Opt-Out Systems of Organ Donation

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TABLE OF CONTENTS

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INTRODUCTION

Opt-Out Systems of Organ Donation

Canadian provinces and territories, apart from Nova Scotia, administer organ donation on an opt-in basis. Under opt-in systems, people register their willingness to donate their organs after death. Those who have not registered may still be donors if their next of kin consent. In contrast, opt-out systems – also known as presumed or deemed consent systems – automatically consider everyone to be a potential organ donor, unless the individual explicitly opts out of donation.

On January 18, 2021, Nova Scotia's new Human Organ and Tissue Donation Act (1) went into effect to transition to an opt-out model. (2) The new legislation aims to increase organ and tissue donation in the province. (3) All Nova Scotians 19-years of age and older will be considered potential donors unless they meet the narrow categories for exemption (e.g., adults who lack mental capacity to consent) or opt-out via the Registry or family refusal. (4) Partial consent for the donation of only certain organs is possible. (5) While Nova Scotia is the first jurisdiction in North America to adopt an opt-out system, other nations such as Spain, Wales, France, and Chile already use such a system with varying degrees of success in increasing donation rates. (6)

The impact of opt-out policies on donation rates remains unclear, as several factors can increase or decrease rates. One study found that countries with opt-out systems had fewer living organ donors than opt-in nations, but there was no significant difference in terms of deceased donation or overall solid organ transplantation rates. (7) These results indicate that other factors affect rates. These factors could include legislation, donor availability, organ donation organizations (ODOs), efforts at education and publicity, quality of the information and reporting infrastructure, and national healthcare investment. (8) Others may oppose opt-out systems due to beliefs that fewer efforts will be made to save the life of a potential donor, personal autonomy is being infringed upon, or marginalized communities will be further disadvantaged. While transitioning to an opt-out system can be a popular idea to improve donation rates, this change does not guarantee an adequate supply of donated organs to meet the need.

THE VIEWS OF HISTORICALLY UNDERREPRESENTED COMMUNITIES IN NOVA SCOTIA

As noted above, one of the concerns related to opt-out systems is whether certain communities might be disadvantaged relative to others, perhaps due to inequities in access to information about the system and how it works (e.g., due to lack of translation into different languages or a failure to design or share information in a culturally appropriate manner, etc.), or because of greater levels of mistrust in the medical system. The views of underrepresented and equity-seeking communities need to inform the roll-out of Nova Scotia's new opt-out system legislation. A recent interview-based study with leaders from faith-based communities, the African Nova Scotian community, the LGBTQIA2S+ community, and newcomers to Canada revealed four main themes: (9)

SUPPORT FOR ODT

All participants supported ODT programs as they aligned with their personal values. Organ donation conformed with the religious beliefs of various faith-based communities. Deemed consent for tissue donation posed a more complex issue for participants, specifically those from the Jewish and Islamic communities due to potential conflicts with religious customs.

TRUST AND RELATIONSHIPS

Participants discussed how broken relationships need to be addressed in order to move forward. Systemic racism within the healthcare system has led to high levels of mistrust, including the fear of being killed to obtain organs. Participants expressed the need to be able to trust healthcare providers to do everything possible to both save their life and respect the dignity of their bodies post-mortem. Men who have sex with men (MSM) noted that their damaged relationship with the blood donation system had impacted their perceptions of the ODT system.

CULTURAL COMPETENCE

All participants discussed how cultural competence and safety are essential at all levels of the ODT system, from legislative drafting to clinical implementation. Governments and health leaders need to recognize the historical and modern harms experienced by communities and respond to their needs.

EDUCATION & COMMUNICATION

Participants expressed a strong desire for increased communication and education about the new opt-out system and ODT as a whole. This communication must be accessible to communities (e.g., the availability of information in several languages) and culturally competent.

Overall, participants possessed a genuine desire to participate in Nova Scotia's new opt-out ODT system, so long as the system was culturally competent and safe.

THE ROLE OF SOLIDARITY IN OPT-OUT SYSTEMS

In the fields of bioethics and healthcare ethics, solidarity refers to the feeling of unity, mutual support, and reliance within a community. Solidarity has been identified as one of the central values that should guide the design and operations of ODT systems in Canada, as these systems fundamentally depend upon the willingness to donate to help others in need. There is currently no other method outside of donation to address ODT needs. The promotion and reflection of solidarity is sometimes used as a rationale for the use of, or transition to, opt-out systems.

Calls for solidarity need to be attentive to the social, historical, and cultural contexts in which the term is used. (10) Solidarity is challenging to define, but there are three critical aspects to consider more in depth:

1. **Relationships:** who are we in solidarity with and what defines that relationship?
2. **Intentional commitments:** what is the aim of our solidarity and where do these commitments stem from?
3. **Actions:** what am I willing to do and give up in order to ensure the well-being of others? (11)

The Canadian publicly funded healthcare system reflects a concept of civic solidarity. (12) It is based on an acknowledgement of universal vulnerability and a willingness to offer mutual support, via the indirect pathway of taxation. ODT asks for more direct and personal expressions of solidarity through the donation of organs for the benefit of those in need. An important aspect of policies based on solidarity is attention to whether everyone actually is “all in this together.” Sometimes an appeal to solidarity presumes that everyone has the same experience and an equal sense of belonging to the community. This universalistic solidarity can then be questioned, as it may lead to actions and policies that overlook and do not address or mitigate the existence and causes of health disparities. (13) Failure to recognize important differences can end up weakening solidarity and, in turn, the policies that rely on its presence.

Residents of Atlantic Canada tend to have a high rate of support for ODT. (14) This high level of support indicates that solidarity may be one of the driving values behind Nova Scotia’s transition to an opt-out system for donation. However, in order to achieve success, the system must remain attentive to the needs of those who do not feel included. Solidarity must also not be taken for granted, meaning ODT programs must continue to promote public trust in the system. For example, Chile’s transition to an opt-out system failed to increase donor rates, likely due to high rates of fear and mistrust of healthcare in the community. (15)

THE FRENCH EXPERIENCE WITH OPT-OUT LAWS

The experiences of Nova Scotia and other countries may be useful to other Canadian provinces. France offers an example of a country with over 40 years of experience with an opt-out approach to organ donation.

The History of Organ Donation Legislation in France (16)

1976

France enacted its first organ donation legislation and adopted an opt-out system for ODT. This choice is grounded in the idea of national solidarity. The legislation does not discuss the role and rights of donor families. Three main principles underpinned the law: no financial rewards, anonymous donation, and presumed consent.

1994

France passed its first law on bioethics. This law reinforced the three main principles of the 1976 ODT legislation. The law provided a description of ways to refuse donation and the obligation on clinicians to inquire with families about a patient's potential refusal to donate. A donation Refusal Registry was created but not implemented until 1998.

PRE-2016

Three valid ways to refuse donation existed in both law and medicine: the Refusal Registry, a family's report that the patient refused, or family refusal.

2017-NOW

France changed its ODT legislation, altering the refusal modalities. Now the ways to refuse donation include the Refusal Registry, patient refusal through a written document, or a signed attestation from families expressing the oral refusal of the patient. The French government states that the objectives of these modifications were to ensure a patient's decision will be followed, to discharge families from having to get involved in such decisions, and to increase donation rates.

Global refusal (including cases of family or patient refusal) remained stable with no major change after the implementation of the new legislation. France did however experience a slight increase in donation rates. Data for 2017 and 2018 shows that family refusal decreased from 21% to 13% and patient refusal increased from 12% to 17%. (17) The Refusal Registry's new inscription rates increased at the time of the legislative change and again right before the application of the law, but overall, rates continue to remain low.

Clinicians felt the option of a signed document from the patient was reassuring to families, as many never specifically addressed the issue of organ donation prior to the patient's death. Although the new system limits the reasons that families can refuse donation to one – the patient's known refusal, this does not appear to have affected how clinicians and organ procurement coordinators act. Where families object, their refusal is usually honoured, even if this is not consistent with the law in some cases. (18)

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