Canadian National TRANSPLANT Research Program

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FAST FACT:
OPT-OUT CONSENT FOR ORGAN DONATION

WHAT IS OPT-OUT CONSENT OR PRESUMED CONSENT?

Opt-out consent refers to a consent framework whereby dying or deceased individuals are considered potential organ donors unless they stated during their lifetimes that they did not wish to donate. This system is referred to as "presumed consent" or "opt-out" consent because individuals are essentially presumed to have consented to donate unless they opted out of organ donation before death.

In contrast, the current Canadian system operates under an explicit consent framework, or "opt-in" consent, which means an individual or his/her next-of-kin must explicitly consent to organ donation for it to occur.[1] There has been discussion among policymakers, patient advocates and in the media about whether Canadian provinces and territories should change to opt-out consent frameworks as a way to increase donation rates. This document provides some information and facts about opt-out consent as a public resource to help inform the debate.

RATIONALE FOR SWITCHING TO OPT-OUT CONSENT

Public opinion data indicates that 95% of Canadians strongly or somewhat approve of organ and tissue donation.[2] However, only 51% of Canadians have actually decided they want to donate organs after death, and only 39% have decided to donate tissues.[2] Of those who have made the decision to donate, only 27% have indicated they have actually put their names on donation registries.[2] The idea behind opt-out consent is that those people who are in favour of organ donation but have either not yet made up their mind or taken specific action to register their consent would be better captured as potential donors under a system where all people are considered donors unless they have specifically objected.[3]

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HOW DOES OPT-OUT CONSENT OPERATE?

There are many jurisdictions around the world – particularly in Europe and South America – that have adopted opt-out consent frameworks. However, there is variation between these jurisdictions in terms of how opt-out consent is operationalized. Some opt-out consent countries have non-donor registries for people to explicitly "opt-out" of donation.[4] Many opt-out consent countries also have a mechanism for people to affirm that they do wish to be a donor.[5] The extent to which the potential donor's family is included in the donation decision is also an important operational issue to consider.

Even though legal authority may exist to procure organs from deceased individuals who have not opted out, many opt-out consent countries nevertheless require authorization by the donor's next-of-kin.[6] There are also many opt-out consent countries that allow families to object to donation even when the individual had joined a donation registry or otherwise expressed a desire to donate.[7] Indeed, a study examining the role of family decision-making in organ donation found that 21 of 25 opt-out consent countries studied allowed families to object and prevent donation from occurring.[7]

In Canada, a similar phenomenon exists, whereby families' wishes are deferred to, even if the individual signed up to be a donor on a donation registry.[8] In considering opt-out consent for Canada, depending on the scheme put forward it is likely that families would still be involved in making the final decision about donation even with opt-out consent. The strong deference shown to potential donors' families may make it difficult to implement a hardline opt-out consent framework that disregards families' wishes. As a result, the potential effectiveness of an opt-out consent system in Canada may depend on whether opt-out consent will positively affect the number of families that decide in favour of donation.

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DOES OPT-OUT CONSENT INCREASE DONATION?

Some studies have found a positive association between opt-out consent and deceased donation rates.[9] Others have indicated that opt-out consent is associated with higher deceased donation rates but lower living donation rates.[10] Another study found that, on average, opt-out consent jurisdictions had slightly higher deceased donation rates, but the author attributed this not to differences in the law but to differences in the organizational structure and management of organ donation systems.[11] A systematic review that analyzed the results of many of these studies similarly concluded that although the evidence suggests an association between opt-out consent and deceased donation rates, this does not mean that switching from opt-in to opt-out consent would necessarily lead to higher donation rates.[12]

The reason it is difficult to determine whether opt-out consent actually causes donation rates to rise is because there are myriad factors that influence deceased donation rates. These include the number of potential donors (i.e. people who die in a way that would allow donation to be possible), resources (including dedicated donation personnel, ICU beds, transplant facilities, etc.), training of health professionals in donor identification and communication with families, public attitudes about donation, and quality assessment and evaluation processes for the donation system.[13]

While it is possible that the introduction of opt-out consent in Canada will positively affect deceased donation rates, this is far from a foregone conclusion. Some countries with opt-out systems have relatively low donation rates.[14] Other countries, such as the United States, have relatively high donation rates despite operating as an explicit opt-in consent system. Spain provides another interesting example. Although opt-out consent was introduced in Spain in 1979, it was not until the government made a major investment in the organ donation system ten years later that Spain became a world leader in deceased donation rates.[15] Presently, although Spain technically has an opt-out consent law, it actually operates more like an explicit opt-in consent jurisdiction as it does not have an opt-out registry and requires explicit family authorization in order for donation to proceed.[16]

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ATTITUDES TOWARD OPT-OUT CONSENT

Our organ donation system depends on public trust. Public acceptance and willingness to adopt an opt-out consent framework would be crucial to its success. In Brazil, for example, an opt-out system was introduced only to be revoked less than two years later in the wake of public backlash.[17] In Chile, the introduction of an opt-out framework without sufficient public education about the system resulted in millions of people opting out.[18]

In Canada, a 2010 survey indicated that only 54% of the Canadian public either strongly or somewhat supported opt-out consent.[19] However, this is up from 50% in 2001, and may not reflect current views on the issue or geographical differences across the country. It is also important to consider the level of support among the medical and organ donation/transplantation communities. A 2011 survey of health care providers in Canada showed 55% of respondents strongly or somewhat supported opt-out consent with a further 8% being neutral.[20]

ONGOING QUESTIONS TO CONSIDER

As discussions about opt-out consent in Canada continue to evolve, the following issues must be considered:

- Is the investment that would be required to implement opt-out consent the best use of resources? Are there other strategies to increase donation rates that should be prioritized instead?
- Is there sufficient support for opt-out consent in the public and organ donation/transplantation communities? What are the most prominent concerns of these communities? Are there particular communities that might be disadvantaged by changing to an opt-out consent model? What impact would opt-out consent have on public support of our donation and transplantation systems?
- What role should family decision-making play in a Canadian opt-out consent system? If a hardline approach is not feasible, will opt-out consent impact family consent rates? Is this the best strategy to influence family decision-making?
- What mechanisms should be devised to allow people to opt-out? What methods of opting out will be recognized? Should opt-out registries operate alongside consent registries? How would the law need to change? Would a change to opt-out in one province/territory affect donation systems elsewhere in Canada?

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