

National Intent-to-Donate Registry

Issue

The call for a national or provincial intent-to-donate registry for organ donation has been made through public requests to governments and health systems and through proposed legislation. In Canada, various provincial registries have been implemented as potential solutions to increase deceased donation. It is often assumed that an intent-to-donate registry will increase organ donation rates; when an individual registers their wishes to become a potential donor through a registry, it is assumed their donation will automatically proceed. However, the actual organ donation process is complex, and registration of an individual's intent to donate alone does not ensure a donation will proceed or that with intent-to-donate registries donor rates will improve.

Currently, the primary purpose of intent-to-donate registries in Canada is to communicate an individual's previously expressed wishes to become an organ donor to the health-care team and their family. Knowing an individual's wishes to become a donor has proven to be a particularly important support to family members who, due to tragic circumstances, are often requested to affirm or determine on their loved one's behalf whether the donation will proceed, and to health-care professionals who discuss organ donation with the family.

Other key factors that are foundational to high-performing organ donation and transplantation (ODT) systems that are proven to increase donation rates, include specialized staff for donor identification, referral and implementation of programs focused on deceased donation — investment in other improvements, such as an intent-to-donate registry, are less likely to yield significant results without these foundational functions of donor programs established.

Background

In 2008, Canadian Blood Services received a mandate from federal, provincial and territorial governments to develop nationally coordinated organ and tissue donation and transplantation (OTDT) programs and services. Significant pan-Canadian collaboration and investment were needed to transform the system to better meet the needs of the thousands of Canadians on organ wait-lists across the country.

Thorough analysis of other OTDT systems internationally was important in identifying the key factors of successful systems and in ensuring the model proposed for Canada included those factors most likely to yield improvements. In high-performing systems such as Spain, every potential organ donor case is identified and moved forward. Despite the existence of a presumed consent (opt-out) model in countries such as Spain, donation is discussed with each family and the family's wishes are honoured, even if the decision is not to proceed with donation. One benefit of an opt-out system is it allows the treating health-care team the opportunity to maintain a potential donor's vital organ functions (i.e., life support) until consent can be obtained from the family. The donor specialist team is accountable for ensuring all

potential donor cases are identified and for training health-care professionals within the hospital to both recognize opportunities for potential organ donation and support families of potential donors. In Spain, donation is strongly supported by health professionals, hospitals and the public.

In the United States, hospitals must identify and refer cases to organ donation organizations (ODOs), which are responsible for hospital development including, professional training and improving support for families of deceased donors. Other accountability mechanisms to ensure donation opportunities are reported include accreditation and audits tied to performance targets associated with ongoing hospital funding and ODO certification.

Together with the OTDT community, Canadian Blood Services developed a national strategic plan, *Call to Action*ⁱ, which included a set of recommendations to improve deceased and living donation and transplantation in Canada. *Call to Action* was tabled with governments in 2011. While it was never formally endorsed, many of the report's recommendations for organ donation and transplantation have been implemented or are in the process of being implemented by provincial and territorial health systems or Canadian Blood Services. National and provincial systems continue to grow and develop.

Recommendation 6 in *Call to Action* called for an integrated interprovincial ODT system and addressed intent-to-donate registries. Below is the excerpt from the report.

Recommendation 6:

It is recommended that the Canadian OTDT system be supported by intent-to-donate registries and that:

- *existing provincial intent-to-donate registries continue to be supported and enhanced,*
- *Canadian Blood Services develop and host registries for provinces where none exist, and*
- *Canadian Blood Services work with provinces to drive a consistent call to action, a consistent mechanism through which people can register their intent to donate, and best practices for intent-to-donate registries, thereby enabling Canadians to optimize the call to action, and declare their wishes regarding donation.*

Current practice

Without full endorsement and funding for *Call to Action* recommendations, health professionals have advised that provincial programs proceed first with the key factors identified by national and provincial program leaders in ODT to help improve organ donation (see Table 1). This work is the current priority, given intent-to-donate registries are not directly linked to increases in donation or transplantation, and would not likely result in more donors at this time without the foundational system improvements required to support donation in hospitals.

Table 1: Factors contributing to increased donation and donation performance by province

	B.C.	ALTA.	SASK.	MAN.	ONT.	QUE.	N.B.	N.S.	N.L.
Mandatory referral	●	●*	■	●	●	●	●	▲	■
Donation physicians	●	▲	■	●	●	▲	■	▲	■
NDD leading practices	●	●	●	●	●	●	●	●	●
DCD programs	●	▲	▲	▲	●	●	■	●	■
% DCD donors, 2015	25	13	10	0	31	11	0	15	0
Leading practices in donor management	●	●	●	●	●	●	●	●	●
Deceased donors, 2015 (DPMP)	20.1**	12.2***	8.8	13.1	19.5	20.8	10.6	21.2****	15.2
Number of donors, 2015	95	52	10	17	269	172	8	20	8
2011–2015 % change in DPMP	76	33	-17	89	22	26	14	-20	-20

* Mandatory consideration

** The population of Yukon is included in the calculation of this rate.

*** The populations of Nunavut and the Northwest Territories are included in the calculation of this rate.

**** Donors from Prince Edward Island are included in the calculation of these rates.

● Implementation complete or near completion

▲ Implementation in progress

■ Implementation not started

Once all of these contributing factors have been implemented, analysis of the potential for further improvement through registries linked nationally could be considered as an additional service to support Canadians in their declarations of intent to donate. Consistent communication with a common message to the public is also required to support and engage Canadians in the act of officially making their wishes known through an intent-to-donate registry. The table below highlights the current intent-to-donate registration mechanisms in place in Canada and the corresponding percentage of the population currently listed, where available.

Table 2: provincial intent-to-donate registration mechanismsⁱⁱ

Prov.	Web-based registration	Linked to health card or driver's licence	% of pop. registered	Notes
B.C.	✓	✓	20	Yes/no registry, long-standing
Alta.	✓	✓	7	Online registry, launched in 2014
Sask.	✗	✗	✗	Orange sticker for health card

Prov.	Web-based registration	Linked to health card or driver's licence	% of pop. registered	Notes
Man.	✓	✓	1	Yes/no registry, launched 2014
Ont.	✓	✓	29	Yes-only registry. People removed from registry upon death.
Que.	✗	✓	32	Régie de l'assurance maladie du Québec registries plus notary registration. Paper forms required.
N.S.	✗	✓	52	Health card registry
N.B.	✗	✓	N/A	
P.E.I.	✗	✓	N/A	Red sticker for health card
N.L.	✗	✓	N/A	

Notably, the number of Canadians who have registered to become potential organ donors through provincial registries remains relatively low overall, yet organ donation rates are improving.

According to the *Organ Donation and Transplantation in Canada: System Progress Report 2006–2015* (released by Canadian Blood Services alongside the Canadian Organ Donation and Transplantation Networkⁱⁱⁱ in September 2016), deceased organ donation rates have increased by 29 per cent in the last decade. There is no direct correlation between the number of registered potential organ donors and the actual number of organs donated in Canada. There is some anecdotal evidence from organ donation programs that suggests that when an individual has previously declared their intent-to-donate through a registry and that information is available to their family, consent to proceed with donation is more likely; however, the majority of potential donors were not registered.

Ultimately, the donation system is expected to benefit from complete adoption of the features of high-performing programs (Table 1) together with consideration of a well-established pathway for Canadians to declare intent to donate that will be recognized and acted upon in hospitals or beyond.

ⁱ *Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians*, April 2011, www.organsandtissues.ca

ⁱⁱ Organ Donation and Transplantation in Canada: System Progress Report 2006–2015, September 2016, www.blood.ca

ⁱⁱⁱ Canadian Organ Donation and Transplantation Network: Together these organizations form a powerful network dedicated to improving donation and transplantation in Canada: the Organ Donation and Transplantation Expert Advisory Committee (ODTEAC); national, provincial and territorial partners, including critical care programs; organ donation programs; transplant programs; national organizations, like the Canadian Institute for Health Information and the Canadian Institutes of Health Research; other research partners, including the Canadian National Transplant Research Program; and health professional associations and health charities.

Opt-out (presumed) Consent and Family Override in Organ and Tissue Donation

Issue

Opt-out (presumed) consent legislation means every adult who dies in hospital is considered to be an organ and tissue donor unless they have registered to “opt-out” of donation. Intent-to-donate registries in Canada operate on an “opt-in” basis, which means adults can register their wishes to become a potential deceased donor — a useful resource when a potential donor is identified and their family is consulted to affirm on their behalf. While law does not require family intervention, at this time it is common practice in hospitals across the nation.

Presumed consent has been gaining attention in Canada, especially in the provinces of Saskatchewan, Manitoba and Nova Scotia, as citizens see this as a method of increasing organ donation.

A family’s decision regarding a loved one becoming a potential organ or tissue donor sometimes conflicts with the wishes a potential donor previously declared through a provincial intent-to-donate registry. This situation is referred to as *family override*. If a family steps in to halt the donation process, a potential donor’s wishes may not be honoured and the chance for one or more patients to receive a transplant may be abruptly eliminated. Canadian practice is to respect the family’s wishes over the potential donor’s registered intent to donate for a number of reasons; including the integral role the family plays in the donation process and a desire not to add to the trauma the family is already experiencing. Upholding a potential donor’s wish according to the law is a gap in the intent-to-donate process, often overridden as a result of health professionals not understanding the law associated with expressed donor wishes. This is a topic which is currently under review and will require ongoing education and awareness to clarify and change current practice.

In many opt-out jurisdictions next-of-kin consent is still obtained (Spain); however, this soft opt-out approach allows health-care professionals to initiate donation logistics and maintain the donor (i.e., life support) until a consent discussion can occur. While the opt-out system is seen by many countries as an effective method for increasing organ and tissue donation rates, evidence of its success is varied. A number of leading countries in organ donation use an opt-in consent model. Overall, evidence indicates the consent model is only one component of a successful donation system.

It is possible to improve donation rates with an opt-out system and management of family override. There remain, however, a number of legal and ethical debates and challenges surrounding these issues.

Background

Presumed consent is one of several consent systems currently in practice around the world. Systems can be described as “soft” (the family is consulted and their wishes respected) or “hard” (family wishes do not

impact the donation process). As described by the United Kingdom's Organ Donation Taskforce, a soft opt-in system is a system in which each individual can decide whether they want to opt in to be a donor. At the time of death, if the individual had opted in and the individual's family voices opposition, it is up to the attending doctor to decide whether to continue with donation. A hard opt-in system is one in which an individual can opt in to be a donor; however, unlike a soft opt-in system, the individual's family is unable to oppose their decision at the time of death.ⁱ

Summary of consent systems used by various international donation jurisdictions

Country	Presumed Consent	Registry Type			Comments
		Opt-in	Opt-out	Combined	
Spain	✓				In practice, family consent is obtained when next-of-kin available (soft opt-out).
Belgium	✓			✓	Combined registry since 1987. Families can object to organ donation (soft opt-out).
United States		✓			Intent-to-donate registries (first-person opt-in) maintained by state, most often in cooperation with the Department of Motor Vehicles. Family consent is not required if the potential donor has registered consent (soft opt-in, in some states hard opt-in is being advanced).
Canada		✓			Registries in several provinces; presumed consent has been discussed but no legislation has been passed (soft opt-in).
United Kingdom		✓	✓		Opt-in registry launched in 1994 in England; accessed mainly by coordinators (organ and tissue) and also by intensive care unit medical staff whenever there is or could be a potential donor. Opt-out registry in Wales; presumed consent bill passed July 2013.
Australia		✓			National registry launched 2005. Family consent is required for donation (soft opt-in).

Consent systems vary among countries. Some leading countries in donation have opt-in systems, while other leading countries have opt-out systems. The soft opt-out approach is currently used in Spain, which has the highest donation rate in the world. However, Spain attributes much of its success to its national transplant network and to having donation specialists in hospitals, and not to presumed consent alone. Canada, the U.S., Australia and the majority of Asian countries have opt-in consent systems and have mixed success. Wales and Italy have adopted the Spanish opt-out model and are seeing an increase in donation, while other countries, such as Sweden, have not experienced a large-scale increase in organ donation rates despite the adoption of an opt-out model.ⁱⁱ Attempts to introduce opt-out consent legislation in Brazil and France led to backlash against organ donation.ⁱⁱⁱ A 2016 bill in the Scottish Parliament for opt-out consent was recently defeated as members of Parliament were unable to agree on the principle of the bill.

Evidence for opt-out systems

- A 2008 study by the U.K.'s Organ Donation Taskforce concluded that the evidence in support of opt-out consent is mixed and does not necessarily significantly increase donation rates. The report identified several legal and ethical issues that hard opt-out systems could face under the European Convention on Human Rights.^{iv}
- A 2014 study using a dataset from European countries from 2000 to 2010 found that countries with opt-out consent systems have deceased donation rates that are 28 to 32 per cent higher than countries with opt-in systems. The study concluded that opt-out consent systems could increase deceased donation rates because people fail to register their preferences and many have no preference for organ donation.^v
- Another 2014 study examined data from 48 countries around the world between 2000 and 2012. It found deceased donation rates were higher in countries with opt-out systems rather than opt-in systems and that opt-out consent leads to a relative increase in the total number of liver and kidney transplants.^{vi}
- A 2016 article in *The Lancet* indicated that soft opt-out legislation in Wales has doubled the number of donated organs within six months of implementation.^{vii} The article does not provide information on any concurrent system changes that may have impacted the donation rate.

Public perception

Since 2001, the majority of Canadian survey respondents have indicated that the wishes of the deceased to donate their organs or tissues at the time of death should take precedence over the family's wishes. Canadians have been neither completely opposed nor completely supportive of opt-out (presumed) consent. However, there has been a steady increase in public support for presumed consent legislation, from 50 per cent in 2001 to 67 per cent in 2015, with high levels of support in Quebec and Atlantic Canada, increasing support in Alberta and Manitoba, and lower levels of support in British Columbia, Saskatchewan and Ontario.^{viii}

Current situation

Several provincial governments have shown interest in exploring options around opt-out consent legislation to increase donation rates. However, before any opt-out system could be considered and successfully implemented in Canada, several levels of consultation and analysis must be performed with experts and with Canadians. In addition to further evidence review, impact analysis and legal review, an ethics review is also required to ensure potential new legislation aligns with Canadian values, and that the rights of individuals are protected and not undermined by the needs of society for organ donation.

In Canada, the work of building a high-performing donation system is still in progress. Donation and transplantation experts from across the country, following much consultation and review of leading systems, suggested the following key factors must be implemented before an alternate consent model is explored:

- Mandatory referral, which helps ensure donation opportunities are not missed.
- The presence of in-hospital donation specialists.
- Optimized programs focused on deceased donation.
- Consistent implementation of best practices.

Once these key factors have been implemented, further consideration can be given to initiatives such as opt-out consent or enhanced intent-to-donate registries.

iNHSBT.2008. The Potential Impact of an Opt Out System for Organ Donation in the UK: An Independent Report from the Organ Donation Task Force. Available at www.nhs.uk/to2020/resources/ThepotentialimpactofanoptoutsystemfororgandonationintheUK.pdf

ii Bramhall, Simon. 2011. Presumed Consent in Organ Donation: A Case Against. *Annals of the Royal College of Surgeons of England*, v. 93(4): 270–272. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC3363073

iii Brahmali, Simon. 2011. *Ann R Coll Surg Engl*. 2011 May; 93(4): 270–272.doi: 10.1308/147870811X571136b

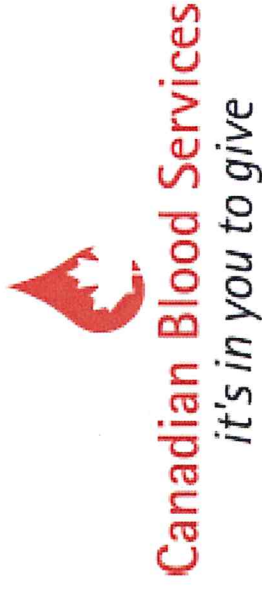
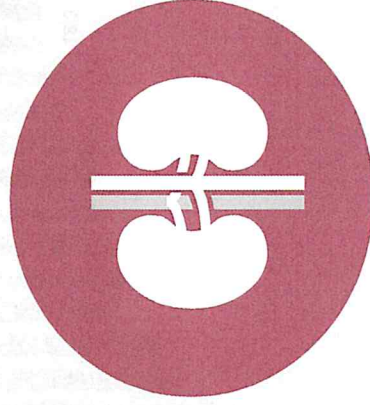
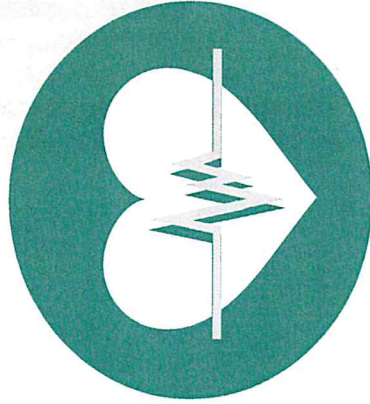
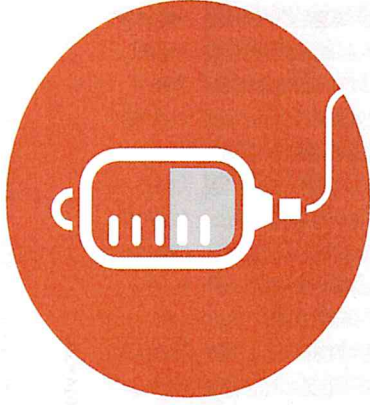
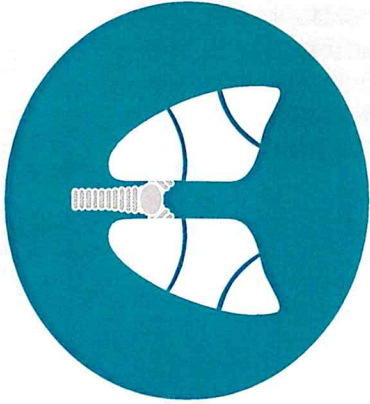
iv Ibid.

v Ugur ZB. Does Presumed Consent Save Lives? Evidence from Europe. *Health Econ*. 2014 Oct 2. [Epub ahead of print]

vi Shepherd, Lee. 2014. An international comparison of deceased and living organ donation and transplant rates in opt-in and opt out systems: a panel study. *BMC Medicine* 2014. 12:131

vii www.thelancet.com Volume 387 June 25, 2016.

viii Organs and Tissue Donation and Transplantation: 2011–2015 Primary Research Summary



Donation and Transplantation Deceased Donation

Advancing Organ & Tissue Donation in Collaboration with Canadian Donation Organizations

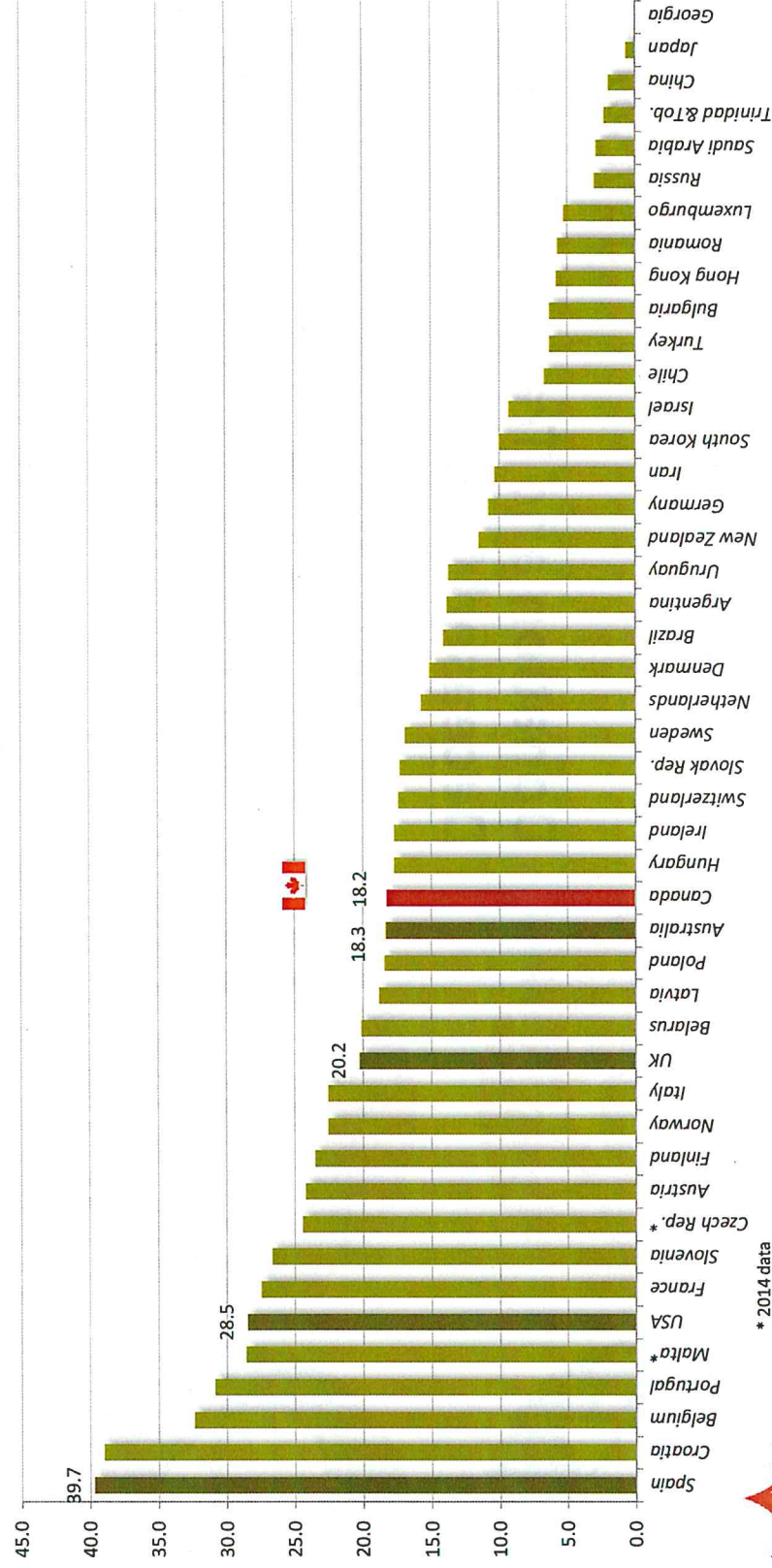


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DECEASED DONATION

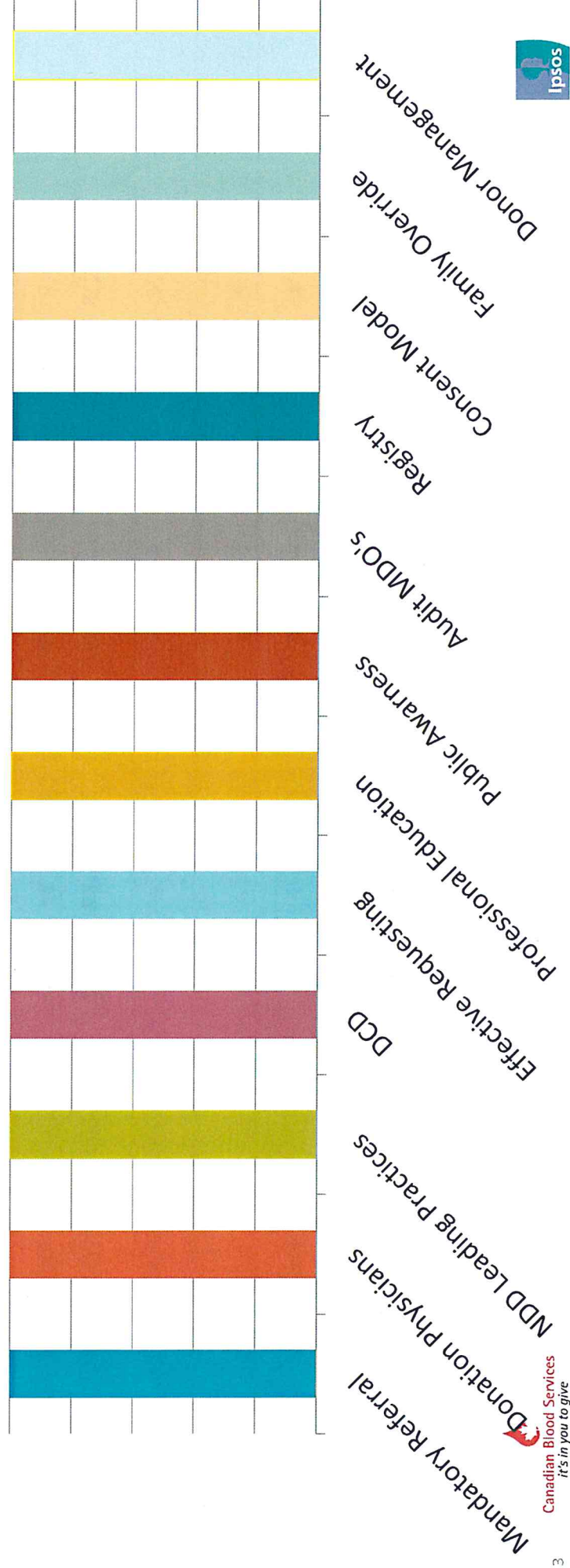
International Deceased Donation Rates 2015



DECEASED DONATION

Factors Affecting Donation Rate

Donation systems have multiple core components which have variable impacts on donation success. Deceased Donation is focused to prioritizing and advancing leading practice in all of these components.



DECEASED DONATION

Factors Contributing to Higher Donation Rates (2015)

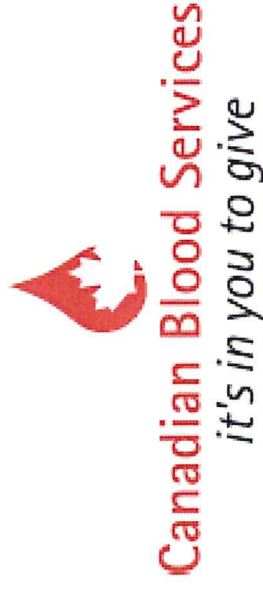
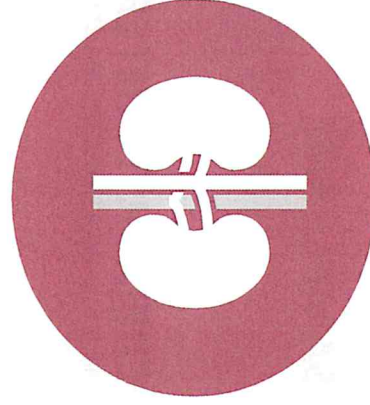
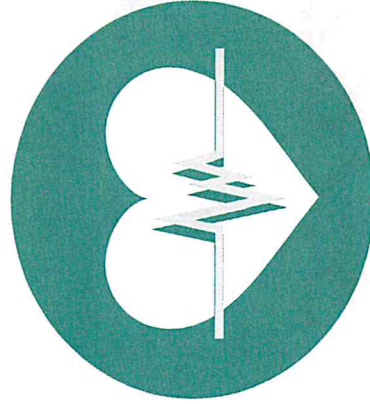
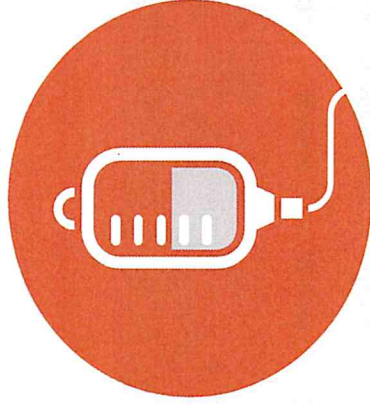
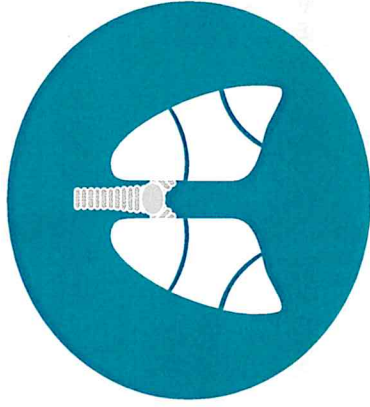
	B.C.	ALTA.	SASK.	MAN.	ONT.	QUE.	N.B.	N.S.	N.L.
Mandatory referral	●	●	■	●	●	●	●	▲	■
Donation physicians	●	▲	■	●	●	▲	■	▲	■
NDD leading practices	●	●	●	●	●	●	●	●	●
DCD programs	●	▲	▲	▲	●	●	■	●	■
% DCD donors, 2015	25	13	10	0	31	11	0	15	0
Leading practices in donor management	●	●	●	●	●	●	●	●	●
Deceased donors, 2015 (DPMP)	20.1*	12.2**	8.8	13.1	19.5	20.8	10.6	21.2***	15.2
Number of donors, 2015	95	52	10	17	269	172	8	20	8
2011–2015 % change in DPMP	76	33	-17	89	22	26	14	-20	-20

* The population of Yukon is included in the calculation of this rate.

** The populations of Nunavut and the Northwest Territories are included in the calculation of this rate.

*** Donors from Prince Edward Island are included in the calculation of these rates.

- Implementation complete or near completion
- ▲ Implementation in progress
- Implementation not started



Organs & Tissues Presumed Consent (General Public Omnibus Question)

DECEMBER 2015



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Credibility Interval

DECEMBER 2015 GENERAL PUBLIC OMNIBUS SURVEY

3,282 **SAMPLE SIZE**

+/- 1.95 **CREDIBILITY INTERVAL**
at 95% confidence interval

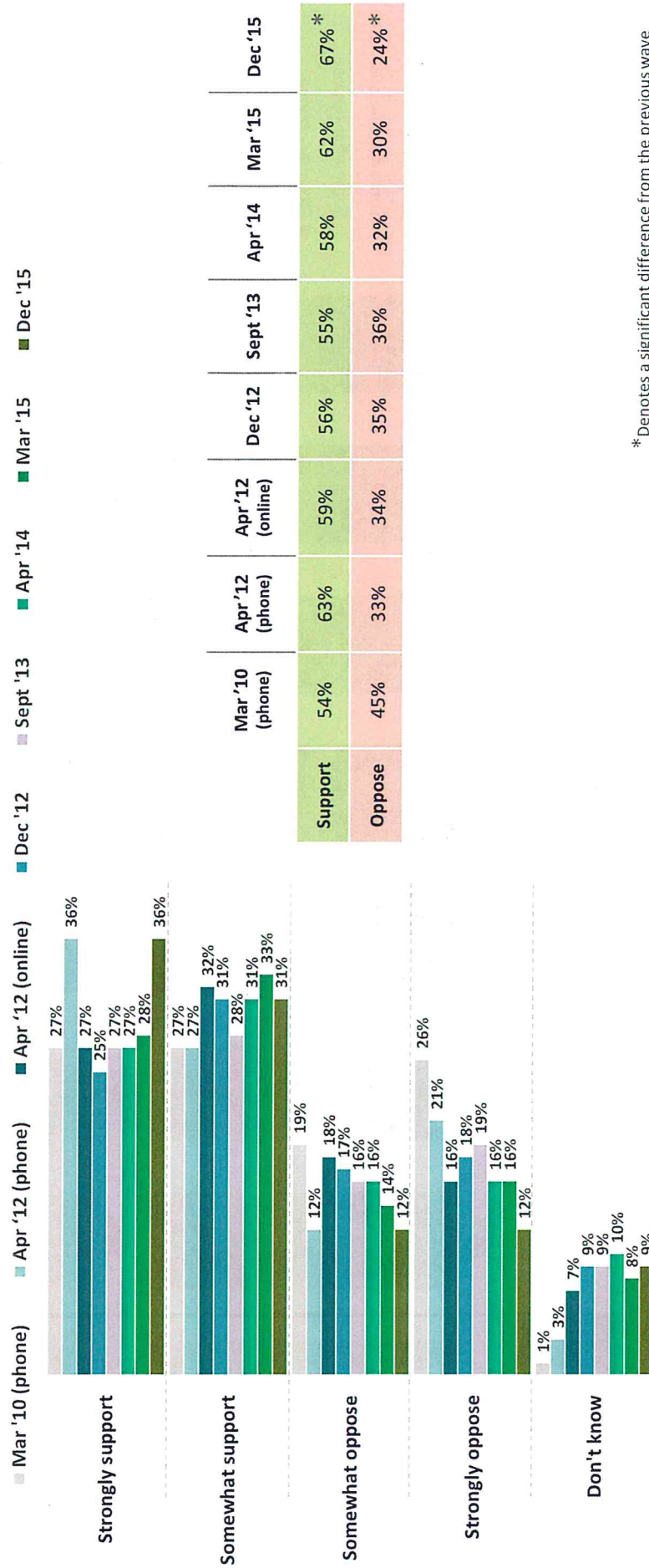
The precision of online polls is measured using a credibility interval. In this case, the poll has a credibility interval of plus or minus 1.95 percentage points.

Statistical margins of error are not applicable to online polls. All sample surveys and polls may be subject to other sources of error, including, but not limited to coverage error and measurement error. Where figures do not sum to 100, this is due to the effects of rounding.

	Total	B.C.	Alberta	Saskatchewan	Manitoba	Ontario	Quebec	Atlantic Canada	New Brunswick	Nova Scotia	PEI	NFLD
SAMPLE SIZE	(n=3,282)	(n=400)	(n=400)	(n=399)	(n=443)	(n=740)	(n=500)	(n=400)	(n=151)	(n=174)	(n=22)	(n=53)
CREDIBILITY INTERVAL	+/- 1.95	+/- 5.6	+/- 5.6	+/- 5.6	+/- 5.3	+/- 4.1	+/- 5.0	+/- 5.6	+/- 9.1	+/- 8.5	+/- 23.8	+/- 15.5

Support for Presumed Consent

AT A NATIONAL LEVEL, SUPPORT FOR PRESUMED CONSENT HAS INCREASED SINCE LAST MEASURED IN MARCH 2015



* Denotes a significant difference from the previous wave

Q. In some countries, when a person dies, that person's organs and tissues, if considered suitable, are transplanted, unless the person has specifically indicated that he or she does NOT want this. In Canada, a person or their closest family members must specifically agree to this before it will take place. Do you strongly support, somewhat support, somewhat oppose or strongly oppose changing the laws and regulations in this country so that organs and tissues are automatically donated unless a person specifies otherwise? Base: All respondents (Mar 2010 phone) n=1,500; (Apr 2012 phone) n=1,001; (Apr 2012 online) n=1,736; (Dec 2012) n=1,406; (Sept 2013) n=1,009; (Apr 2014) n=1,024; (Mar 2015) n=1,003; (Dec 2015) n=3,282.

Support for Presumed Consent, by Province

STRENGTH OF SUPPORT IS LOWER IN ALBERTA AND SASKATCHEWAN

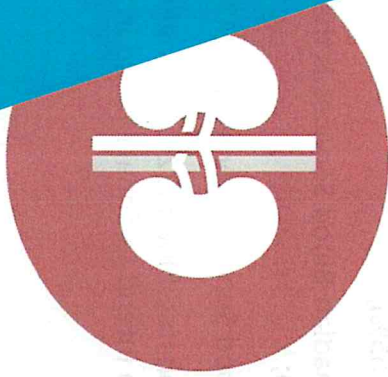
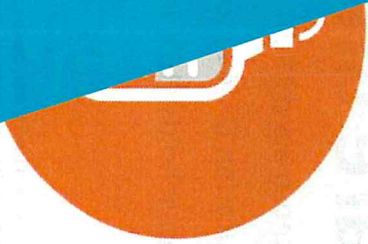
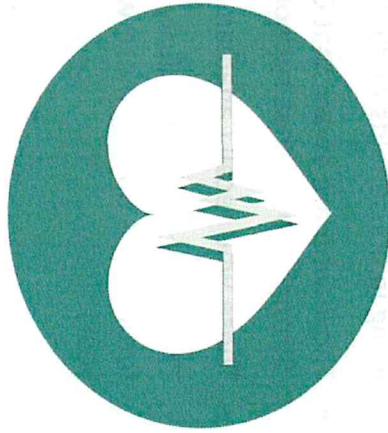
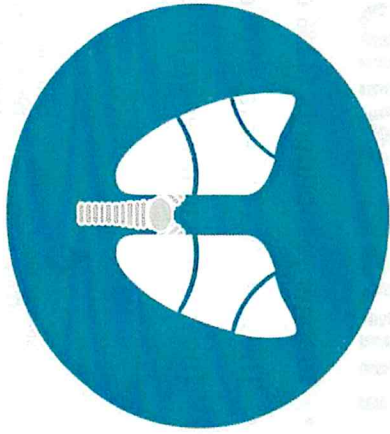


Greater Support for Presumed Consent Among...

- Females (39% 'Strongly support'), compared to Males (34%);
- Those living in higher income households (72% of those in households of \$60k+ 'Strongly/Somewhat support'), compared to those living in households of <\$40k (65%);
- Those who are aware that Canadian Blood Services is the organization that manages the blood system in Canada (72% 'Strongly/Somewhat support');
- Those who recall Canadian Blood Services advertising (42% 'Strongly support'); and,
- Those who have previously donated blood (72% 'Strongly/Somewhat support') and those who intend to donate blood in the near future (86% among those who intend to donate blood in the next 6 months / 77% who intend to donate within 6 months to 1 year).

Those who are undecided include:

- Younger respondents (11% of those aged 18-34 / 10% of those aged 35-54), compared to older respondents aged 55+ (7%);
- Those with a lower level of education (15% among those who have not completed high school); and,
- Those living in lower income households (10% in households earning <\$60k).

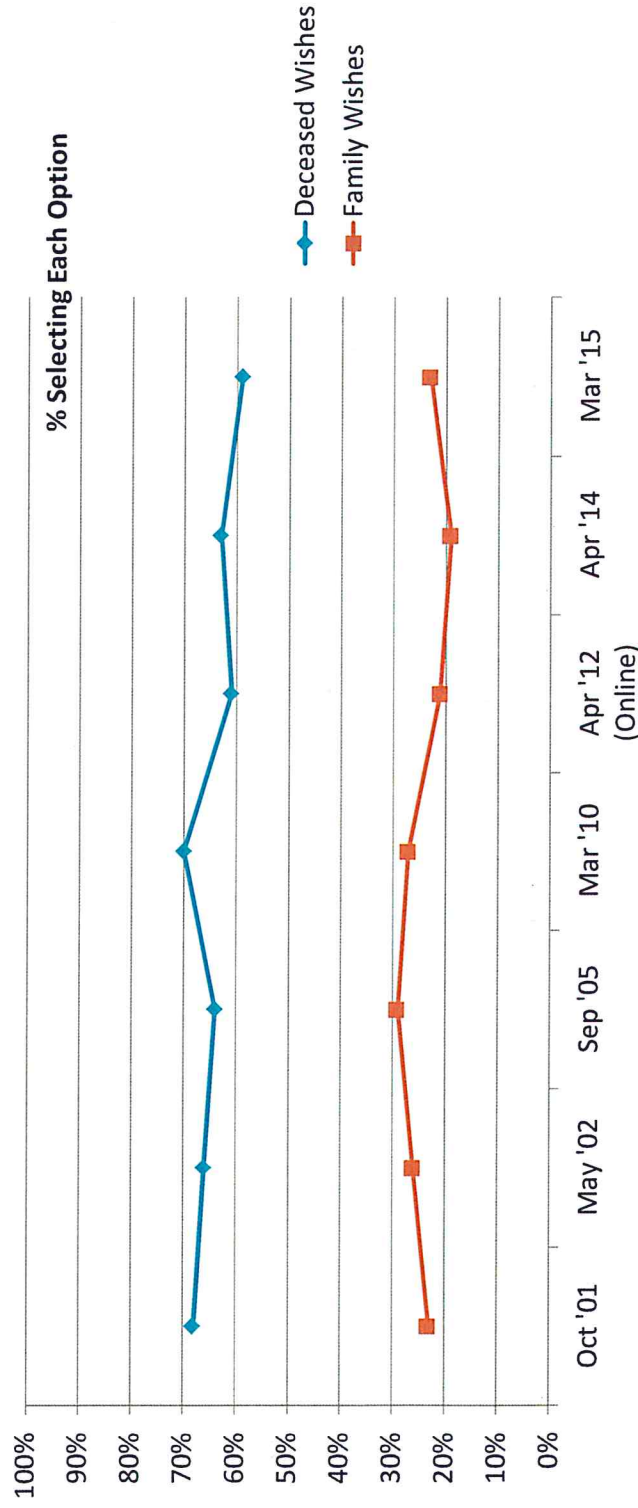


ORGAN & TISSUE DONATION AND TRANSPLANTATION – DECISION UPON DEATH

Deceased Wishes Believed to Take Precedence After Death

Since 2001, the majority of respondents believe the wishes of the deceased to donate their organs or tissues at the time of death takes precedence over the family's wishes.

Those who think the family's wishes take precedence have remained in the minority for the past 15 years.

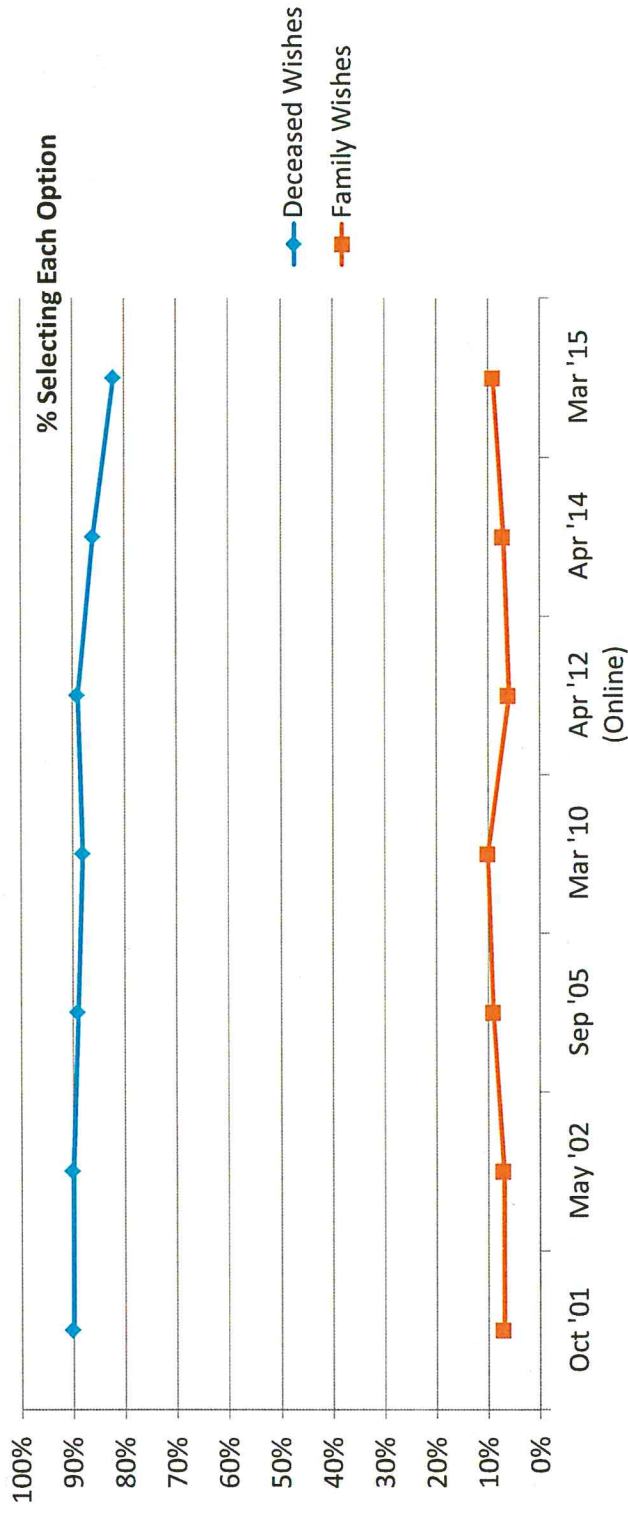


DECISION UPON DEATH

Belief Deceased Wishes SHOULD Take Precedence

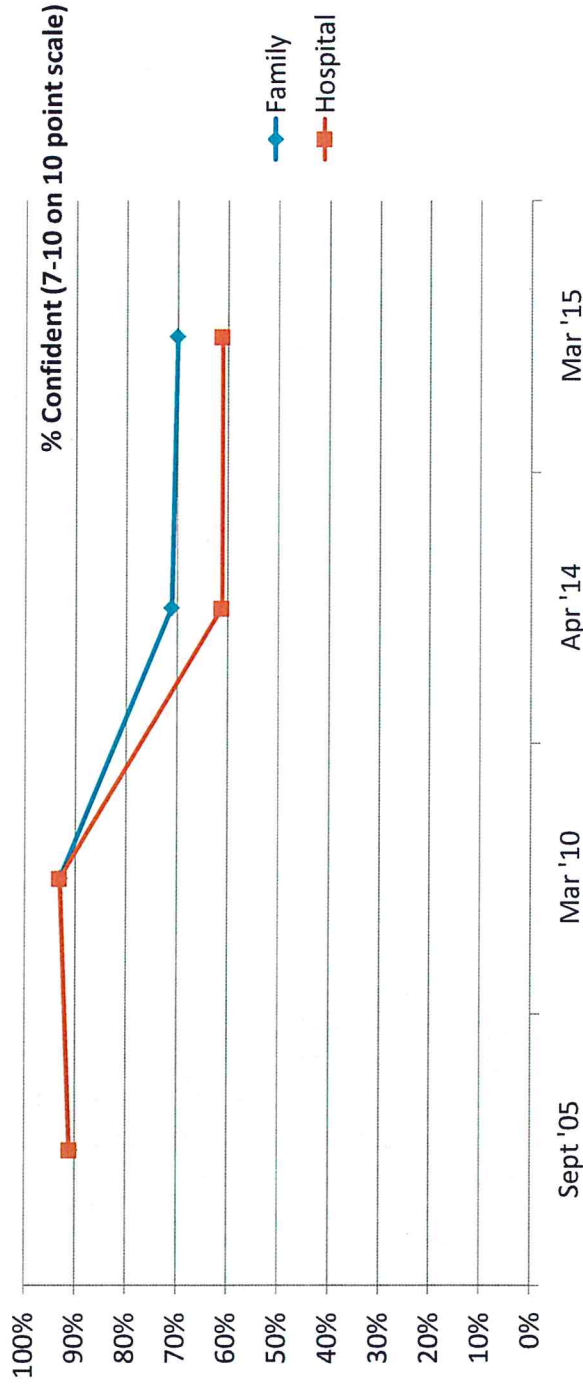
When asked whose wishes should take precedence, the majority of respondents favour the deceased.

Support for the wishes of the family have not risen about above one in ten since measurement began in 2001. However, there has been a decline in support for the wishes of the deceased since 2012 (89% to 82%). This could indicate that some Canadians may be changing their stance on the issue.

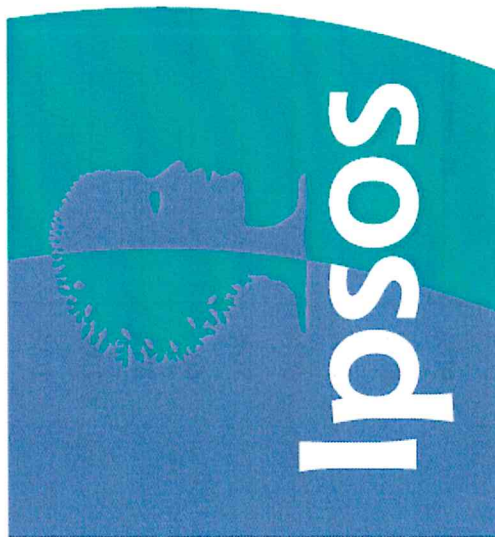


Trust that Donor Intentions will be Respected have Decreased

When measured in 2005 and 2010 (based on a single question about confidence that one's wishes regarding organ and tissue donation would be acted upon at time of death), nine in ten (91%) Canadians were confident that their donation intentions would be respected. In Spring of 2014, when asked separately the confidence in one's family to act upon their wishes and confidence in the hospital, many indicated a lower level of confidence in both to actually carry out their wishes (*than perhaps considering at a 'system' level*). Though there is a marked decrease in confidence since 2010, many have greater confidence in their family (70%), than the hospital (61%).



How confident are you that your wishes regarding organ and tissue donation will be acted upon at the time of your death? Base: All respondents (Sept '05) n= 1505; Those who have discussed decision to donate with the person who would act on their behalf in the event of a medical emergency: (Mar '10) n=591 / Using a scale of 1 to 10 where 1 means 'not at all confident' and 10 means 'very confident', how confident are you that your wishes regarding organ and tissue donation will be acted upon by the hospital at the time of your death? How confident are you that your wishes regarding organ and tissue donation will be acted upon by your family at the time of your death? % shown '7, 8, 9, 10' on a 10 point scale. Base: Canadian General Public, aged 18+ (Apr 2014) n=1,024; (Mar 2015) n=1,003



Canadian Blood Services
it's in you to give



Respecting Regulations Under the Human Tissue Gift Act, 2015

Submission to the Saskatchewan Standing Committee on Human Services and the Saskatchewan Ministry of Health

Introduction

Canadian Blood Services appreciates the opportunity to provide this submission with respect to regulations that may be promulgated under the Human Tissue Gift Act, 2015 (the “Regulations”). The purpose of this submission is to request that the Standing Committee on Human Services and/or the Ministry of Health, as appropriate, consider including provisions in the Regulations that would allow information sharing without consent for the purpose of facilitating the donation, procurement and/or transplantation of tissues (which includes organs), and for purposes of planning, delivering, evaluating and/or monitoring the national coordinated organ and tissue donation and transplantation (OTDT) program (collectively referred to herein as “OTDT System Performance”).

Canadian Blood Services

Canadian Blood Services is a unique organization in Canadian health care. While it provides national, integrated services across Canada, the organization was created and is funded by the provincial and territorial governments (except Quebec). As a biologics manufacturer, it also falls under the regulatory powers of Health Canada.

Canadian Blood Services is also a non-profit, arm’s-length, charitable corporation. Provincial and territorial ministers of health serve as members of the corporation under the Canada Not-for-Profit Corporations Act and appoint its board of directors. The ministers of health collectively approve our three-year corporate plan and annual budget.

In addition to managing Canada’s national integrated blood supply, Canada Blood Services operates the OneMatch Stem Cell and Marrow Network, diagnostic services in certain provinces and Canadian Blood Services’ Cord Blood Bank.

Since 2008, at the request of federal, provincial and territorial governments (except Quebec), Canadian Blood Services has played a leadership role in the national system for organ and tissue donation and transplantation. Collaboratively with provincial programs, we provide national programs and services to advance the practice of organ and tissue donation and transplantation in Canada (the “OTDT Mandate”), including:

- Strategic plan development and implementation.

- Canadian Transplant Registry programs.
- System performance improvement.
- Leading practices, professional and public education.

The Canadian Transplant Registry includes:

- **The Kidney Paired Donation (KPD) program.** The KPD program matches incompatible living donor and recipient pairs to find matches for patients requiring kidney transplantation.
- **The National Organ Waitlist (NOW).** The NOW has replaced the previous paper-based system for interprovincial organ listing and sharing.
- **The Highly Sensitized Patient (HSP) program.** The HSP program provides a national database for deceased donation, enabling real-time identification of potential matches for patients, who, due to a sensitized immune system, are the most difficult to match for possible organ transplantation.

Related databases and services are also in place to support the registry for organ transplantation.

As part of the matching process in the NOW and the HSP program, health-care professionals, transplant centres and organ donation organizations from across the country are required to disclose personal information, including medical history and lab test results (i.e., transmissible diseases and blood group), of potential organ recipients and deceased donors to Canadian Blood Services in order that the registries may identify potential matches. In turn, Canadian Blood Services is required to disclose personal information of matched recipients and deceased donors to health-care professionals, transplant centres and organ donation organizations from across the country so that the matches may be assessed and the transplants may proceed.

Finally, the OTDT Mandate includes responsibility for system performance improvement (i.e., OTDT System Performance). Discussions are currently underway with the Canadian Institute for Health Information (CIHI) regarding Canadian Blood Services' assumption of the Canadian Organ Replacement Register (CORR) as part of this OTDT System Performance responsibility. Through the CORR, CIHI collects data from hospital dialysis programs, transplant programs, organ donation organizations and independent health facilities to track patients from their first treatment for end-stage organ failure (dialysis or transplantation) to their death. Assuming CORR functions will require Canadian Blood Services to collect and use donor and recipient personal information, including pre- and post-donation and pre- and post-transplantation information, which is currently being collected and used by CIHI. This expansion of responsibility will also include the collection and use of personal information from donors and recipients who may not have otherwise participated in the Canadian Transplant Registry (e.g., local living kidney donors and recipients, local deceased donors and recipients, and donors and recipients who donated or received a transplant prior to the development of the Canadian Transplant Registry).

Specific recommendations for regulations to allow information sharing

For Canadian Blood Services to fulfil its OTDT Mandate and to ensure a robust system for OTDT data collection is put in place, we recommend that provisions be included in the Regulations that will permit Saskatchewan OTDT programs (e.g., organ donation organizations, transplant centres and living donor centres) to share living and deceased donor and recipient personal information, including personal health information, with Canadian Blood Services *without consent* for purposes of (1) facilitating the donation, procurement and/or transplantation of organs, and (2) OTDT System Performance.

When the Canadian Transplant Registry was in development, a consent-based model was designed for personal information as it was the most expedient path to implementation across jurisdictions, and was considered appropriate for the primary purpose of providing health care to the individual (i.e., facilitating the donation, procurement and/or transplantation of organs).¹

In a consent-based model, consent must be given for the collection, use and disclosure of personal information. This consent-based model allows for consent to be withheld, withdrawn or to limit the collection, use or disclosure of certain personal information, all of which would detrimentally impair the ability of Canadian Blood Services to collect and use comprehensive information for OTDT System Performance. OTDT System Performance can assist with strategic planning, annual reporting to governments and the public, as well as identifying opportunities to leverage established successes to enhance donation and transplantation across the country. We respectfully submit that the collection and use (by Canadian Blood Services) and disclosure (by participating OTDT Programs to Canadian Blood Services) *without consent* is essential and must be permitted to achieve these objectives. Otherwise, individuals could withhold, withdraw or limit their consent for these purposes, resulting in incomplete and inaccurate OTDT System Performance data. It is also our understanding that CIHI currently collects, uses and discloses the personal information of donors and recipients for CORR without consent, which avoids such consequences.

We respectfully submit that Saskatchewan exercise its regulatory-making power under section 22(c) of the *Human Tissue Gift Act, 2015*, to draft a regulation regarding the sharing of personal information and personal health information for the purpose of donation. In particular, Saskatchewan would be able to permit: participating OTDT Programs to share *without consent* living and deceased donor and recipient personal information and personal health information with Canadian Blood Services for the purposes of (1) facilitating the donation, procurement and/or transplantation of organs, and (2) OTDT System Performance; and Canadian Blood Services to collect, use and disclose *without consent* living and deceased donor and recipient personal information and personal health information across jurisdictions for these purposes.

¹ Data sharing agreements were also negotiated with participating OTDT programs for the sharing of personal information and personal health information for Canadian Transplant Registry purposes outlining each party's obligations for the protection of the information. The agreements include provisions relating to the purpose for sharing, access requirements, security, termination, secure destruction, etc.

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This regulation will authorize Canadian Blood Services to fulfil its OTDT Mandate and will also ensure that a robust system for the collection of OTDT System Performance data is in place — one that is not dependent upon individual consent, which can be withheld, withdrawn or limited. Canadian Blood Services has in place stringent privacy controls for the protection of personal information and personal health information that is collected, used and disclosed by Canadian Blood Services, which are applied nationally.²³ Canadian Blood Services recognizes the need to consider and balance privacy rights and access to quality and timely information. In this case, the significant benefits realized by OTDT System Performance for patients and governments should outweigh any potential privacy concerns. These benefits include an increase in transplants for Canadian patients currently on waiting lists and economic benefits to governments when patients receive transplants and no longer require costly treatments such as dialysis.⁴

Contact information

Questions or comments concerning this submission may be directed to the attention of:

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² See Canadian Blood Services' privacy policies online at www.blood.ca/en/about-us/important-notice.

³ Current data sharing agreements may require revisions to reflect updated legislation.

⁴ See Canadian Blood Services' *Organ Donation and Transplantation in Canada: System Progress Report 2006–2015*, online at <https://www.blood.ca/en/media/access-organ-transplants-rise-canada>

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Closing

Canadian Blood Services appreciates the opportunity to provide this submission to the Standing Committee on Human Services and the Ministry of Health. Having the ability to effectively carry out the OTDT Mandate is vital to national OTDT System Progress and Canadian Blood Services' responsibility to provide support, coordination and delivery of a nationally coordinated OTDT program for organ and tissue donation and transplantation. We believe it is essential that the legislation allow sharing of personal information *without consent* in order that we may operate optimally on behalf of those we serve.

