

Perspectives on Opt-Out Versus Opt-In Legislation for Deceased Organ Donation: An Opinion Piece

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What was known before

Opt-out legislation for deceased organ donation has been used in many countries. While all Canadian provinces except Nova Scotia currently use an opt-in approach, some provinces are either implementing or considering opt-out legislation to bridge the gap between organ supply and demand.

What this adds

This review discusses the potential advantages, pitfalls, and considerations for implementation of opt-out legislation for organ donation.

Introduction

While the deceased organ donor rate in Canada has increased by >50% since 2010, the supply continues to lag behind demand, and 223 Canadians died while waiting for a kidney transplant in 2019.¹ Presumed consent has been suggested as a strategy to reduce this gap. While Canadian provinces and the United States employ opt-in models, the presumed consent approach is the practice in many other countries, including Austria, Belgium, France, Wales, and Spain, (the last of which has the highest deceased donor rate in the world.)² In April 2019, Nova Scotia passed legislation to become the first North American jurisdiction to adopt presumed consent legislation, and this legislation

went into effect on January 18, 2021.³ In addition to the legislation, Nova Scotia simultaneously adopted other elements of health system transformation including mandatory notification for all patient deaths, approach of families for all medically suitable deceased donors, and center reporting of donor performance.⁴ Alberta is considering similar legislation, and other provinces are closely watching the impact of presumed consent legislation in Nova Scotia. The best method for Canada to increase donation rates while maintaining public trust and support remains to be determined.

In this opinion piece, we will present key considerations around the public perceptions toward presumed consent, impact of presumed consent on availability of transplant organs, effect of presumed consent on deceased and living donor rates, and important considerations of the potential effect of presumed consent on populations who experience systemic barriers to transplant, including Indigenous people.

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What is Presumed Consent, How Do Individuals Perceive It, and to What Should We Compare It?

Understanding what is meant by “presumed consent” is key to understanding the controversy around it. Presumed consent or “opt-out” models refer to donation practices which presume that an individual deemed medically suitable to be a deceased organ donor has authorized postmortem removal of their organs for transplantation, unless the individual took a premortem action to register their dissent. Affirmative consent or “opt-in” systems ask individuals to register their authorization for organ donation premortem, usually through an online registry which is linked to their health care identifier number and can be accessed by organ donor organizations if they become eligible to donate. Each province currently runs an online registry, with registration rates varying widely. Factors like the ease of use of the registry and public awareness factor into the success of registries.

Attitudes toward organ donation are highly favorable. Surveys of individuals and health care professionals in Canada have shown that >80% would be willing to donate at the time of their death.^{5,6} Since surveys suggest that most of the public is in favor of deceased organ donation and willing to donate their organs after death, proponents of presumed consent argue that this system will make it easier for the people to make a choice consistent with their values, while still honoring the wishes of the minority of individuals who decide that organ donation is not the right choice for them.⁷ In countries that employ an opt-out system, rates of registered dissent are very low (ie, <0.5% in 8 European countries in a 2012 report),⁸ though this does not necessarily translate into higher rates of actual donation because families still have the right to refuse donation in most systems.⁸

But is presumed consent actually consent? Does it need to be? Consent for medical interventions on living people require 3 important criteria to be met: the individual needs to have the capacity to make the decision, the individual needs to be making the decision voluntarily, and the consenting individual needs to have the appropriate information that they need to make an informed choice.⁹ Opt-in strategies often ask an individual to sign up on an online registry in a process that takes minutes, involves no personal interaction and generally does not meet this standard. Similarly, opt-out systems rely on individuals to know that the law exists and take active measures to register their dissent. Legally, donation decisions do not need to meet with informed consent standard and are more appropriately characterized as authorization to proceed with donation after death.¹⁰ So, presumed consent is a misnomer, with a more appropriate term being “opt-out,” “nondissent,” or “presumed authorization.”

Attitudes of the general public toward “presumed consent” have been quite variable. In a review from the United Kingdom, there was wide variation in the level of support for presumed consent with the lowest support identified in surveys conducted prior to 2000 (28-57%).¹¹ In a more recent 2019 survey of 1000 Canadians,¹² 63% were either “definitely” or “probably” in favor of an “active donor registration system” (every person over 18 is an organ donor unless they specifically opt-out). Although surveys of the general public do not reflect the views of all Canadians (and notably details about case-mix, and representation of minority groups were not included in this survey), terminology is crucial when capturing public opinion. Since the transplant system relies on continued public trust and support, it is important to use the terms that most accurately describe what is being proposed. For that reason, we proposed that discussion or legislation preferentially use the term “opt-out” instead of “presumed consent.”

One misunderstanding of opt-in models is the false assumption that individuals who neglect to “opt-in” while alive are excluded from being deceased donors (ie, their families are not asked to authorize organ donation on their behalf). In this calculus, the huge gap between the group that supports organ donation (usually over 90% of the population) and those that register (between 20-30% depending on the province) can be bridged by making the default choice authorization for donation.¹³ Of course, registration to donate, or not to, does not necessarily translate into actual donation because family authorization is still required in most current opt-out models, but this “nudge” in the donation direction could work. In a study of 161 subjects, it was identified that individuals are not likely to change their “default” state (opt-in or opt-out) when given the choice but that an opt-out strategy more closely approximates what individuals would do without an established default.⁷

However, a nudge toward a default choice may not be necessary because premortem opting-in is not necessary for donation to proceed, in most cases. In reality, most organ donor organizations in Canada practice “mandatory approach” in which the family or loved ones of any individual who is potentially eligible to donate are asked for authorization to proceed with donation, regardless of the individual’s registration on a living donor registry. For those who have registered, clear direction is provided that organ donation was something that the potential donor considered when he or she was conscious/capable and promotes the importance of donation to the larger community. This knowledge can give families assurance that they are acting consistently with the wishes of their loved ones. For those that have not registered in an opt-in system, families are asked to make a decision based on what they believe that their loved one would have wanted. Authorization rates in this second group (those who did not register to donate) are still very high,

suggesting that families can and do authorize donation in the absence of the pro-active registration. So, while an opt-out model may potentially increase the number of donations, the scale of that improvement cannot be calculated by assuming that almost all Canadians who have not opted-in under the current approach will become donors under a new law. Leading critics of opt-out legislation have decried this perception of opt-out “as a magic tool that will boost organ donation . . . with mass media contributing to spreading the idea.”¹⁴ A more data-driven approach that acknowledges the complexities of organ donation and continued performance monitoring to identify missed opportunities may identify other barriers to increasing donor rates that can be managed with other improvements.

Does Opt-Out Legislation Lead to an Increase in the Number of Potential Donors?

In Canada, there is a large discrepancy between the number of potential and actual deceased donors. In a 2014 evaluation using data from the Canadian Institute for Health Information (CIHI), 2.6% or 3088 of the 117 156 inpatient deaths in Canada were determined to be potential organ donors, but only 520 became actual donors.¹⁵ Using the most recent Canadian Organ Replacement Register (CORR) data, only 3053 organ transplant procedures were performed in Canada in 2019.¹ Since each deceased donor can donate up to 8 life-saving organs, there is evidence of missed donor potential. This missed donor potential extends to organ donation after circulatory death. In a cohort study conducted within Ontario, Canada, from 2013 to 2015, of the 1407 individuals with planned withdrawal of life-sustaining therapy, 251 potential donors (34% of suitable individuals) were either not referred or referred too late (ie, at the time of or after withdrawal of life-sustaining therapy) to consider donation.¹⁶

How might this change under opt-out legislation? In an opt-out system, the number of extra donors would be determined by the next-of-kin refusal rate, the opt-out rate and whether or not eligible donors that were neither considered nor discussed with family under an opt-in system would be donors under opt-out legislation. The potential impact of these determinants was assessed in a previous modeling study conducted out of the United Kingdom that used donor audits to extrapolate the number of extra donors over baseline under different hypothesized opt-out and next-of-kin refusal rates.¹⁷ Under the existing opt-in strategy, it was estimated that there were 6050 solid organ donors over a 10-year period. Under opt-out legislation, the authors determined that even with a 5% opt-out rate, there would be 230 extra donors over baseline.¹⁷ Here it was assumed that adopting an opt-out strategy would lead to the addition donors that were neither considered or discussed with family under the

existing opt-in approach. A family refusal rate lower than the baseline of 40% would have a large positive impact on the number of potential donors, whereas a higher opt-out or refusal rate would lead to fewer donors than the opt-in strategy.¹⁷ Two important questions need to be addressed when considering the results of this study and how these results could be extrapolated to donation practices in Canada. Is it a guarantee that an opt-out strategy would mitigate all situations where donation was neither considered nor discussed (under an opt-in model)? Without infrastructure (including donation coordinators that service each intensive care unit, established pathways for those with brainstem death or prior to cardiac death and extensive knowledge translation activities to increase awareness) simply adopting the law may have little impact on donation rates. Is it unrealistic to assume the next-of-kin refusal rate would decrease under opt-out legislation? In a survey conducted out of Hong Kong, participants were asked about their intention to donate the kidneys of a deceased family member under different hypothetical situations.¹⁸ Interestingly, 51% stated they would agree to donate a family member’s organs under opt-in legislation when the wish of the deceased individual was not previously known. In contrast, this proportion rose to 73% under opt-out legislation.¹⁸ Although reasons underpinning this difference are not available, it is hypothesized that the decision to opt-out is so important that those with the means would make their wishes known well in advance. This assumption would make individuals more willing to donate a family member’s organs when the decision was not known, as they would be reassured that the deceased individual did not feel so strongly about opting out. Whether adoption of an opt-out system truly improves next-of-kin rates is inconclusive. In Spain, organ donation refusal rates did not change after adoption of presumed consent legislation, but fell over a subsequent 13-year period from 25% to 15%, suggesting that this was more reflective of system changes (including modifications to the process around approaching and communicating with families).¹⁹ Family refusal rates in opt-out versus opt-in countries are highly variable and no systematic direct comparisons (due in part to the poor data on next of kin consent rates) are available.²⁰ The fall in donation rates in Chile after presumed consent was likely the result of a higher next of kin refusal rate, emphasizing that the response of next of kin refusal rates may not be favorable to donation rates depending on how the legislation is perceived.²¹ In summary, the effect of opt-out legislation on the number of potential donors is highly variable depending on the opt-out rate, the change in family refusal rate, and whether changes in legislation are accompanied by corresponding changes in infrastructure. In fact, in a highly functional donation system that is already identifying most potential donors and approaching next of kin, an increase in the number of donors would only occur if family refusal rates fall as a result of opt-out legislation.

How Does an Opt-Out Approach Influence the Rate of Live and Deceased Organ Donation and Transplantation in Other Countries?

Overall, rates of deceased donor kidney transplantation are higher in countries with opt-out legislation than those with opt-in,²² as are deceased organ donation rates. In a 2017 European report, the highest deceased organ donation rates (inclusive of both donation after brain death and cardiac death) were in countries with opt-out legislation including Spain (47 per million population; pmp, Portugal (34 pmp), Croatia (33.3 pmp), Belgium (30.5 pmp), and France (29.7 pmp).²³ In contrast, the highest organ donation rate in an opt-in country was the United Kingdom (excluding Wales, 22.5 pmp)²³ which is similar to Canada's rate (21.9 pmp, 2017).²⁴ In a comparison of deceased donor organ rates worldwide, countries with opt-out legislation tended to have much higher rates (22.6 pmp, 95% CI: 9.3-33.8) than those with opt-in legislation (13.9 pmp, 95% CI: 3.6-23.1).²² But while opt-out legislation has been successful in increasing the donation rates in many countries, it is far from universal. In Chile, donation rates dropped in the year after the introduction of opt-out legislation and recovered back to the pre opt-out rate of 6.5 pmp by 2 years after the legislation was enacted.²¹ This effect was likely the result of a large increase in family refusal rates (which rose from 32-41% to 50.4% in the year following the enactment of legislation) and an increase in the proportion of nondonors in the National registry.²¹ In Brazil, opt-out legislation needed to be repealed because of its deleterious effect on the organ donation rates,²⁵ driven by increases in those registering themselves as nondonors (due to some being fearful of organ procurement prior to death) and a lack of sufficient infrastructure to support the identification of donors.²⁵ In Wales, which introduced opt-out legislation in 2016, there has been an increase in the consent rates for donation, but the actual deceased donor rate have not yet changed.²⁶⁻²⁸

Is the link between opt-out legislation and deceased donation rates causal? In situations where causation cannot be ascertained using a randomized controlled trial, instrumental variables can be used to estimate causal relationships. Shepherd and colleagues conducted an analysis of the effect of opt-out legislation on deceased donor rates in 48 countries over a 13-year period (2000-2012).²⁹ Analyzing the data using the instrumental variables of the country legal system (civil versus common law) and levels of nonhealth philanthropy, they found that deceased donor rates were higher in opt-out versus opt-in consent (14.24 vs 9.98, difference of 4.27 donors pmp).²⁹ Although this analysis suggests that the legislation type itself may directly influence deceased organ transplant rates, it was unable to account for variability in the application of legislation, or other processes that are in place to facilitate deceased organ donation. This latter point is important, acknowledging that not all opt-in countries

necessarily have relatively lower deceased donor rates. In the United States, deceased donor rates have been consistently high (most recently 33 pmp) despite opt-in policy.³⁰

As previously mentioned, some of the variability in deceased donor rates after adoption of opt-out may be due to the need for additional resources and infrastructure to make a deceased donation program successful. In Spain, changes in donor rates did not occur shortly after the adoption of opt-out legislation. Instead they rose 10 years after opt-out legislation and more closely corresponded with the establishment of the Organizacion Nacional de Transplantes (ONT) in 1989.² The ONT focused on effective donor identification, facilitation of transitions to actual donation and promotion of public support for deceased donation. Initiatives in these and other areas (for example, elective nontherapeutic intensive care to facilitate donation of organs, care pathways inclusive of donation for palliative patients, donation physician specialists, media hotlines, and incentivization of donation in peripheral hospitals) have led to an incremental rise in the Spanish deceased donor rate since its implementation.² In Nova Scotia, legislation will be accompanied by infrastructure (including, as mentioned, mandatory notification of donors, approach of families of medically suitable donors, and a scientific program of study to evaluate outcome, implementation, and public perception).⁴ The impacts of this additional infrastructure and "culture of donation" are evident in Nova Scotia in 2020, where the rates of donation reached their highest over the last 15 years, prior to adoption of the law.³¹ While this may be an anomaly, some of this improvement may also be the result of efforts to educate health care workers about how to identify donors and creating awareness of donation with the public.³¹ Therefore, it is both intuitive and expected that without existing or planned infrastructure, adopting opt-out (outside of its potential effect on next-of-kin refusal rates noted above), may not have a sizeable impact on deceased organ transplantation. In contrast, with infrastructure in place, increases in deceased organ transplant rates would be expected.

While most studies of opt-out legislation are focused on changes to the deceased donor rate, the living donor rate is generally lower in opt-out countries.²² In a longitudinal study of 44 countries performing kidney transplantation, while deceased donor rates were higher in opt-out nations, living donor rates were lower (2.4 pmp versus 5.9).²² Some of the possible reasons behind this include changes in public perception toward live donation, a lack of resources (as more efforts are used to sustain higher deceased donor rates) or that live donation is discouraged or forbidden. Regarding the latter, after opt-out came into practice in Belgium, the transplant law explicitly discouraged the use of live donors.³² While the observed impact on live donation rates is only association, it emphasizes that at very least, live donation rates should be monitored closely, and live donation should continue to be promoted even if opt-out legislation is adopted.

What is the Effect of Opt-Out Legislation on Minority Groups?

Maintaining the support and trust of the donating public is vitally important in the organ donation system because the public supplies organs for donation and funds the healthcare system which manages these transplants. One concern with opt-out legislation is that those who object to donation on personal or religious grounds may not be able to easily register their dissent or may not trust that their dissent will be respected. When Wales was considering its opt-out legislation, faith-based groups expressed concerns, stating that organ donation should be an altruistic gift that is proactively given and that education of the public would be a better approach than presuming consent.^{27,33} An independent report of the U.K. Organ Donation Taskforce examined the attitudes of religious and minority groups toward opt-out legislation. While most supported the concept of organ donation and believed that an opt-out system would improve the rate of organ donation, the majority opposed a change in the law. Reasons for opposing the law included concerns that “hard-to-reach” groups would not have the information they needed to opt-out, that individuals would not feel comfortable expressing an opt-out choice, that it would alter the relationship between state and individual, and that it potentially provides the government with a level of control that could be abused.³⁴ The concepts of altruism and gift giving were considered important, and the idea of removing the affirmative opt-in was seen by some as “dehumanizing.” In a study of African Americans, only 28% would be in favor of an opt-out policy, citing concerns with mistrust of the medical system and wanting to clearly understand their loved one’s wishes as important to their decision to authorization donation.³⁵

In Canada, we must consider how a legislative change may affect the trust that underrepresented and minority groups have in the donation and transplantation system and in the medical system in general. We do not have strong data to tell us how groups like immigrants and refugees, minority faith communities, Indigenous Canadians, and other people of color may view opt-out legislation individually, or how their communities may react to a change in the law. We do know that families of recent immigrants are less likely to consent to deceased donation compared with families of long-term residents and that Indigenous Canadians, while overwhelmingly in favor of organ donation, are less likely to agree to donate their own organs than the general public.^{36,37} The long legacy of colonization and systemic racism in Canadian healthcare has led to mistrust of the medical profession, and while there are efforts underway to rebuild trust with communities, the Truth and Reconciliation Calls to Action remind us that there is much more still to do.³⁸ A scoping review of what is known of donation attitudes in Canadians marginalized by race or ethnicity emphasized the importance of family and community in making donation decisions, the importance of respecting individual beliefs and decisions toward donation, and the importance of trust building.³⁹

It is possible that adopting legislation which requires active dissent would further alienate those who have been

disenfranchised and weaken the trust that still needs to be rebuilt. Even a single case that is mishandled has the risk of affecting attitudes toward donation in the larger community and donation rates, as has been seen in other jurisdictions. Any opt-out legislation that is enacted should carefully consider these effects, and speak to communities affected to get their perspectives, and recognize that these attitudes are likely not homogenous within or among groups of people.⁴⁰

Conclusion

The changing legislation in Nova Scotia will be an important test of opt-out legislation in Canada. If it works to improve deceased donor rates without adversely affecting living donor rates, more lives could be saved, and the gap between supply and demand could close, but it is also possible that the donation rate will not significantly improve. Success should be measured not only by the change in donation numbers, but also by the public response to the change. We should be especially cognizant to listen to the voices of Indigenous Canadians and those from other minority groups—do they feel heard in this process and empowered to express their choices? Careful monitoring of both will be important to inform policy in other Canadian jurisdictions moving forward.

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