even go further arguing that an opt-in system is the only way to provide clear evidence that the person wanted and intended to donate [10, 16].

### **3. Is consent really necessary?**

As previously mentioned the generally accepted premise is that it is wrong to proceed without consent and for some authors this is dogmatic, claiming that the only scenario in which it may be acceptable to remove an individual's organs is when there is clear evidence that this was his will, without room for speculations or assumptions [16].

However, others defend that an opt-out policy can be justified not based on any presumption or inference but on a theory that rejects the very premise of consent requirement [29, 30]. Based on a concept of “normative consent” –“ when it is wrong to withhold consent to something, the moral force of that lack of consent may be null and void”[30] - it is argued that it is morally wrong for the majority of the population not to consent to the collection of their organs (small individual effort vs. great benefit for others<sup>6</sup>) and consequently their consent for such procedure may not be necessary[29, 30].

According to the authors, this concept would be applicable using an opt-out system because, although people who do not register their dissent are considered donors, people with strong anti-donation feelings (and ones who simply for their own reasons, do not wish to donate) have the power to register their rejection and therefore not be subject to the intervention [29-31].

One of these authors takes this argument further and in a different direction by introducing the possibility of a new premise in which to base further discussion, it being that donation

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<sup>5</sup> An opt-in system may be subject to symmetric criticism: It is possible that not all citizens are aware of the possibility to donate or don't know how to register their intent [25].

<sup>6</sup> *Vide infra* the discussion about the concept of “easy rescue”.

is always permissible unless the individual refuses - the act of refusal would have the power to change the initial *status quo* – if this premise is taken to be true, consent would not only not be required but in reality would not even be applicable [29].

It is counter-argued nonetheless that this concept's use in this situation would more coherently justify an organ conscription policy – the indiscriminate procurement of organs – unbalancing towards totalitarianism a supposedly democratic system [32]. Its advocates disagree stating that, by allowing people the possibility to register as non-donors, this system maintains voluntariness [27], personal autonomy and choice[29-31] as part of the process.

Finally, according to the author's line of thought, an opt-out policy would have the objective of facilitating potential donations not because the subjects consent but because they do not object to it [8].

### **3.1. Individuality vs. Community – Easy rescue**

“Transplantation is a community endeavor that requires community obligation because it can only be achieved through organ donation”[27] - The very process of organ donation demands not only a discussion from the individual's point of view but also one that focuses on his part as member of a community.

Several authors argue that in most citizens' cases organ donation represents a situation of easy rescue since they are saving someone's life (or enhancing their quality of life) at little or no cost to themselves [29, 30, 33]. For this reason according to them there is a duty to donate/consent to donating [30], even more so when the objective is to help fellow citizens [30], being that some even compare refusal to withholding help from someone in need [33].

According to this argument because “most people do not sacrifice anything of moral significance when their organs are removed”, they have the moral duty [33] or even an obligation [31, 33] to donate. Because there is a possibility that the moral significance of the action represents too great a cost to bear from the individual's point of view (or even his family's [31]) he has at all times the right to register his objection[30].

Other authors, defending an even closer connection between individuals in a community, advocate that, in a democratic society facing such a serious problem there may be justifications to limit some rights that may constrain deceased donation (such as the right



to privacy and family life or the right to conscience and religion) in order to protect the potential recipients at risk [12]. In line with this train of thought, theoretically it can even seem justifiable resorting to a system in which the right to object would be dependent on the reason presented or even a system where there is no right for refusal, but for practical and political but also theoretical reasons it may seem better to allow any individual who feels this inclination as well as the motivation to act upon it the right to register it [33].

Not as a justification but rather as a potential effect of the establishment of this policy it is suggested that it may help people understand more clearly the way in which they can be physically independent but at the same time invested in their community's interests [33].

Regarding the notion of easy rescue some authors nonetheless argue that while it is currently advocated as a duty to provide basic assistance in an emergency, its employment to the case in question, such an invasive procedure, would be going too far, treating "people" as mere means to an end [16].

### **3.2. The autopsy example**

Nowadays in many countries autopsies are performed ,when required under the law, without the individual's [13, 25, 34] or his family's [17] consent or a possibility for refusal, even though they can also be considered to be a violation of the physical integrity of the corpse[33, 34]. To ethically validate this procedure a principle of justice is evoked, being that some authors argue that if these are ethically accepted justifications why isn't it ethically accepted to perform similar interventions when the principle at play is much more important (if not the most important of all) – the preservation of life[34]?<sup>7</sup>.

## **4. Defaults**

The real difference that comes with a change of policy from opt-in to opt-out systems can be defined as changing the default position from non-donation to donation [13] and the different effects defaults may have are due to a variety of factors:

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<sup>7</sup> One possible justification for this fact is presented: autopsies may be publicly more acceptable because they may serve the purpose of fulfilling the family's doubts regarding the death[23].

When it comes to organ donation as well as in so many other situations one can say that certain types of inertia interpose between the real wishes of an individual and the act of both making a decision and acting upon it [10, 29]. This clearly affects donation rates in opt-in systems, in which they can be quite lower than the reported will to donate [35]. It is almost unanimous that whatever the policy implemented it will inevitably be affected by this phenomenon [30].

It is a fact that defaults affect personal choice[35], in their decision people feel they need to have very strong reasons to deviate from the default and in cases of doubt the default is usually chosen [25]. A recent study shows that different default positions (different policies) alter the very meaning people attach to being a donor as well as the way they scale it as a moral obligation, thus taking effect in their decisions[36]. Participation or non-participation as a donor depends very much on the individual and collective meaning that is assigned to the choice at hand: When the default is organ donation the act seems like something natural, that everyone does unless some extraordinary factor renders the individual particularly reluctant to donate. On the other hand when the default is not to donate, the act appears to be something noteworthy and exceptional, not something one would do absent motive [36].

Some authors find the change of meaning that comes with a change in default a negative consequence, because in their opinion an opt-out system turns the act of donation into a default rather than a selfless act of solidarity [35] or a voluntary gift [10], depriving it of its altruistic meaning – even arguing that some recipients find it easier to accept the organs knowing they were voluntarily given [10]. Opposing this perspective others argue that, actually, the main objective should be to save lives, not to make people feel good about donating [8] because the main value of donation is instrumental, not expressive[26]. And besides, making the morally correct process easier does not invalidate or diminish its expressive value [26].

Specifically arguing in favor of an opt-out system several authors believe that the choice (they consider) morally correct should be the default[25, 31], leaving the burden of registration to people opposing it (making the less morally correct choice) [28]. From the community's point of view and in agreement with the referenced study, some say that one positive change possibly brought by an opt-out system could be a change of mentality, to instill an understanding that this should be the expected behavior of any citizen[37] while underlining the value of community involvement towards common good[33]. A change

in this direction may represent the establishment of a new perspective - facing donation as an acceptable and even natural part of dying [3].

## **5. Is the removal of organs from people who don't agree really worse than the non-donation of the ones' who agree?**

Whatever the policy in place there is no doubt there will be “mistakes” [13, 22, 30]:

By leaving to the dissenters the burden of officially registering their position, there is a risk that some people will have their organs removed against their will (because they never registered their opinion) [10, 13, 14, 29], this may even be one of the main reasons some members of the public oppose the implementation of an opt-out policy [13, 29].

On the other hand, using an opt-in policy there would be people willing to donate their organs but whose organs aren't used for the same reason[13]. Can one really say that the compromise of a right to self-determination is greater in the first than in the second case[8]? Wouldn't one be right in also considering the consequent needless loss of (quality of) life of the potential recipients when comparing both situations[8]?

In this case the severity of each fault must be compared in light of the magnitude we attribute to two different rights: the right not to have our mortal remains tampered with without consent vs. the right to a decision regarding their use [22], being that some authors vehemently defend that in this case action without consent would be more objectionable than inaction despite consent[24, 25].

## **6. *Post-mortem* rights**

What is the cadaver? Some authors state that the person in herself does not survive death, at least not her corporeal form as her body ceases to exist leaving in its place what is described as “non-unified remains of an earlier living body”[38]. Therefore, this can represent another argument in favor of adopting an opt-out system because, if the stated premise is right, it is not the person or the person's body that will be tampered with, so even if in that context the intervention is carried out without consent, neither the person's autonomy nor her rights to physical integrity or self-determination are compromised because they are not applicable [38]. It may be argued that if this is so, it doesn't make

sense for people to have the right to refuse donation, but as referred by one particular author “it is consistent to give people a choice even if they have no right to it”[26].

Nonetheless this theory has its critics who, disagreeing with such a drastic separation between person and cadaver, claim that those rights are in fact applicable and are consequently insulted when there is organ procurement without consent[16].

## **7. Does death really precede the intervention and the preparation towards it?**

The search for an accurate definition of the concept as well as the moment of death is the focus of an everlasting discussion.

This topic may be relevant for the argument at hand because, if it is considered that the person is still alive during the procedure or the preparation for it, one may say that it invalidates the easy rescue principle on which to base an opt-out system (and with it the previously discussed “normative consent” factor)[32]. Accepting this fact it is discussed that the dignity of the process of dying or even the person’s own dignity may be compromised [23] submitting her to procedures, some of them very invasive, with no clinical benefit to her as goal[16]. However, couldn’t taking what was stated as a fact, be taken even further calling into question the very process of cadaveric donation? (since we would be taking organs from people who are still alive or even anticipating their “death” in the process)[31].

Despite its described importance, the discussion of the concept and time of death is beyond the scope of this paper.

## **8. Minorities**

It is stated that an opt-out system, by allowing people to register their disagreement would not be prejudicial to people with religious beliefs that go against this type of procedures[30].

Anyway it is also suggested that as a safeguard measure certain ethnic or religious minority groups may choose to register their refusal as a community[10], just as can be decided on a state level not to apply this kind of system to the mentally incapable and

non-citizens (a policy already in place in countries like Belgium and Singapore) [23]. Specifically regarding the first two mentioned groups this measure can, however, cause social discomfort regarding the appropriate distribution of efforts/duties as well as questions about the role that an autonomous individual decision should play in this process [10].

## **9. Family**

Consulting the family during the decision process (essential according to some[10]) may be seen as a safeguard of the system so as to ensure that the actual wishes of patient are respected[8, 23] (as long as dialogue about the theme is promoted[39]) and also as important to the families themselves, because they can find comfort in being part of the decision[10].

An opt-in system may bring more assurance to the family that the deceased effectively wanted to donate his organs because that wish will be officially registered [22, 27] but on the other hand an opt-out system may allow even more protection for individuals who do not want to donate, since there is an official registry of their will that may serve as a guide for unsure family members [8, 28]. Still noteworthy is the fact that, as it affects potential donors' perspectives about donation, a change to an opt-out system can potentially have the same effect on the family's decision [8].

But should family opposition really prevent the procedure? [12]. According to some, organ removal against the will of the family can be inappropriate, counter-productive and even damage the doctor-patient-family relationship [10], but won't giving them a final say allow their views and opinions to overshadow the deceased's decisions [8, 16, 23], going against all principles of autonomy and respect for individual freedom[12, 23, 27]? Another advantage of a system that does not consult the family or at least does not directly depend on its authorization, may be that it relieves them of the heavy burden of making a decision at such an emotionally charged moment [12], and although some say this argument may come across as paternalistic, others consider that by doing so we would be relieving them of a decision that shouldn't be theirs in the first place[12].

Despite what was described, it may be reasonable to think that implementing a system that does not involve families could create public discomfort [23] as well as cause mistrust towards the donation program or even the national health system itself [10]. This could have very negative consequences since the family's feelings are very important to the actual success of this type of policy[23] - besides their possible contribution towards the decision, their support is also essential when it comes to providing information about the deceased that may be relevant to the procedures[10].

## **10. Public policy**

There are important differences between the theoretical discussion of a subject and the discussion of its real application as a policy or law since (among other aspects) the second requires one to take into account the context in which it would be applied – in this case a certain community with a certain background [33, 40] (for example regarding organ donation the political context is of the utmost importance[12, 29, 40]).

A policy like the one discussed here can (specially if poorly justified) trigger negative feelings in the general population: it can be perceived as a loss of autonomy [41], as some type of governmental intrusion on individual choices[14, 29, 33] or even as a state's attempt to claim ownership over its citizen's remains[33]. Any type of bad publicity or distorted interpretation of the system may generate anti-donation feelings possibly causing the mass registration of people as non-donors jeopardizing the very goal it aimed achieving [14, 33, 37].

Concerning organ donation therefore it is not just what may seem theoretically justified that is important, but also what will seem justified in the eyes of the public [33], relevant in this particular case mainly because no donation policy can work absent public support[10, 42]. In conclusion, when it comes to effectively implementing these legislations, public opinion surveys regarding donation in general and will to donate, as well as concerning specific donation policies (maybe including to some extent its justifications) and rights to family objection may be of the utmost importance.

## Final Considerations

When it comes to empirical results, the direct effects of an opt-out policy cause differences of opinion, but these are much greater regarding the ethical discussion.

Concerning the first, it is important to highlight that in fact countries with this policy in place have higher donation rates, although it seems difficult to establish causality. This difficulty may be attributed to the almost exclusive use of observational studies and it will not be easy to overcome since, by the very nature of the matter in question, experimental studies are very difficult or even impossible.

As far as the second goes, the argument is complex and a variety of themes are debated, however the main focus remains, as initially described, on the different opinions regarding the relative importance of two basic ideas: the perspective of the donor individual reflected on the importance of autonomy and the requirement of clear and explicit consent, and the perspective of potential recipients and the community as a whole defending the urgent need to increase organ availability.

First of all it is important to underline the general rejection of “presumed consent” as a concept, based on the incoherence of presuming an action that is known not to have taken place.

The policy in question may, nonetheless, be defended using other arguments:

- Some preserve the premise of consent necessity (“implicit consent”) – in this first case it is stated that if the meaning of inaction is generally known, information is easily available and registering dissent is effortless, if someone does not register he is, by his inaction, implicitly consenting;
- Others, on the other hand, reject it (“normative consent”) - in this second case the claim is based on the principle that there is a moral obligation to help when from one’s minimal sacrifices can result substantial benefit to others (easy-rescue effect);

However, none of these theories is immune to criticism or counter-argument.

Besides justifications, potential effects of this system are discussed as it can change people’s perspectives towards donation turning it into something natural and generally accepted – this phenomenon could be an important fact to address in future discussion.

Also stressed throughout the literature is the real importance family members have in the decision, even when they have no legal right to it. Taking this into account, once again two conflicting forces are compared : the compromise of the deceased's authority and autonomy when relatives have the final say versus the potential discomfort felt by the families for not being a part of the decision process.

Despite what great relevance the theoretical discussion of these issues may have, it is fundamental to have in mind that in discussion is a legal measure that will regulate a procedure associated with a heavy emotional component, and therefore it is as important to have an ethically valid proposal as is the coherent application of measures and the public presentation of an explanation that people can both understand and relate to.



## Competing interests

The authors have declared that no competing interest exists.

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## Anexos



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