**Differential impact of opt-in, opt-out policies on deceased organ donation rates: a mixed conceptual and empirical study**

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# Abstract

**Objectives:** To increase post-mortem organ donation rates, several countries are adopting an opt-out (presumed consent) policy, meaning that individuals are deemed donors unless they expressly refused so. Although opt-out countries tend to have higher donation rates, there is no conclusive evidence that this is caused by the policy itself. The main objective of this study is to better assess the direct impact of consent policy defaults *per se* on deceased organ recovery rates when considering the role of the family in the decision-making process. This study does not take into account any indirect effects of defaults, such as potential psychological and behavioural effects on individuals and their relatives. **Design:** Based on previous work regarding consent policies, we created a conceptual model of the decision-making process for deceased organ recovery that included any scenario that could be directly influenced by opt-in or opt-out policies. We then applied this model to internationally published data of the consent process to determine how frequently policy defaults could apply. **Main outcome measures:** We measure the direct impact that opt-in and opt-out policies have *per se* on deceased organ recovery. **Results:** Our analysis shows that opt-in and opt-out have strictly identical outcomes in eight out of nine situations. They only differ when neither the deceased nor the family have expressed a preference and defaults therefore apply. The direct impact of consent policy defaults is typically circumscribed to a range of 0% to 5% of all opportunities for organ recovery. Our study also shows that the intervention of the family improves organ retrieval under opt-in but hinders it under opt-out. **Conclusions:** This study may warn policy makers that, by emphasizing the need to introduce presumed consent to increase organ recovery rates, they might be overestimating the influence of the default and underestimating the power granted to families.

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| Strengths and limitations of this study  * We used a mixed methods approach combining conceptual analysis and empirical data to estimate the potential impact of consent policies in a novel manner. * We compared the result of the decision-making process under opt-in and opt-out in nine different situations determined by the preferences of the deceased, the preferences of the family, and the default. * We obtained data from 21 countries in the five continents. * The study considers only the direct effect of opt-out on organ retrieval rates, but not its potential indirect effects, such as psychological and behavioural effects. * The main limitation of the study is the heterogeneity of sources, sample sizes and time periods for the data collected. |

# Introduction

There is an international trend to move from explicit consent (opt-in) to presumed consent (opt-out) policies for deceased organ retrieval: Chile (2010), Finland (2010), Greece (2013), Uruguay (2013), Wales (2015), Colombia (2016), Iceland (2019), the Netherlands (2020), England (2020), Scotland (2021), the province of Nova Scotia in Canada (2021), and Switzerland (2022) have implemented opt-out policies in recent years. Australia, Denmark, Germany, Israel, Romania, and several states in the USA have been discussing this as well[1].

Some studies suggest that presumed consent laws contribute to increased organ donor rates[2–7], while others dispute this claim[8–13]. Research reviews within this field point out an association between presumed consent legislation and higher organ recovery rates, but they also warn against the assumption that the introduction of presumed consent legislation *per se* is its sole cause[14–17]. International evidence tends to show that opt-out systems can be effective as part of a wider package of measures, but the body of evidence that opt-out legislation in isolation causes increases in organ donation rates lacks robustness and is sparse[18]. Consent policies may, in fact, be just one factor among many, with infrastructure or organisational changes producing greater gains than legislative change alone[19,20]. The role families are allowed to play in the process of organ retrieval decision-making may be another factor tempering the effectiveness of presumed consent policies[9,21–23].

To measure the potential impact of legislative change *by itself*, in isolation of other measures, it is important to distinguish between consent policies’ direct and indirect effects. Opt-out policies can be conceived as behavioural nudges: non-coercive means aimed at fostering specific behaviours to promote beneficial outcomes[24,25]. By setting organ donation as the default and taking advantage of people’s tendency to prefer the *status quo* (i.e. their propensity to stick with the current state of affairs or choose default options), opt-out policies aim to foster higher rates of organ donors. The underlying assumption for moving towards opt-out is that the default would almost automatically turn those who are undecided or unconcerned about organ donation into actual donors[26,27]. This is what we call a direct effect of the consent policy.

Changing the legal default donor status from non-donor under opt-in to donor under opt-out can have multiple indirect or secondary effects. For example, it may enable the initiation of organ preservation measures before ascertaining the deceased’s preferences or obtaining the authorisation of the family. This could explain the higher prevalence of uncontrolled donation after circulatory arrest protocols—which require expeditious organ preservation measures—in opt-out countries as compared to opt-in countries[28,29]. Other indirect effects are psychological and behavioural, such as increasing people’s awareness and conversations within families about organ donation, influencing the meaning they assign to donating or not donating[30], altering their registration behaviour[31,32], fostering professionals to identify and refer potential donors and approach their relatives when the deceased failed to register any preference, and changing the conversation between health professionals and relatives[6,33]. In Wales, an increase in family authorisation rates could be explained by such indirect factors, including increased societal concern about organ scarcity, growing confidence of families in healthcare professionals, and specialist nurses’ training and familiarity with the legislation[34]. However, the introduction of opt-out legislation can also have negative effects, such as the lone wolf effect[35], lower incentives for living donation[36], heightened reactance arising from perceptions of unwarranted government control[37], or even backlash, as it occurred in Chile and Brazil[38,39]. In sum, although there is a vast body of empirical literature on the indirect effects of consent policy defaults, overall the available evidence is often conflicting and inconclusive[15,17].

In this article, we aim to determine the direct effects of consent policies *per se*, in isolation of other measures and country-specific confounding factors. To do so, we focus on the outcome of the decision-making process as determined solely by the preferences of the deceased, the preferences of the family, and the default. First, we propose a conceptual model showing the differential impact that opt-in and opt-out policies can have *per se* on organ recovery rates, i.e. regardless of the country in which they are implemented. Then, we provide empirical evidence for the model based on comprehensive data from six European nations and partial data from 16 other countries worldwide. Finally, based on available data on deceased and family preferences, we estimate how changing the default and role of family, *ceteris paribus*, can directly affect retrieval rates.

# Methods

The development of the research question and outcome measure was informed by the results of a systematic review on public knowledge and attitudes towards consent policies for organ donation[40] and by a conceptual framework of the role of family in organ retrieval decision-making[41]. The review’s results suggested, on the one hand, that people's awareness of the consent model is lower in opt-out countries than in opt-in countries, which raises ethical concerns with regard to the respect of individual autonomy, and, on the other hand, that despite the general tendency in Europe and elsewhere to move from opt-in to opt-out policies, a majority of the public tend to prefer opt-in and mandatory choice to opt-out when two or more options are offered. The framework’s results suggested that there is no significant difference between opt-in and opt-out policies when family preferences are considered.

## Conceptual model

We used the following conceptual model to assess how consent policies can impact organ retrieval rates. This model allows for an examination of the consent policies *per se*, regardless of country-specific confounding factors such as organisation and infrastructures, professionals’ training, incentives, media campaigns, cultural backgrounds, etc.

First, we broke down consent policies into their core components[42]. As their name suggests, opt-in and opt-out policies are relative to individual preferences. This is the first element to consider. Organs may be retrieved when people expressed their consent as *post-mortem* organ donors (opt-in) and they may not be retrieved when people expressed their refusal (opt-out). In some countries, such as Germany and the Netherlands, individuals can also choose to delegate the decision to their relatives or a designated proxy. This introduces family preferences as a second element to consider. Indeed, whether the deceased’s organs are recovered or not may eventually depend on the next-of-kin’s attitudes towards donation. The third element is the default option set by each policy when no preferences have been expressed whatsoever. In such circumstances, organs can nevertheless be retrieved under opt-out, based on presumed consent, whilst they cannot be retrieved under opt-in.

The procedures deemed valid to express a preference regarding organ donation are also an important part of consent policies. These procedures may include consent and/or refusal registries, organ donor cards, living wills and other written documents, as well as conversations with relatives. Although some of these procedures can exist in a given country, they may be inconsequential as long as people are unfamiliar with them. For example, in France, the refusal register is by law the main procedure to express a decision, but less than 0.5% of the total population were listed in it by 2017[43]. For the sake of simplicity, considering the diversity and varying degrees of use of these procedures, we decided not to include them in our analysis. In the following analysis, we will consider the preferences of individuals and relatives, and the role they play under each policy, regardless of the means by which these preferences can be expressed in any given country.

Secondly, based on the aforementioned core components of opt-in and opt-out (individual preferences, family preferences, and defaults), we identified all the situations where the retrieval outcome depends on individual and/or family preferences or the lack thereof[42]. When relatives’ preferences are *not* taken into account, only three possible situations arise, as the deceased person may have either: (*A*) expressed their consent to donate; (*B*) expressed their refusal to donate; or (*C*) failed to express any decision regarding donation, in which case the default applies. When relatives *are* consulted, their own preferences regarding the recovery of organs from their loved ones may be either (*a*) favourable, (*b*) unfavourable, or (*c*) unknown. The combination of the preferences of the deceased and those of the family thus creates a total of nine (3x3=9) situations (Table 1).

Table 1. ***Consent-related situations that affect the retrieval outcome under both opt-in and opt-out policies***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Family preferences** | | |
| **a) Favourable** | **b) Unfavourable** | **c) Unknown** |
| **Deceased’s preferences** | **A) Consent** | Agreement in favour | Conflicting preferences | Deceased’s consent |
| **B) Refusal** | Conflicting preferences | Agreement against | Deceased’s refusal |
| **C) Unknown** | Family authorisation | Family opposition | Default applies |

Thirdly, we compared the outcomes of opt-in and opt-out policies in these nine situations. For example, whenever the deceased expressed their willingness to donate (*A*) and the family also expressed their authorisation (*a*), organ recovery is most likely to proceed in either opt-in and opt-out policies. This way, by comparing the two policies in each and every scenario, the identification of the situations producing the same retrieval outcome under both policies and those producing variable outcomes is straightforward. This allowed us to evaluate the relative impact of opt-in and opt-out policies *per se*, regardless of the country-specific confounding factors where these policies are implemented.

## Review of the empirical data available

We sought empirical data to confront our conceptual model with real-world national figures.

*Eligibility criteria*. Openly available data, from peer-reviewed articles or grey literature reports from official sources (governments, transplant organisations), from any country, without language restrictions, published in the last ten to fifteen years, reporting the expression of preferences or the lack thereof, from either the deceased person or their relatives, in all cases of potential/eligible deceased donors. Studies were eligible when the data reported were detailed enough to determine the relative frequency of the situation where defaults apply according to our conceptual model, that is, when both the deceased’s preferences and the family’s preferences are unknown (Table 1, situation *Cc*). Studies were ineligible when the data for this outcome of interest were not reported or could not be determined using the reported data.

*Information sources*. We searched the Pubmed and Google Scholar databases, and the ResearchGate platform, from August 2020 to February 2021. We also used Google’s search engine to find and consult the websites of ministries of health and national transplant organisations, when available. The search for data ended in February 2021, although we continued to examine some reports after that date, especially from Austria and Denmark.

*Search strategy*. We used the following sequences of English terms to search Google Scholar, Pubmed, and ResearchGate: *potential donor(s)*, *potential organ donor(s)*, *organ donor audit*, *potential organ donation*, *organ donation activity*, *organ donation referral*, *organ donation statistics*, *organ transplantation statistics*. We also used the corresponding sequences of terms in French and in Spanish (e.g. “statistiques don organes”, “estadísticas donación de órganos”). In addition, in the case of Pubmed, we searched the MeSH terms: “Tissue and Organ Procurement/statistics and numerical data” and “Organ Transplantation/statistics and numerical data” in combination with country names.

*Selection process, data extraction and quality assessment.* One reviewer screened and collected data from each report. We contacted national officials and researchers to help us locate relevant data from their respective countries, if any, and also to clarify or confirm the information we had collected. To determine the eligibility of some reports, we used automated translation tools (e.g. Google Translate) and solicited help from native colleagues. To ensure accuracy, we contacted representatives of health ministries and national transplant organisations for clarifications or for confirmation of our findings. Evidence for the Netherlands, the United Kingdom, and Denmark have been double-checked and confirmed through personal communications with the *Nederlandse Transplantatie Stichting* (NTS), the National Health Service (NHS), and the *Dansk Center for Organdonation*, respectively. Evidence for Germany has been checked with the assistance of German researchers on organ donation. In a few instances, when no written source of information was available, we contacted the heads of national transplant organisations and other officials for comments.

*Risk of bias*. To limit potential bias caused by country-specific characteristics, such as religious and cultural background, population size, income per capita, health expenditure, and organ donation and transplantation systems, our search specifically targeted—but was not restricted to—a broad range of countries with very diverse characteristics from all continents (except Antarctica) and all of the continental subregions devised by the United Nations geoscheme—except for Melanesia, Micronesia, and Polinesia because no deceased organ donation has been reported there. This list includes the following 56 countries: Algeria, Argentina, Australia, Austria, Belarus, Belgium, Brazil, Canada, Chile, Colombia, Cuba, Croatia, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Iran, Ireland, Israel, Italy, Japan, Kazakhstan, Kenya, Lithuania, Malaysia, Mexico, the Netherlands, New Zealand, Nigeria, the Philippines, Poland, Portugal, Romania, Saudi Arabia, Singapore, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Thailand, Türkiye, the United Kingdom (in general) and Wales (in particular), the United States, and Uruguay. The countries in this list represent more than two-thirds of the 70+ countries having reported any deceased organ donation activity to either the World Health Organisation’s Global Observatory on Donation and Transplantation ([GODT](http://www.transplant-observatory.org/)) or to the International Registry in Organ Donation and Transplantation ([IRODaT](https://www.irodat.org/)).

More detailed information about the sources and methods is available in a Supplementary File.

## Patient and Public Involvement

No patient involved.

# Results

## Model results

The three core components of consent policies that influence the outcome of the decision-making process (organ retrieval or non-retrieval) are: (i) the deceased’s expressed preferences, if any; (ii) the next-of-kin’s preferences, if any; and (iii) the default option set by each policy.

When family preferences are *not* taken into account, a side-by-side comparison of opt-in and opt-out policies shows that they have identical retrieval outcomes in two out of three situations, that is, whenever the deceased had either consented or refused organ donation (Table 2). These two policies only differ in one situation: when the deceased person failed to express any decision and the default therefore applies. In this situation, the absence of an explicit consent precludes organ retrieval under opt-in while the absence of an explicit refusal allows it under opt-out.

When *both* the individual and the family preferences are taken into account, a side-by-side comparison of opt-in and opt-out policies shows these policies having rigorously identical outcomes in eight situations out of nine (Table 3). The sole situation when these policies make a difference is when their defaults apply, that is, when the preferences of both the deceased and their family remain unknown to the medical team.

Table 2. *Outcome (organ retrieval vs non-retrieval) from organ recovery decision-making based on the deceased’s decision and the model of consent.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Deceased’s decision** | **Consent** | **Refusal** | **Unknown** |
| **Opt-in** | ✔ | ✗ | ✗ |
| **Opt-out** | ✔ | ✗ | ✔ |

Table 3. *Outcome (organ retrieval vs non-retrieval) from organ recovery decision-making based on the deceased’s decision, family attitudes, and the model of consent.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Deceased’s decision** | **Consent** | | | **Refusal** | | | **Unknown** | | |
| **Family preferences** | **In favour** | **Against** | **Unknown** | **In favour** | **Against** | **Unknown** | **In favour** | **Against** | **Unknown** |
| **Opt-in** | ✔ | ✔ or ✗ | ✔ | ✗ | ✗ | ✗ | ✔ | ✗ | ✗ |
| **Opt-out** | ✔ | ✔ or ✗ | ✔ | ✗ | ✗ | ✗ | ✔ | ✗ | ✔ |

Check-marks (✔) mean that organs may be retrieved; X marks (✗) mean that organs may not be retrieved. When the deceased had consented, organs will likely be retrieved unless the family objects, this being the case for both policies. If the family is against organ retrieval, the likely outcome under opt-in and opt-out will depend on whether the family is allowed to overrule (veto) the deceased’s consent. When the deceased had refused to donate, organ retrieval is unlikely to proceed under any circumstances (regardless of family preferences or the default rule), as this would be contrary to the ethical principles of organ retrieval and transplantation 28. Finally, when the deceased had failed to express any preference, there is no difference between opt-in and opt-out whether the family authorises or opposes organ retrieval: in both cases, the expressed preferences of the family will be respected. The only situation where consent policies actually differ in their outcome is when both the preferences of the deceased and those of the family are unknown. Family preferences can be unknown to the medical team in the following circumstances: the deceased had no remaining family or close friends to be consulted, they may have not been contacted in time or may be too emotionally distressed to be consulted about organ recovery, or they could hold conflicting views on the matter.

According to this conceptual model, when comparing the outcomes of each situation in the tables above, the differential impact of opt-in and opt-out policies is entirely determined by the default, which only applies when preferences have *not* been expressed. This does not exclude the existence of a differential impact of consent policies based on indirect effects, such as the meaning assigned to the act of donating or not donating, people’s registration behaviour, or family authorisation rates. But whether and to what extent these indirect effects can increase organ recovery rates may depend on contingent factors that vary from country to country or population to population, including religious and cultural backgrounds, public attitudes towards the donation and transplantation system, health professionals’ training, etc.

## Empirical evidence

We obtained relevant empirical data from 21 countries in the five continents. Considering the diversity of sources and varying quality of the data, we classified the evidence obtained in two tiers: confirmatory evidence and additional supporting evidence. *Confirmatory evidence* includes comprehensive statistics from either government backed official reports or retrospective studies. *Additional supporting evidence* includes partial statistics from official reports and retrospective studies.

*Confirmatory evidence.* We found comprehensive nationwide statistics from official sources in Denmark, Germany, the Netherlands, and the United Kingdom, and from peer reviewed retrospective studies in Sweden and Wales. In addition, we found comprehensive statistics from a retrospective study of all patients who died at one of the largest hospitals in Denmark between 2000-2003 and 2007-2010. Our findings show that, when families intervene, the situation where defaults apply according to our analysis—i.e. when both individual and family preferences are unknown—is limited to a range of 0% to 4% of all organ retrieval opportunities, based on the available empirical data from these six countries (Table 4; see supplementary file for more detailed information about the data, sources, and methodology).

Table 4. *Actual frequency of each scenario among potential organ donor cases when both the deceased’s decision and the family’s preferences are considered in Denmark, Germany, the Netherlands (NL), Sweden, the United Kingdom at large (UK) and Wales in particular.*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Deceased’s decision** | | **Consent** | | | **Refusal** | | | **Unknown** | | |
| **Family preferences** | | **In favour** | **Against** | **Unknown** | **In favour** | **Against** | **Unknown** | **In favour** | **Against** | **Unknown** |
| **Denmark** | Opt-in  N=235a | n/a | n/a | 6 %h | n/a | n/a | 8 %h | 32 % | 51 % | 3 % |
|  | N=163b | n/ai | 2 % | n/ai | n/a | n/a | 7 %h | 61 %i | 29 % | 1 % |
| **Germany** | Opt-in  N=1,399c | n/a | n/a | 32 %j | n/a | n/a | 9 %j | 42 % | 16 % | 2 % |
| **NL** | Opt-in\*  N=1,039d | 19 % | 3 % | 0 % | n/a | 0 % | 15 % | 16 % | 43 % | 4 % |
| **Sweden** | Opt-out  N=1,275e | n/a | 0 % | 35 %h | n/a | n/a | 14 %h | 36 % | 14 % | 2 % |
| **UK** | Opt-in\*  N=1,542f | 37 % | 2 % | 0-1 % | n/a | 5 % | 0 % | 33 % | 20 % | 0-2 % |
| **Wales** | Opt-out  N=182g | 49 % | 7 % | 0 % | n/a | 19 % | 0 % | 15 % | 10 % | 0 % |

Each row corresponds to one possible scenario that combines the deceased’s decision (consent, refusal, or unknown) and the family’s preferences (in favour, against, or unknown). The frequency of each scenario is indicated as a proportion of the total number of cases of potential organ donors in each country. For instance, out of 1,039 cases of potential organ donors in the Netherlands in 2018, 16% of these cases correspond to the situation where the deceased’s decision was unknown and the family authorised the removal of organs, 43% correspond to the situation where the deceased’s decision was unknown and family opposed recovering the organs, and 4% correspond to the scenario where both the deceased’s and the family’s decisions were unknown. These figures show how potential donors cases are distributed among the nine possible scenarios. Because some potential donors do not become effective donors, the official percentages of organ retrieval/non-retrieval in each country may differ slightly from those displayed in this table. See the additional file for further details.

\* The Netherlands, England, and Scotland implemented an opt-out system in 2020.

a Potential donors in a single hospital over two periods of 3.5 years each (2000-2003, 2007-2010).[44]

b Potential donors nationwide in 2020.[45]

c Potential donors after the determination of death in 2018.[46]

d Potential donors in 2018.[47]

e Eligible organ donors from 2009 to 2014.[48]

f Potential donors after brain death (DBD) alone, from 1 April 2018 to 31 March 2019, in the UK at large (including Wales).[49]

g Potential donors from December 2015 to February 2016.[50]

h Detailed family preferences data when the deceased had consented or refused is not available and is reported here as unknown.

i In all cases of actual donors, we have not been able to determine the proportion of individuals who had registered their consent, i.e. whether organ recovery could proceed based on the deceased’s consent (first and third columns) or on family’s authorisation (seventh column). All these cases (61%) are reported here as if the deceased’s wishes were unknown and the family had authorised, but an unknown proportion of them should appear as cases of consent from the deceased.

j In Germany, according to DSO officials, when the deceased has expressly consented or refused organ donation, the opinion of the family is almost always known (personal communication). However, as the family is not allowed to authorise or oppose the recovery of organs, and the percentages of families who would support or oppose organ recovery in these circumstances is not available, all these cases are reported as unknown.

*Additional supporting evidence.* We found partial statistics from 16 countries regarding the situation where policy defaults apply according to our analysis. In particular, we found nationwide statistics from official sources in Belgium, Chile, Colombia, Ireland, Spain, Sweden, and Switzerland. We also found retrospective studies, mostly from a single hospital and varying periods of time, in Australia, Brazil, Finland, France, Hong Kong, South Africa, South Korea, Spain, Türkiye, and the United States. In addition, we obtained informal comments and assessments through personal communication with officials from Belgium, Colombia, Denmark, Finland, France, South Korea, and Spain. More detailed information about the data, sources, and methodology is available in the Supplementary file.

Results suggest that the potential differential impact of opt-in and opt-out policies, according to our analysis, is limited to a range of 0% to 2% of all retrieval opportunities in six countries (Australia, Chile, Colombia, Finland, South Korea, and Spain), to a range of 3% to 5% in six countries (Belgium, France, Hong Kong, Switzerland, Türkiye, and the United States), and to more than 5% in three countries (Brazil, South Africa, and Sweden). These results coming from a wide variety of countries are consistent with those detailed in Table 4.

## Estimation of potential retrieval rates under different policies in six countries

To better assess the relative impact of the family’s intervention in each consent system, all other things being equal, we estimated the potential for organ retrieval in four distinct scenarios (Fig. 1). On the one hand (left), we considered opt-in and opt-out policies based on the deceased’s wishes alone, without any family intervention. On the other hand (right), we considered opt-in and opt-out policies based on both the deceased’s and the family’s wishes. In other words, for each reviewed country, we estimated the potential for organ retrieval if the policy in place in that country was: (α) opt-in and deceased’s wishes alone; (β) opt-out and deceased’s wishes alone; (γ) opt-in with family intervention; and (δ) opt-out with family intervention (see the supplementary file for more information about the data and methodology).

FIGURE 1 HERE

The estimated potential retrieval rates in these four scenarios, according to our analysis of defaults, suggest that individual consent policies only make a significant difference when family preferences are disregarded. In this case, moving from opt-in to opt-out may dramatically increase the number of potential donors from which organs can be retrieved (left bars). However, when families are allowed to intervene and their own preferences are taken into consideration, then the potential retrieval outcomes under opt-out are just a little higher than under opt-in (right bars). Here, we only consider the direct effects of a change in policy, all other things being equal, and not the indirect effects that a change in policy would most certainly entail.

# Discussion

Our analysis of the core components of consent policies (individual preferences, family preferences, and defaults) shows that opt-in and opt-out models perform identically in all but one situation, i.e. when preferences have not been expressed and therefore defaults apply. It is the frequency of this particular situation that determines the direct impact of consent policies *per se*, in isolation of other measures and indirect effects, on organ recovery rates.

*If only the preferences of the deceased person were taken into account*, the opt-out would allow the recovery of organs from all individuals who have expressed no preference, while the opt-in would prevent it. Depending on how often this situation would happen in a given country, switching from opt-in to opt-out could dramatically increase organ recovery rates.

However, there are few countries in the world where only the preferences of the deceased person are considered[3,21,41,51–53]. On the contrary, most opt-in and opt-out countries worldwide allow the family, either *de jure* or *de facto*, to make a decision when the deceased had not, and even to overrule the deceased’s consent to donate (cf. Supplementary file)[9,41,53].

*If both the preferences of the deceased and those of the family are taken into account*, then the opt-out enables the recovery of organs when both individual and family preferences are unknown to the medical team. This is obviously a less frequent situation. Based on empirical data, if any of the reviewed opt-in countries decided to adopt an opt-out policy, the application of the default *alone* in this particular situation could, by itself*,* increase organ recovery by 0% to 5%. Conversely, if any of the reviewed opt-out countries decided to adopt an opt-in policy, this legal change *alone* could *by itself* decrease organ recovery by 0% to 5%.

However, it appears that some opt-out countries are not taking full advantage of the opportunity provided by presumed consent to retrieve organs without explicit authorisation. In France, Sweden, and Türkiye, we found that “family disagreement” and “relatives could not be contacted” were mentionned as reasons for non-donation. This means that organs were *not* recovered when both individual and family preferences were unknown to the medical team. Indeed, doctors may feel reluctant to procure organs without any expressed consent or authorisation, even when they are legally allowed to do so. In Belgium, Finland, and Spain, officials informed us that, to their knowledge, the situation where the deceased didn’t express any preference, the family could not be reached or make a decision, and organs were nevertheless procured—according to the law—is very rare. In addition, a review of organ donation laws in the EU pointed out that in Cyprus and Greece organs cannot be legally recovered without the authorisation of the deceased’s relatives [54]. Therefore, the direct effect of changing the default alone might be smaller than indicated above because, in practice, the opt-out default is not necessarily implemented to its full potential. That said, changing the default may also cause indirect effects, including on the behaviour of individuals and families, which could increase or decrease organ recovery beyond the figures indicated above, but such effects are beyond the scope of this work.

Previous studies have shown that in most countries, both opt-in and opt-out, families are consulted in order to make a decision on organ donation [9,53]. Furthermore, we have previously shown that, in most countries, the role of the family in organ donation decisions is greater in clinical practice than according to the law [41]. However, we had not been able to assess how common it is for families to be consulted in a given country. A contribution of this article is to provide both qualitative and quantitative insights into how and to what extent family preferences are used in organ donation decisions. On the one hand, we can now state quite confidently that when the deceased did not leave a written record of their preferences, family members are almost always consulted, either as witnesses to the deceased's wishes or to make a decision based on their own preferences. This applies to those countries we have been able to include in this study. However, we lack sufficient data from some opt-out countries where the results might be different, including Argentina, Colombia and Uruguay where recent laws prevent the next-of-kin from opposing organ recovery, as well as Austria, where this has been the case for a long time. In France, although families can no longer legally object to the recovery of organs since 2017 (but can only act as a witness to the deceased's wishes), family objections have not disappeared but rather increased since then, reaching 37% in April 2022 (46% in the Paris region), according to a press release from the Agence de la Biomédecine (dated 15 June). All this affects the direct impact of consent policies *per se*, because whenever preferences are taken into account, defaults are not applied.

On the other hand, our study shows that the intervention of the family improves organ retrieval under opt-in but hinders it under opt-out (Fig. 1). Though this may seem counter-intuitive, a plausible explanation for this phenomenon is the following. The intervention of the family increases the proportion of likely organ donors under opt-in policies (Fig. 1, blue bars) in all examined countries, as family authorisations in absence of the deceased’ consent outnumber family oppositions when the deceased had consented. In other words, as a majority of deceased individuals fail to express their preferences before death, a majority of organs could not be retrieved in opt-in countries but for the next-of-kin’s authorisation. Meanwhile, family intervention decreases the proportion of likely organ donors under opt-out policies (Fig. 1, orange bars). Indeed, when the deceased consented or their preferences are unknown, family oppositions prevent the retrieval of organs that would otherwise be retrieved. In other words, the organs of all those who remained silent could be retrieved in opt-out countries if it was not because of opposition from families.

The power of our approach stems from the combination of conceptual analysis with real-world statistics from multiple and diverse countries, allowing us to measure the frequency of that particular situation where opt-in and opt-out policies actually differ in their application. In other words, our study is the first to examine the impact of opt-in and opt-out by focusing on what makes these policies different from each other. To our knowledge, this specific information has never been actively sought nor specifically published before in the scientific literature, and it is seldom reported in official statistics even in countries, such as Spain, with advanced organ donation and transplantation programmes. This makes the data we obtained the best empirical evidence available to date.

That being said, the data reported here are indicative rather than representative, meaning that the aggregated data provide a general estimate of the frequency of the situation where the default option is applicable, but individual figures should be treated with caution. Indeed, these figures were extracted from a wide variety of sources with significant differences in their definitions, samples, methods and dates. As a consequence, two reports from the same country may give different results, as is the case for some of those we have examined (e.g., Denmark). In addition, the type of information we were looking for is not usually reported by healthcare professionals, nor is it usually compiled in statistics or, when compiled, publicly available, or, when available, usable for this study’s purpose. Thus, we were unable to find relevant data sources in many countries and, where we did, the data provided was often incomplete, inaccurate or difficult to extract. For example, reports often detail the reasons why organs could not be retrieved, including 'lack of consent', but are usually ambiguous about whether this refers to the expressed refusal of the deceased, the expressed opposition of relatives, both, or, conversely, the absence of expressed consent or authorisation. In contrast, it is much rarer to find useful information for cases where organs have been retrieved, apart from the occasional vague mention of consent. For these reasons, we were unable to include data from numerous reports. The best available results are those reported in Table 4. For the rest of the data available, in view of the above limitations, we have opted to provide only ranges of values rather than specific figures for each country. We hope that this study will serve to alert clinicians and authorities to the need to collect more comprehensive and detailed data on the organ donation preferences of the deceased and their families.

Our study focuses specifically on the direct effects of consent policies, as defined in the introduction. It does not take into account indirect or secondary effects of policy defaults or the effects of other factors and measures that may accompany or follow legal changes. Our conclusions should be interpreted within this scope.

Our results may warn contemporary organ retrieval policy makers that, by emphasising the need to introduce presumed consent, they might be overestimating the direct influence of policy defaults, and underestimating the power granted to families in expressing their preferences and making decisions about organ donation. Improving infrastructures, coordination and training, communication to the public, and modifiable factors influencing family authorisation might prove more effective for increasing organ retrieval rates than moving from opt-in to opt-out.

One way around families’ capacity to overrule both explicit and presumed consent would be to lessen the authority families currently have in the decision over donation[55]. The USA amended its Uniform Anatomical Gift Act in 2006 to restrict the family’s authority to veto the deceased’s first-person authorization (opt-in). Belgium amended its law (opt-out) in 2007 by removing the option for the family to oppose organ procurement. Other countries, including Uruguay (2013), Colombia (2016), France (2017), and Argentina (2018) changed their opt-out laws to prevent relatives from opposing organ recovery both when the deceased had expressed no preference (presumed consent) and when the deceased wished to become a donor (explicit consent).

The effectiveness of such restrictive measures remains to be assessed. Their governance quality should also be assessed, although we may lack proper data to do so[56]. Recent systematic reviews have raised concerns by suggesting that the population in opt-out countries tend to be less aware of their consent system than in opt-in countries[40] and that a majority of the public supports the involvement of the family in organ recovery decision-making and, in particular, their role as surrogate when the deceased has expressed no preference[57,58]. This adds to the ongoing ethical debates over the family veto[59] and opt-out policies acceptability[60].

Fig 1: Retrieval rates under four different policies, if only the policy changes, all other things being equal

This figure uses the available data on deceased’s and family’s preferences in six countries to estimate how changing the default and the family’s role, all other things being equal, may affect retrieval rates. For each country, four possible situations are considered, from left to right: (α) opt-in and deceased’s preferences only; (β) opt-out and deceased’s preferences only; (γ) opt-in and both deceased’s and family preferences; (δ) opt-out and both deceased’s and family preferences. Data for this figure results from adding the percentages of the scenarios shown in Table 4 (Denmark, Germany, the Netherlands, Sweden, the United Kingdom, and Wales). For each country, the situation that is actually in place in the country is signalled by an arrow. Changing the policy in place in any given country would almost certainly cause some indirect effects that we are not taking into consideration here because we don’t know the nature, the sign, and the intensity of such effects in this particular country.

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