
Background Paper for the OTDT Committees

Intent to Donate – Environmental Scan

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1. Introduction

A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, ***Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians***, can be found at organsandtissues.ca, along with the other background documents in this series.

Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.

- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the ***Call to Action*** report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.

For more information on these documents or the ***Call to Action*** report, please contact:

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B. Scope

According to a recent survey, awareness of, and support for, the need and opportunity for organ donation in Canada is high, with 95 per cent of Canadians approving of organ donation. Despite this support, only 51 per cent of Canadians have indicated their intent to donate by signing a donor card or registering online (where available). Of those who have made a decision about their intent to donate, 84 per cent indicate that they have discussed their wishes with the person who would act on their behalf in a medical emergency.¹

Anecdotal reports indicate that existing registries are hampered not only by relatively low levels of registration, but also donation and registration information that is not uniformly accessible. If intent is indicated on a driver's license, donor card

or health card, it may not be with the donor when donation consent is required. If a record of expressed intent is stored in a database, not all hospitals or relevant staff may have timely access to the information. In some cases, donors registered in one province may be in hospital in another while traveling or after having moved. These limitations have led to a discussion of how the system can be improved. More information is required, however, to inform decisions regarding registries and other OTDT system improvements.

This report summarizes environmental scan research performed by Canadian Blood Services and its partner, Deloitte. Information is a combination of primary research and interviews with jurisdictions in Canada and around the world.

¹ Canadian Blood Services. (2010). Views Toward Organs and Tissues Donation and Transplantation.

2. Purpose and Objectives

Improving donation rates essentially involves enabling the public to turn support for organ and tissue donation into action. The purpose of this report was to conduct an environmental scan and analysis of existing systems and strategies for registering intent (a non-binding indication of personal wishes) or consent (a legally-binding agreement) to donate nationally and internationally. Specific objectives were to:

- Provide deeper and broader understanding of:
 - Existing systems to document intent to donate (e.g., registries, donor cards, use of driver's licenses or healthcare insurance cards) and mechanisms to operationalize the systems (e.g., stand-alone databases, or jurisdiction-wide registries).
 - Usefulness of existing systems in encouraging and supporting donor intent and consent, and in supporting the identification, referral and consent processes within the donation process (e.g., accessibility to the public, designed for use by healthcare professionals, and organ procurement officers).
 - Effectiveness of existing systems in increasing donation (using measures such as percentage of population registered and percentage of organ donors who had registered).
- Document costs of developing, maintaining and operating intent-to-donate registries nationally and internationally.

3. Approach

The Intent to Donate (ITD) Environmental Scan addressed five issues:

- I. Strategies used to increase donation (including the type of information collected);
- II. Value of ITD registries and evidence of their effectiveness;
- III. Lessons learned from other jurisdictions;
- IV. Costs of implementing and maintaining ITD systems; and
- V. Legislative enablers of these systems.

To address these issues, a literature review was performed and one-on-one interviews were conducted with representatives in various Canadian and international jurisdictions:

- British Columbia (BC)
- Nova Scotia (NS)
- Ontario (ON) (Ministry of Health and Long-Term Care, and Trillium Gift of Life Network)
- Alaska (Donate Life)
- California (Donate Life)
- Pennsylvania (Gift of Life Donor Program)
- Florida (Donate Life)
- Eurotransplant (several European countries)
- Spain (Organizacion Nacional de Transplantes)
- United Kingdom (NHS Blood and Transplant)

Research Questions

Table 1 lists the research questions that guided the environmental scan interviews and literature review, along with their justification.

Table 1: Summary of Research Questions

Question	Utility
<ol style="list-style-type: none"> 1. What strategies or mechanisms are used to enable members of the public to register their intent or consent to be a donor? 2. What type of information is captured or collected by existing systems (e.g., opt-in or opt-out, consent or intent to donate, types of organs and tissues to be donated, etc.)? 3. What is the value of intent to donate systems from the following perspectives and how is value measured (e.g., hits on registry, satisfaction, etc.)? <ol style="list-style-type: none"> a. Increasing awareness (among the public and/or health professionals) of organ and tissue donation? b. Encouraging and enabling members of the public to record their intent or consent to be a donor? c. Enabling health professionals to act on a person’s documented intent to donate? 	<ul style="list-style-type: none"> • Inform understanding of mechanisms used to record intent to donate. • Inform understanding of impact of intent to donate systems on public and professional awareness. • Inform development of potential National System Design options and recommendations related to intent to donate registration.

<p>4. Based on findings from the environmental scan, what evidence and experience have Canadian and international jurisdictions had with registries impacting intent to donate registration rates and actual donation rates?</p> <p>5. What are the lessons learned by jurisdictions who have registries?</p>	<ul style="list-style-type: none"> • Inform understanding of the contribution of registries (and other mechanisms used to document intent to donate) to increasing intent registration and organ donation.
<p>6. What financial (infrastructure and operating) resources are required to implement and operate registries? What costs have been incurred to develop, implement and operate intent to donate registries?</p>	<ul style="list-style-type: none"> • Inform understanding of the investment required to achieve increased intent registration and donation.
<p>7. What enablers (policy, legislation, governance, etc.) are required to support implementation of national (single system or linked provincial/state/regional systems)?</p>	<ul style="list-style-type: none"> • Inform development of National System Design options and implementation considerations.

4. Summary of Findings

A. Strategies used to increase donation

There are many ways to enable citizens to express consent (legal) or intent (indication of willingness) to donate, including:

- Presumed consent (legislated or not);
- Registries (intent, consent, opt-out, opt-in, combined opt-in and opt-out);
- Organ donor cards;
- Designation on health card, motor vehicle license or other identification card;
- Discussion with family or next of kin; and
- Documentation in a will, advance directive or other legal document.

In Canada, mechanisms vary across the provinces. Seven provinces use provincial healthcare cards as a means of indicating intent. Of those seven, three (ON, QC and NS) use a combination of registries and healthcare cards, with the card renewal process representing an opportunity to register. In

three other provinces (AB, SK and NB), intent to donate is indicated on the healthcare card. PEI provides an option to indicate intent using a healthcare card or a driver's license. Of the remaining three provinces, two (MB and NF) have organ donor cards, and one (BC) offers online or mail-in options to indicate registration in a provincial organ donor registry. Overall, four provinces already have registries (BC, ON, QC and NS). In the United States, many states have opt-in registries linked to driver's license registration through partnership with the states' Departments of Motor Vehicles (DMV).

Canadian practice appears to be consistent in asking family members for consent, regardless of whether consent has been recorded. Asking family members for consent was reported also to occur in Australia, Spain and the United Kingdom—despite

legislation that recognizes first-person or presumed consent, which exist in Spain and the United Kingdom, respectively. In the United States, most states recognize first-person consent and do not require next of kin to proceed with organ donation.

Type of information captured in registries.

In opt-in registries, the key information captured is the person's wish to be an organ donor (i.e., the affirmative response). Additionally, in some jurisdictions (such as Ontario) more specific

information is collected, including willingness to provide organs for research, and whether specific organs should be excluded. In opt-out or combined opt-in/opt-out registries, the person also has the option of deciding that they do not wish to be a donor (i.e., the negative response). Depending on legislation, registry entries may be recognized as legal consent, or merely a preference that can be used to inform discussions with next of kin. Most registries, by virtue of their connection with existing healthcare or driver's license databases, also collect basic demographic information.

B. Value of ITD registries and evidence of effectiveness

Provincial and international jurisdictions reported that their ITD registries were valuable in several respects:

- **Supporting public awareness.** Registries can provide a call to action in support of targeted marketing and awareness campaigns. Collecting demographic information through a registry allows for improved targeting of certain segments of the population.
- **Supporting the process of acquiring consent.** Registries can help inform donor families of loved ones' wishes. For health professionals or donor coordinators, registries provide an accessible source of information about consent, and an entry point to a conversation about donation with family.
- **Increasing effectiveness and efficiency.** Online registries are viewed as being more secure and timely than manual systems. They contribute to timely donor identification and management, which may translate to higher rates of graft survival and organs transplanted

per donor and save the additional costs associated with obtaining consent from family.

- **Increasing the number of people registering consent, thereby increasing the number of donors who registered consent.** Most jurisdictions reported that new online registries resulted in an immediate and significant increase in the number of registrants, as well as a greater proportion of donors who had indicated consent in a registry.

Given the multiple efforts underway to impact organ donation in most jurisdictions, it is impossible to isolate the impact that one mechanism has on increasing donation. Despite agreement regarding the above benefits of ITD registries, there is limited evidence to indicate their ability to increase donation rates; however, anecdotal evidence from Canadian provinces, the US and the UK indicates a belief that registries have led to an increase in donors.

C. Lessons learned from other jurisdictions

Interviews with representatives of Canadian and international jurisdictions yielded the following advice related to developing ITD registries.

- **Development and implementation**

It was strongly recommended to build registries around existing routine activities and to partner with organizations responsible for those activities. For example, US jurisdictions gain donors by using the turnstile aspect of DMV license renewal and identification cards (so-called because almost all adults must pass through). Donate Life California recommended against relying on a website for collecting consent, as 98 per cent of its registrations have come via the DMV. Attaching registration to government-operated activities has led to registries being viewed as a better and trusted way to collect data that simultaneously reduces costs.

- **Enabling registries.** Professional education about consent registries is central to the success of these systems; the biggest challenge to advancing donor designation is clinicians who are unfamiliar with notifying families about a loved one's registered consent. The development and piloting of a registry should involve clinicians, OPOs and tissue and eye banks—as well as donor and recipient communities. A strong marketing and public awareness campaign was also believed to help

leverage the technology of online registries.

- **Cautions.** One respondent cautioned against overselling the benefits of a registry as a standalone tool to impact donation. In particular, statements that a registry will improve organ donation rates may not be justifiable. Registries do not replace processes for the clinical identification of donors; rather, they facilitate obtaining consent when a potential donor is identified. It should also be noted that a variety of other approaches can be used to increase donation, such as a combination of presumed consent legislation, the use of donor cards, the practice of asking families for consent, and infrastructure to support donation (national coordination, medical champions, reimbursement of hospitals for donation, etc.).
- **Considerations.** While it is difficult to link registries directly with increased donation, almost all respondents felt that registries are useful to increase awareness and contribute to overall marketing activities. Registries provide a call to action for marketing messages and allow interested individuals to take immediate action in support of donation. Further, registry activity can act as a performance measure for marketing initiatives. Healthcare staff and physicians report that registry information can inform discussions with family members and provide families with a measure of relief and comfort when loved ones' wishes are known. This information must be considered when determining the overall value of registries.

D. Costs of Implementing and Maintaining LTD Systems

Cost data were obtained through interviews with jurisdictional representatives. Capital and development costs varied with size of population served and the development model selected (e.g.,

standalone vs. leveraged existing system). Operating costs also varied depending on whether staff costs were included. In some instances, development costs were no longer available or

were offset by partnerships with existing systems, for example partnerships with the Department of Motor Vehicles in certain states. Development costs ranged from approximately \$400,000 to \$700,000 and annual operating and maintenance costs

ranged from approximately \$10,000 to \$50,000. Variances in practices, partnerships and registry management make it difficult to do an accurate comparison between programs.

E. Legislative Enablers

First-person consent laws have enabled care providers to act on registered consent without approaching family members first. In Canada, under the legislation of provincial human tissues gift acts (or equivalent) a person who meets the statutory age requirement has the authority to consent to post-mortem donation. In all provinces except Manitoba, this consent is binding, which means that it must be followed unless a legal exception applies. In Manitoba, it is legally permissible for physicians to respect family opposition donation. In Quebec, the expressed

wishes of the individual must be followed except for a compelling reason.

In the United States, all but four states have legislation recognizing first-person consent. The recently revised Uniform Anatomical Gift Act allows hospital staff to act immediately when a potential donor is available and has previously expressed a desire to donate through a registry. Countries such as Austria, Belgium and Spain have presumed-consent legislation that empowers care providers to obtain organs without obtaining consent from the family.

5. Conclusions

The Environmental Scan has explored existing systems used to document a person's intent or consent to donate organs in several Canadian and foreign jurisdictions. A particular focus was placed on consent legislation, and the way in which intent or consent is captured.

In interviews with key representatives, the ability of online registries to increase donation rates was found to be difficult to demonstrate quantifiably; however, donor registries are believed to have qualitative value in terms of increasing public awareness, streamlining donation processes, and facilitating a discussion with families and next of kin. Even in jurisdictions that recognize first-person consent, families are usually provided the

option of refusal, which highlights the importance of the way in which families are approached and engaged by care providers and donor coordinators following a death of a potential donor.

Interviews also provided specific insights into the most effective approach to implementing a registry. The most common recommendation in this regard was partnership with existing government organizations. This partnership approach has the dual benefits of leveraging the credibility of public institutions, while using the turnstile nature of their processes (such as health card or driver's license renewal) to engage the widest possible audience. The costs of implementing a registry

varied widely depending partly on the costs of integrating with shared databases.

Several respondents noted that registries represent only one valuable tool in a system that is focused

on increasing organ and tissue donation. These jurisdictions noted that while registries have multiple benefits, they must, to be most effective, be part of a system of initiatives to increase donation.

APPENDIX: Environment Scan

The Process of Providing Intent/Consent

The first important element in convincing a person to donate is awareness about organ and tissue donation and transplantation. Once an individual is aware of the issue, they make a decision about whether or not they wish to donate. The next step is to take action. This can take many forms, e.g.

registering to be a donor, telling family about the decision. If the opportunity to donate arises, indication of a desire to donate will inform and guide family members and professionals into action and donation, when possible. This research was focused on action: the mechanisms that can be used to express consent and the use of these mechanisms in the donation process.

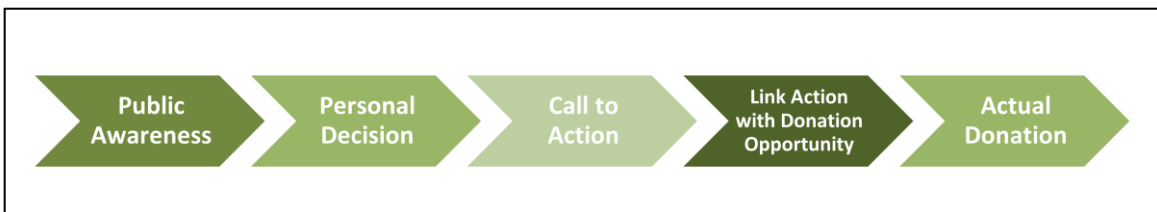


Figure 1: Process flow, indicating the steps an individual takes up to donation.

Difference between intent and consent

Generally registries collect either intent or consent to donate. Expressing intent is a way for individuals to indicate to family members their wish to be a donor. Consent, in contrast, provides legal protection for health professionals to obtain organs without necessarily consulting with next of kin. Most jurisdictions report that they will consult with, and usually not overrule families or next of kin. More details about the legislation of consent are provided in Table 4 (page 14) and Table 5 (page 15).

Tissue considerations

Methodologies for designating intent and consent, while often focused on organ donation, have incorporated tissue donation as well. A number of tissue specific issues require consideration in the development of designation methodologies:

- There are many urban and rural areas in Canada where there are no systems in place to recover tissue. This is a particular issue for the recovery of musculoskeletal, cardiac and skin

tissues. Implementation of intent- or consent-to-donate registries should consider strategies and approaches required for locations where recovery systems are not in place.

- The public is generally unaware of the extent to which tissues are used today, and of the modalities of tissue recovery and processing. Public awareness strategies have focused predominantly on organ donation and transplantation. Strategies should include information about tissue utilization, recovery and processing, including the commercial aspects of the industry and associated ethical considerations.

Expressing Consent

There are many ways to express consent:

- Presumed consent (legislated or not);
- Registries (intent, consent, opt-out, both opt-in and opt-out);
- Organ donor cards;
- Designation on health cards, motor vehicle licenses or other identification cards;

- Discussions with families or next of kin; and
- Expression in a will or other legal document.

A review was performed to find which mechanisms to obtain consent are used in Canadian provinces and in several international jurisdictions.

Canada

In Canada, mechanisms for indicating consent vary by province. Three provinces (AB, SK and NB) rely solely on the signing of a healthcare card; two provinces (MB and NL) use an organ-donor card system independent of any other mechanism; one province (PEI) provides an option to indicate intent using either a healthcare card or driver's license; three provinces (ON, QC and NS) use a combination of registries and healthcare cards; and one province (BC) offers online or mail-in options to indicate a decision to donate, which is maintained

on a registry. In all provinces, current practice is to obtain consent from next of kin or family before donation, regardless of the existence of an individual's consent or registration. A comparison of registries across Canada is presented in Table 2, below.

In all provinces, the practice is to acquire next-of-kin or family consent prior to donation. Although the expression of a desire to donate is not currently being used as consent, the existence of a record of a decision to donate informs discussions with family members, provides a call to action for public awareness activities, informs healthcare providers and donor coordinators in their discussions with family and anecdotally eases the stress on a donor family. These factors indicate usefulness of registries beyond merely providing consent.

Table 2: Comparison of Registry Types across Canadian Provinces

Prov.	Organ DPMP* (2008)	Tissue DPMP* (2008)	Registry	Mechanism to Indicate Intent	Performance	Access to Information
BC	12.3	116	Opt-in and opt-out	Register online or by completing a registration form and returning it by mail. Registration forms available from BC Transplant, also mailed with driver's license renewals.	734,000 registered (17% of population). Do not track number of yes/no.	Information is accessible by ICU staff in hospital online using patient's health card number. Information is also accessed by calling BC Transplant.
AB	11.4	92	No	Sign healthcare card and indicate either <i>yes</i> or <i>no</i> . Can designate specific organs or tissues.	Unknown	Information is kept by the individual. Not usually accessed by OPO.
SK	12.0	30	No	Apply a sticker to health card. Stickers mailed with health card when renewed and indicate only willingness to donate, not consent. No form is completed.	Unknown	Information is kept by the individual. Not usually accessed by OPO.

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MN	11.7	151	No	Sign donor card, which is available online and at all Autopac dealers (licensing agents).	Unknown	Information is kept by the individual. Rarely accessed by health providers.
ON	13.6	123	Opt-in only	Register when renewing health-care card or by completing and mailing a form available from Trillium Gift of Life or the Ministry of Health and Long-Term Care.	Approximately 27% of people with photo identification health-care cards are registered.	Information accessed by specific TGLN staff following donor referral.
QC	19.4	N/A	No	Sign and affix a sticker to the back of health card. Registry is independent and maintained by notaries.	Unknown	Unknown
NB	16.5 (Atlantic combined)	234	No	Sign health care card with either <i>yes</i> or <i>no</i> to donation. Health cards are renewed every three years.	Yes: 262,210 (36% of pop) No: 224,923 (31% of pop)	Information is kept on a database that is searched by OPO when family is uncertain of an individual's wishes. Information on the database is used to identify communities to target for education and awareness.
NS		152	Opt-in only	Register via healthcare card with requirement to reconfirm when renewing card (every four years).	~500,000 people registered (50% of population)	Registry information is accessed by donor coordinator once potential donor referred.
PEI		0	No	Affix a red sticker on health card or have a red heart engraved on driver's license at renewal.	Unknown	Unknown
NL		14	No	Sign organ donor card or check the box on the driver's license renewal form.	Unknown	Information is not readily available to donor coordinators or hospital staff.

* DPMP = Donors per million population

Other countries

Of the top performing countries in organs donated per million population, most maintain some form of donor registry, including Belgium, the United States, France and the Netherlands. Countries without registries include Germany and Switzerland. Although registries exist in most countries, regardless of whether they have

presumed consent legislation, the type of registry, the percentage of the population registered and the use of the registry varies. In almost every case, registries are supported by public awareness initiatives and family consent. A comparison of registries in international jurisdictions is presented in Table 3.

Table 3: Comparison of Registry Type across International Jurisdictions

Country	DPMP (2008)	Presumed Consent	Registry Type			Number of registrants	Comments
			Opt-in	Opt-out	Comb.		
Spain	34.2	✓					In practice, family consent is obtained when next-of-kin available (17% of families refuse donation). Use the donor-card approach to bridge discussion with families at time of death.
Belgium	25.5	✓			✓		Combined registry since 1987. Families can potentially object to organ donation.
USA	26.1		✓			79.7 million (Dec. 2008) 38.2% of drivers or 26% of total population	Donor designation registries (first-person opt-in) maintained by state, most often in cooperation with the Department of Motor Vehicles (DMV). Family consent is not required if donor has registered consent.
Canada	14.6		✓				Registries in four provinces; all other regions have process for potential donors to consent (e.g., donor cards and designation on health card).
United Kingdom	13.5		✓			16.743 million (28% of total population)	Opt-in registry launched in 1994. Accessed mainly by co-ordinators (organ and tissue) and also by ITU medical staff whenever there is or could be a potential donor. Accessed between 30 and 50 times/day.
Australia	12.1		✓			1.3 million (6% of total population)	National registry launched 2005. Family consent is required for donation.

Consent Legislation

The success of a registry is dependent on the existence of consent legislation that legally protects care providers for following an individual's intent or consent to donate. The specific details of consent legislation, in terms of the precise authority granted to physicians, vary internationally and within Canada.

Canada

In Canada, under provincial human tissues gift acts, or equivalent legislation, a person who meets the

statutory age requirement has the authority to consent to post-mortem donation. In all provinces except Manitoba this consent is binding, which means that it must be followed unless a legal exception applies. In Manitoba, it is legally permissible for physicians to respect family opposition to donation. In Quebec, the expressed wishes of an individual must be followed except for a compelling reason. A comparison of the legislation across Canadian provinces is presented in Table 4.

While the law is clear that in most provinces next-of-kin or family consent is required only in situations where first-person consent does not

exist, current practice is to seek family consent prior to donation. Family wishes are usually respected regardless of individual consent.

Table 4: Comparison of Consent Laws across Canadian Provinces

Prov.	DPMP (2008)	Legislation	Authority to Act
BC	12.3	<i>Human Tissue Gift Act</i> , R.S.B.C. 1996, c. 211 (“Act”) <i>Consent to Donation Regulation</i> , B.C. Reg. 65/99 (“Reg”)	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 3(4) Act).
AB	11.4	<i>Human Tissue and Organ Donation Act</i> S.A. 2006, c.H-14.5	Consent is binding and authorizes: <ul style="list-style-type: none"> • any medical practitioner to make any examination necessary to assure medical acceptability of the donation; and • the use of the body or the removal and use of the specified tissue or organ for the specified purpose (s. 8(1)).
SK	12.0	<i>The Human Tissue Gift Act</i> , R.S.S. 1978, c. H-15	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 4(3)).
MN	11.7	<i>The Human Tissue Gift Act</i> , C.C.S.M. c. H180 as amended by <i>The Human Tissue Amendment Act</i> , S.M. 2004, c. 40	No provision
ON	13.6	<i>Trillium Gift of Life Network Act</i> , R.S.O 1990. c. H.20	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 4(3))
QC	19.4	Civil Code of Québec (C.C.Q.), S.Q. 1991, c. 64	No provision
NB		<i>Human Tissue Gift Act</i> , S.N.B. 2004, c. H-12.5	Consent is full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 3(3)).
NS	16.5 (Atlantic combined)	<i>Human Tissue Gift Act</i> , R.S.N.S. 1989, c. 215,	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 4(3)).

PEI		<i>Human Tissue Donation Act</i> , R.S.P.E.I. 1988, c. H-12.1	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 10(1)).
NL		<i>Human Tissue Act</i> , R.S.N.L. 1990, c. H-15	Consent means full authority for any physician to: <ul style="list-style-type: none"> • make any exam necessary to assure medical acceptability of the tissue; and • remove such tissue (s. 4(3)).

Comparison with international jurisdictions

A number of countries have presumed-consent laws that support donation in the absence of a formal expression against donation by the individual. In these countries, family or next-of-kin consent is not required, and donation can proceed unless it goes against the explicit desires of the deceased. Countries with presumed-consent laws include Spain, Belgium, France and Austria. Eight of

the twelve countries that report more donors per million population than Canada have presumed-consent laws. Countries that have more donors per million populations, and that do not have presumed-consent laws, include the United States, Ireland, the Netherlands and Germany. A comparison is summarized in Table 5.

Table 5: Comparison of Consent Laws in Other Jurisdictions

Country	DPMP	Law	Source	Practice
Spain	34.2	Presumed consent		Families are approached to ensure they are aware of the wishes of the individual.
Belgium	25.5	Presumed consent		
United States	26.1	Donors can express their wishes regarding organ donation in a number of ways including signing a donor card or other record; registering with a state registry; registering with the MVA; in a will; or verbally with at least two witnesses (one of whom is disinterested). An individual may refuse to make an anatomical gift using similar methods of expression as above. The donor's autonomous decision regarding the making of an anatomical gift is to be honoured and implemented and is not subject to change by others. Families do not have the power, right or authority to consent to, amend, or revoke donation decisions made by donors.	Uniform Anatomical Gift Act (2006)	Historical practice has been to obtain family consent; however, states are moving toward honouring the <i>Uniform Anatomical Gift Act</i> and acting on first-person consent where registries exist.

		A family member may make an anatomical gift on an individual's behalf in the absence of donor designation.		
Canada	14.6	Under provincial human tissues gift acts (or equivalent), a person who meets the statutory age requirement has the authority to consent to post-mortem donation. This consent constitutes full authority for the removal and use of body parts for donation. In all provinces except Manitoba, this consent is binding, which means that it must be followed unless a legal exception applies. In Manitoba, it is legally permissible for physicians to respect family opposition to donation. In Quebec, the expressed wishes of the individual must be followed except for a compelling reason. What constitutes a compelling reason is not defined therefore family override may be permissible depending on interpretation.	Family Override of Valid Donor Consent to Post-Mortem Donation: Issues in Law and Practice, Jocelyn Downie, Alison Shea, and Chantelle Rajotte. December 2006 Uniform Human Tissue Gift Act (1990)	Current practice is to seek family consent prior to donation. Family wishes are respected regardless of individual consent. Anecdotally, no case is known where a family's wishes were overruled in favour of an individual's expressed wish to donate.
United Kingdom	13.5	The code of practice and guidance issued under the Human Tissue Act make it clear that the known wishes of the deceased individual take precedence over the views of relatives and that family or next of kin do not have a legal right to veto the wishes of the person who has died.	Human Tissue Act (2004) Human Tissue Legislation Guidance from the BMA's Medical Ethics Department	It is considered good practice to speak to the family and follow their wishes.
Australia	12.1	As part of the new national reform of organ and tissue donation, the family of every potential donor will be asked to give their consent to donation if the situation arises.	http://www.donatelife.gov.au/Discuss/Discuss-with-your-Family.html Accessed 2009-11-26	Registering as a potential donor informs the medical staff and may be part of the discussion with next of kin although all potential donor families are approached for consent.

United States Donor Designation Collaborative

In the fall of 2006, Donate Life America launched the Donor Designation Collaborative as a national effort to improve donation rates by ensuring that each state has an effective system for allowing individuals to designate themselves as donors. Currently, 46 states and the District of Columbia have first-person consent registries where consent is legally binding and cannot be overridden by

family members. Four states have intent registries that document the wish to donate but, ultimately, the family remains responsible for authorizing consent.

One of the initial goals of the Donor Designation Collaborative is to achieve 100 million actionable donor designations. As of December 2008, 79.7

million people were enrolled in state donor registries. According to Donate Life America, 25.2 per cent of total organ donors and 27.2 per cent of tissue donors in 2008 had joined a registry before their death. This is an increase from the previous year, in which 19.1 per cent of organ donors and 26.7 per cent of tissue donors had joined a registry prior to death.

The donor designation registries in the United States, combined with the recently revised *Uniform Anatomical Gift Act*, allow hospital staff to act immediately when a potential donor is available and has previously expressed a desire to donate through a registry. Based on this information, donor management can begin without family consent. As a result, conversion rates now equal the percentage of population registered, and time from identification to donation has been reduced.

Registry Costs and Benefits

Through one-on-one interviews with representatives of several provincial and foreign jurisdictions, several benefits of enabling expression of consent through registries have been identified:

- Encouraging discussion about wishes with family members;
- Informing healthcare providers and consent requestors;
- Potentially reducing the stress of healthcare providers in approaching families;
- Measuring the success of marketing and public awareness activities;
- Potentially reducing the stress of family in knowing and following the donor’s wishes; and
- Providing demographics relating to consent to inform social marketing strategies.

To provide further insights, interview respondents were asked to:

- elaborate on the benefits of their registries;
- provide evidence for their effectiveness in increasing donation rates;
- indicate associated capital investments and operational costs; and
- describe lessons learned.

Table 6 below provides a summary of the reported costs, benefits and lessons learned. Note that feedback has not been attributed for the publication of this report.

Table 6: Comparison of Reported Benefits and Lessons Learned in Various Jurisdictions

	Evidence for Effectiveness	Insights*
Respondent #1	<ul style="list-style-type: none"> • 50K new registrants/year • Increase of around 150 registrations/day with new system • Families and care providers report that system eases donation process • 20%–30% of donors on registry • More secure and timely than phone-based process 	<ul style="list-style-type: none"> • User pilot testing of registry before implementation was key. • Awareness marketing campaign was key. • Be careful of language used to sell registry (avoid promises of encouraging donation rates).

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Respondent #2	<ul style="list-style-type: none"> • 10K–20K new registrants/year • 50% of population is registered • System eases donation process with family • Difficult to determine whether donation rates impacted 	<ul style="list-style-type: none"> • Donation brochure was “too dense”; now using emotional appeal to promote. • Have targeted provider education first. • Can rely on health card renewal (every five years) to promote.
Respondent #3	<ul style="list-style-type: none"> • About 16%–20% of population has been registered as affirmative 	<ul style="list-style-type: none"> • Need to be strong, transparent consultations in development of a registry. • Survey on public wishes is strongly recommended. • Ensure there is no duplication of existing provincial registries.
Respondent #4	<ul style="list-style-type: none"> • Over 7 month period, found a 5% increase in registration 	<ul style="list-style-type: none"> • How family approached is critical: recommend that doctor approaches with coordinator to ensure higher consent rate. • Mail-in form does not yield a good response. • Best practice: affirmative action registry, easy link transaction, online access and robust public campaign.
Respondent #5	<ul style="list-style-type: none"> • 55% of population registered • 55% of donors were on registry (used to be 5%) • 35% of referrals are from registry (used to be 10%) 	<ul style="list-style-type: none"> • Differences in family refusal rates indicate that the way the family is approached matters.
Respondent #6	<ul style="list-style-type: none"> • Purpose is to help gain consent • Current proportion in state: 14% (US average: 28%) • 17% of donations assisted by registry (US average: 28%) 	<ul style="list-style-type: none"> • Use providers who have already build systems; e.g., iNet, TransplantConnect. • Use turnstile effect of license renewal to gain donors. • Do not rely on website (98% come through DMV). • Biggest barrier: physicians not used to notifying family (vs. asking for consent). • Recommend radio to advertise. • Some geographical regions have intrinsically higher donation rates that are hard to improve upon.

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<p>Respondent #7</p>	<ul style="list-style-type: none"> • About 44% registered (55%–60% for younger population) • Number of donors has increased about 150% since 1993 • About 44 donors per million 	<ul style="list-style-type: none"> • Strongly recommend consent registry, not intent. • Advise against mailing donor cards (expensive to sort). • Advise attaching to existing gov't systems. • Should be linked to something people have to do anyway (i.e., license renewal). • Raise funds through voluntary checkbox on form.
<p>Respondent #8</p>	<ul style="list-style-type: none"> • 29% of population registered • Observed increase in number of potential donors on registry • Perception is that Florida leads US in number of potential organs 	<ul style="list-style-type: none"> • Consent does not expire (does not have to be renewed). • Department of motor vehicles and Florida Coalition on Organ Donation were crucial partners .
<p>Respondent #9</p>	<ul style="list-style-type: none"> • Rates (about 25%) were not affected by registry use • Comparing countries, presumed consent may double donation rates 	<ul style="list-style-type: none"> • Donation rates can double with presumed consent. • Personal contact has been key in Europe: legislation and public education have had little impact. • Coordinator involvement yielded higher rates in Germany. • Key issue: identifying donors at hospital.
<p>Respondent #10</p>	<ul style="list-style-type: none"> • Rates of transplantation have not been affected by the lack of a registry 	<ul style="list-style-type: none"> • Mass media to increase public awareness of donation is critical.
<p>Respondent #11</p>	<ul style="list-style-type: none"> • No information collected 	<ul style="list-style-type: none"> • Active in making partnerships with a variety of agencies and organizations to add registration to their forms.

* Insights represent the views of individuals as shared during one-on-one interviews.