A Program of Research to Evaluate the Impact of Deceased Organ Donation Legislative Reform in Nova Scotia: The LEADDR Program

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Background. This is the first time deemed consent, where the entire population of a jurisdiction is considered to have consented for donation unless they have registered otherwise, will be implemented in North America. While relatively common in other regions of the world—notably Western Europe—it is uncertain how this practice will influence deceased donation practices and attitudes in Canada. Methods. We describe a Health Canada funded program of research that will evaluate the implementation process and full impact of the deceased organ donation legislation and the health system transformation in Nova Scotia that includes opt-out consent. Results. There is a need to evaluate the impact of these changes to inform not only Nova Scotia and Atlantic Canada, but also other provincial, national, and international stakeholders. Conclusions. We establish a rigorous academic framework that we will use to evaluate this significant health system transformation.

INTRODUCTION

In recent years, Nova Scotia’s deceased organ donation rates have remained stagnant, while other provinces have reported dramatic increases concurrent with substantial investment of financial resources to support implementation of internationally recognized best practices by their organ donation programs.1 Recognizing the need to provide adequate support to implement key components of high performing deceased donation systems, the Nova Scotia provincial government collaborated with Legacy of Life and Critical Care Organ Donation, Nova Scotia Health Authority, Halifax, NS, Canada. In Nova Scotia, there is a need to evaluate the impact of these changes to inform not only Nova Scotia and Atlantic Canada, but also other provincial, national, and international stakeholders. This work is funded by a Health Canada, Health Care Policy Contribution Grant through the Organ Donation and Transplantation Collaborative. All authors contributed to the conception and design of the work as well as drafting and revising of the article. All authors approve the final version of the article. The authors declare no conflicts of interest. This work is funded by a Health Canada, Health Care Policy Contribution Grant through the Organ Donation and Transplantation Collaborative. The views expressed herein do not necessarily represent the views of Health Canada. Supplemental digital content (SDC) is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal’s Web site (www.transplantationdirect.com). Correspondence: Matthew J. Weiss, MD, CHU de Québec-Université Laval, 4100 Rue Molson Bureau 200, Montréal, QC H1Y 3N1, Canada. (matthew-john.weiss@chuquebec.ca).

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Life and Critical Care Organ Donation to identify solutions, including much needed legislative reform. On April 12, 2019, the Nova Scotia legislature passed modifications to the Human Organ and Tissue Donation Act (HOTDA). This multifaceted update of the legal framework surrounding deceased donation and transplantation includes strengthening of requirements for mandatory referral of potential donors and a deemed consent (“opt-out”) model. In a deemed consent model, it is presumed that those who have not registered their objection to donation wish to become donors if medically suitable. Once implemented on January 18, 2021, Nova Scotia will become the first jurisdiction in North America with deemed consent. The upcoming legislative change has acted as a catalyst for the provincial government to provide frontline resources and infrastructure, including support for donation-focused physicians throughout the province, healthcare professional education, performance metric reviews, accountability frameworks, and public awareness campaigns. These well-described components of high performing donation systems are expected to increase donation rates in the province.

For decades, deemed consent models have been implemented in several jurisdictions internationally and are a component of the highest performing donation systems in the world. However, the impact and effectiveness of deemed consent remains both poorly defined and controversial. As in Nova Scotia, consent model reform is typically introduced as part of a broad healthcare system transformation, making it difficult to determine the isolated impact of deemed consent. While some jurisdictions, including recent data from Wales, have shown a positive impact on donation rates with deemed consent systems, another report analyzing data from 35 developed countries found no significant difference between the rates of donors per million population in countries with or without a deemed consent model. Other studies have reported neutral and potentially negative impacts in the short-term, particularly on living donor rates. In addition, it is unclear if deceased donation rates in donors per million population are an appropriate metric. Rates of deceased organ donation depend on multiple factors that are unaffected by the deemed consent model, such as the number of patients who are medically suitable for donation and access to hospital facilities with the capacity to facilitate the donation process.

While Nova Scotia implements donation and transplantation system transformation, there is a need to evaluate the impact of these changes to inform not only Nova Scotia and Atlantic Canada, but also other provincial, national, and international stakeholders. To do so, the Legislative Evaluation: Assessment of Deceased Donation Reform (LEADDR) Program was created to evaluate the implementation process and full impact of HOTDA and the health system transformation in Nova Scotia. LEADDR is the result of the collaboration of key partners: Nova Scotia Health Authority including the Legacy of Life and Critical Care Organ Donation Programs, Nova Scotia Department of Health and Wellness, Canadian Donation and Transplantation Research Program, Transplant Québec, and Canadian Blood Services, with funding support from Health Canada’s Health Care Policy Contribution Program.

**PROGRAM DESIGN AND METHODS**

The LEADDR is a collective of interprofessional clinicians, administrators, researchers, and other stakeholders that will study the effects of HOTDA implementation and the implementation process itself. Outcomes will not be limited to quantitative measures such as the numbers of donations or transplants, but we will also examine issues such as stakeholder views and attitudes on organ donation and transplantation. Stakeholders will be defined as anyone implicated in the donation and transplant system, from patients to healthcare administrators across Canada. The overarching goal is to apply rigorous, scientific methods to generate knowledge that provincial, national, and international stakeholders can use to inform and implement legislative changes in other jurisdictions.

The LEADDR program is guided by a steering committee that provides advice, direction, and oversees 3 principal activities that will encompass the evaluation of HOTDA and the health system transformation. The steering committee is comprised of multidisciplinary representatives from each of the partner organizations, as well as a patient partner, Activity co-leads, and administrative support from all over Canada (Table S1, SDC, http://links.lww.com/TXD/A299). Membership on the steering committee was initially determined by soliciting partner organizations for members with interest and needed expertise. Subsequent membership, including patient partners, was determined by initial membership to ensure adequate representation from stakeholders.

The steering committee is tasked with investigative priority setting, budgetary and administrative oversight of the entire program, and development of knowledge translation and communication plans. Projects are divided between 3 Activities designed to investigate complementary aspects of the legislative reform and system transformation. Figure 1 includes a list of the currently approved projects and anticipated timelines. Projects within each Activity were originally proposed by collaborators who submitted to the LEADDR program for funding with Health Canada. Division between the activities was done in accordance with the stated goal of each Activity and the overall program.

A series of telephone and videoconference consensus building meetings were held between June 2019 and February 2020, resulting in the creation of the steering committee, detailed terms of reference, and definition of the vision and priorities of the LEADDR initiative and its Activities. This consensus building strategy culminated with a face-to-face meeting in March 2020, where we finalized the selection of projects and associated substudies.

**Activity 1: Define and Measure the Quantitative Impact of the Legislative Reform**

Activity 1 aims to define and measure the quantitative impact of the legislative reform. This will be largely evaluated through the performance of potential donor audits (PDAs). PDAs evaluate each death to determine if the person met criteria for referral to the local organ donation organization, if that referral actually occurred, if consent for deceased donation was given, and if the potential donor became an actual donor. PDAs are essential elements for system improvement and are the only method to evaluate rates of identification and referral or consent for donation. PDA results are also less likely to be biased by unrelated trends in donation and transplantation activity by focusing on the aspects of the system that HOTDA could realistically impact. For example, if fewer patients die in circumstances that would permit them to become organ donors, but all of those potential donors were...
identified and referred and the consent rates increased, the effect of the HOTDA could be considered positive for donation, even if there were fewer overall donors. Three to 5 y historic performance as measured by PDAs will be generated and will be used to predict the impact of HOTDA.

Ultimately these quantitative measures from PDAs in Nova Scotia will be compared with other Canadian provinces’ PDAs using interrupted time series methodology. This will allow us to compare the underlying trends in other provinces and evaluate the change after HOTDA implementation. We will aim to collect 3–5 y of data (this will depend on availability of data from comparator provinces), and we will be able to determine if other events, such as the announcement as opposed to the implementation of HOTDA, had effects on the measured outcomes. It will be impossible to eliminate all confounding elements in these comparisons, but we will choose comparator provinces with systems that most resemble Nova Scotia’s but without deemed consent. In addition to these clinical makers, we also will apply interrupted time series methodology to the Nova Scotia and national intent to donate registries.

Beyond clinical performance accountability, the metrics generated from the PDA will be used to create realistic estimates of the expected economic impact of HOTDA. This analysis will initially focus on kidney transplantation, where expected and observed changes in donation rates will be used to estimate the costs of transplant activity compared with potential savings in dialysis.

Further Activity 1 projects will include the impact of HOTDA on transplant outcomes including living donation and transplantation and short and intermediate posttransplant outcomes. Protocols for the study of these outcomes, which will include a cohort analysis of patients transplanted in the pre and post-HOTDA eras, are finalized and currently being submitted for research ethics approval. It is our intention to submit the research protocols of all Activity 1 projects for publication once approved by the research ethics boards.

Activity 2: Understanding Experiences of Deemed Consent Internationally

Activity 2 is focused on collecting and synthesizing the published knowledge related to implementation of deemed consent throughout the world, including both quantitative and qualitative literature. Understanding the need to review diverse source materials around deemed consent, the steering committee selected co-leads and team members of this Activity with clinical, legal, and ethical expertise.

Initial review of existing publications suggested that a single report would cover too many divergent topics, and we chose to divide the topics into more focused literature reviews. The selected areas of focus are as follows: (1) the current state of ethics and law associated with deemed consent, nationally and internationally; (2) stakeholder attitudes toward deemed consent (public, healthcare personnel, and other populations in Canada and internationally); (3) the effect of deemed consent in international communities on organ donation metrics of success (transplant and donation rates, automatic referral rates, etc.); and (4) understanding the current state of knowledge among the Canadian public about deemed consent. All reviews are being performed by teams with experience in either systematic or narrative review syntheses and include support from health information specialists to create comprehensive search strategies. These reviews will provide valuable insight into the knowledge gaps around deemed consent implementation and allow stakeholders to anticipate strategies that would increase or decrease the chances of successful deployment.

Activity 3: Understanding Public and Healthcare Professional Knowledge and Attitudes

Deemed consent for deceased organ donation is a novel concept in Canada and North America. In addition to the quantitative data collected in Activity 1, comprehensive evaluation of the impact of the implementation of HOTDA will require a careful understanding of public and professional knowledge and attitudes. Doing so will allow mapping of concerns from the general population and identification of subgroups who may be likely to have specific viewpoints on deemed consent. This will ensure that education and implementation efforts are tailored to address actual barriers to HOTDA implementation. All of the methods described below will be applied to populations in Nova Scotia and to the rest of Canada when appropriate.
We are analyzing existing national and provincial data from sources such as web-based surveys and focus groups of the general public and key stakeholders to understand attitudes and knowledge related to organ donation and transplantation. The primary source of this data is national polling commissioned by Canadian Blood Services over the last 10 years. While these polls were not specific to Nova Scotia participants, they consistently included at least some questions pertaining to a deemed consent model and included a proportion of Nova Scotians consistent with the overall population of Canada. Analysis of this data will guide the development of surveys and focus groups that can be applied to various populations within Nova Scotia.

In parallel to the above analysis, we are performing a national and provincial analysis of the media response and user comments dialogue to Nova Scotia’s deceased organ donation legislation reform. Using well-developed media analysis techniques, we will identify expressed concerns to HOTDA, which will again inform future polling as well as implementation tools crafted to address these issues.

Prospective electronic surveys and focus groups within Nova Scotia from primary care providers and medical and nursing professionals working in emergency departments and intensive care units are also currently underway. Within the general population, we anticipate that certain groups may have particular concerns with deemed consent. Many studies of deceased donation have identified that linguistic, religious, and/or ethnic minorities can have higher levels of distrust of the healthcare system in general and distrust specifically related to organ donation. Thus, we will collect data from historically underrepresented communities including Indigenous and African Nova Scotians, lesbian, gay, bisexual, transgender and queer or questioning and others, Faith communities, newcomers to Canada, and communities with low literacy rates. Collectively, the data from both professionals and community members will inform the ongoing implementation of HOTDA, particularly around the tailoring of education and training targeted to relevant providers.

**DISCUSSION**

Over the next 3 years, these 3 activities will provide a comprehensive analysis of implementation of the health system transformation, including legislative reform, in Nova Scotia. This program will ensure that we understand the impact of implementation, including increased clinician awareness of the need to identify and refer potential donors, the number of people who agree to become donors, the economic impact, the number of transplants, and the attitudes of the diverse groups touched by the donation and transplantation system. Although no other North American jurisdiction has chosen to implement deemed consent, considerations of consent model changes are a frequent source of interest among both the general public and elected officials. The public discussion of these issues is often emotionally and morally charged, but there is a lack of high-quality research to support claims either for or against implementation of these reforms. By embedding these evaluations in the implementation phase and including multiple clinical and administrative decision-makers in the planning of this research program, we are confident we can develop evidence from multiple spheres of expertise that will inform other areas considering a change to their own consent model.

Our program will have some inherent difficulties and limitations. First, according to the 2016 census, the population of Nova Scotia is approximately 925,000 people, and the province is relatively geographically isolated from other North American population centers. While possibly a limitation for generalizability, it has advantages in terms of data gathering since all donation and transplantation activity is coordinated through a single center in the city of Halifax. The population is also less diverse than some other areas of North America. According to 2016 census data, approximately 6% of the population was classified by Statistics Canada as part of visible minority populations, compared with 22% in the rest of Canada. Understanding this demographic reality, we are planning to focus efforts on understanding the impact of these reforms in the existing underrepresented population. A final limitation for the Nova Scotia implementation is that some of the outputs from Activity 2 and 3, including literature reviews and pre-implementation polling, could have been more effective for Nova Scotia implementation if done before drafting and implementation of HOTDA. However, the law was passed and deadlines for implementation were decided before the funding of the LEADDR program. Thus, some of our outputs will be useful for clinical implementation that is ongoing in Nova Scotia.

These insights will inform decision makers and stakeholders nationally and internationally and position Nova Scotia and Canada as leaders of understanding the realities of deemed consent in North America.

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