



Canadian Blood Services
it's in you to give

Canadian Blood Services

Intent to Donate Environmental Scan Final Report

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Introduction

Background

As of April 1, 2008, Canadian Blood Services accepted a new mandate from federal, provincial, and territorial governments (except Quebec) related to organ and tissue donation and transplantation (OTDT). Currently, Canadian Blood Services is working with a national Steering Committee and expert committees in organs and tissues to develop the strategy for a national OTDT system for Canada. One of the areas of focus for the strategy relates to enabling the public to express their intent to donate and to translate that intent to increased donation.

According to a recent survey, awareness of, and support for, the need and opportunity for organ donation in Canada is high, with 95% of Canadians approving organ donation. Despite this support, only 51% of Canadians have indicated their intent by signing a donor card or registering online (where available). Of those who have made a decision about their intent to donate, 84% indicate that they have discussed their wishes with the person who would act on their behalf in a medical emergency¹

Anecdotal reports indicate that existing registries are hampered by relatively low levels of registration and 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 at the time these decisions are being made. If a record of expressed intent is stored in a database, not all hospitals / relevant staff have access to the information in a timely manner. In some cases, the donor may be registered in one province but has moved or is traveling and is in a hospital in a different province. These limitations have led to a discussion of how the system can be improved. However, more information is required to inform decisions regarding registries and other OTDT system improvement options.

This report presents a summary of environmental scan research performed by Canadian Blood Services and its partner, Deloitte. Information is a combination of primary research and interviews with jurisdictions within Canada and worldwide.

Purpose and Objectives

Improving donation rates requires answering the question of how systems can better enable 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:

1. Provide deeper and broader understanding of:
 - a) Existing systems to document intent to donate (e.g., registries, donor cards, utilization of driver's licenses or health care insurance cards, etc.) and mechanisms to operationalize the systems (e.g., stand-alone databases, jurisdiction-wide registries, etc.).
 - b) Usefulness of existing systems in encouraging and supporting donor intent/consent, and in supporting the identification/referral and consent processes within the donation process flow (e.g., accessibility to the public, designed for use by health care professionals, Organ Procurement Officers (OPOs), etc.).

¹ Canadian Blood Services, Views Toward Organs and Tissues Donation and Transplantation, 2010

- c) Effectiveness of existing systems in increasing donation (using measures such as percentage of population registered and percentage of organ donors who had registered).
2. Document costs of developing, maintaining and operating intent to donate registries, nationally and internationally.

Summary

Interviews with individuals from national and international jurisdictions indicate that it is difficult to isolate or quantify the impact of intent or consent registries on organ and tissue donation rates. However, donor registries are believed to have qualitative value in terms of increasing public awareness, streamlining donation processes, and facilitating discussions with family/next of kin. Even in jurisdictions recognizing first person consent, families are usually asked for consent. This highlights the benefit of a registry in supporting care providers in discussions with families following death.

Several respondents noted that registries represent 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 need to be part of a system of initiatives to increase donation in order to be most effective.

Approach

Research Questions

The Table 1 below provides 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 |
| <ol style="list-style-type: none"> 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? 5. What are the lessons learned by jurisdictions who have registries? | <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. |
| <ol style="list-style-type: none"> 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? | <ul style="list-style-type: none"> • Inform understanding of the investment required to achieve increased intent registration and donation. |
| <ol style="list-style-type: none"> 7. What enablers (policy, legislation, governance, etc.) are required to support implementation of national (single system or linked provincial/state/regional systems)? | <ul style="list-style-type: none"> • Inform development of National System Design options and implementation considerations |

In addition to literature research, one-on-one interviews were performed with several Canadian and international jurisdictions:

- British Columbia
- Nova Scotia
- Ontario (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)

Summary of Findings

The Intent to Donate (ITD) Environmental Scan aimed to address five themes:

1. Strategies used to increase donation (including the type of information collected);
2. Value of intent to donate registries and evidence for their effectiveness;
3. Lessons learned from other jurisdictions;
4. Costs of implementing and maintaining ITD systems; and
5. Legislative enablers of these systems.

To address these areas, a literature review was performed and several jurisdictions were consulted, including several Canadian provinces, US states, and some Western European countries.

Strategies to Increase Donation

There are multiple 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/next of kin; and
- Documentation in a will, advance directive or other legal document.

In Canada, mechanisms vary across the provinces. Seven provinces use their provincial health care card as a means of indicating intent. Of those seven, three (ON, QC, NS) use a combination of registries and health care 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 health care card. One province (PEI) provides an option to indicate intent using a health care card or a driver's license. Of the remaining three provinces, two (MB, 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 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 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.

Value of Registries and Evidence of Effectiveness

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

- **Supporting public awareness.** Registries can act as a “call to action” in support of targeted marketing and awareness campaigns. Collecting demographic information allows for improved targeting of certain segments of the population.
- **Supporting the process of getting consent.** Registries can act as a tool to inform donor families of loved one's wishes. For health professionals and/or Donor Coordinators, they 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 processes. They contribute to timely donor identification and management, which may translate to improved Organs Transplanted per Donor (OTPD) and graft survival rates 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 in most jurisdictions to impact organ donation 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 an ability to increase donation rates. Anecdotal evidence from Canadian provinces, the US, and the UK, however, indicates a belief that registries have led to an increase in donors.

Lessons Learned

Interviews with representatives of Canadian and international jurisdictions yielded the following advice related to developing intent to donate 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 make use of the “turnstile” aspect of DMV license renewal and identification cards to gain donors (so-called because almost all adults have to pass through). Donate Life California recommended against relying on a website for collecting consent, as 98% 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

One key enabler of consent registries was professional education, and the biggest challenge to advancing donor designation was clinicians who were not used to notifying families about their loved ones' registered consent (rather than asking families for consent). The development and piloting of a registry should involve clinicians, OPOs and tissue/eye banks as well as the donor community and the recipient community. 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 stand alone 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, but 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. Health care staff and physicians report that registry information can inform discussions with family members and provide a measure of relief and comfort when their loved ones wishes are known. This information must be considered when determining the overall value of registries.

Costs

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., stand-alone vs leverage existing system). Operating costs also varied depending on whether staff costs were included. A summary of cost information obtained from jurisdictions interviewed is provided in Table 2.

Table 2: Summary of Cost Data

| Jurisdiction | Capital / Development Costs | Annual Operating / Maintenance Costs | % of Population Registered |
|-----------------------------|---|---|--|
| British Columbia | <ul style="list-style-type: none"> • ~\$103,000 was invested to upgrade registry in 2008* • Estimated \$20,600 for online registry portion* | <ul style="list-style-type: none"> • Annual license fees are about \$20,600, \$25,000 and \$30,000 for years 1, 2 and 3 | <ul style="list-style-type: none"> • 17% |
| Ontario | <ul style="list-style-type: none"> • \$700,000* | <ul style="list-style-type: none"> • \$300,000* | <ul style="list-style-type: none"> • 27% of those with photo health card (or about 13% of the population, assuming that half have photo health cards) |
| Alaska | <ul style="list-style-type: none"> • Implementation: ~\$97,390* • Enhancements: ~\$21,632* | <ul style="list-style-type: none"> • ~ \$10,816 - \$16,224* | <ul style="list-style-type: none"> • Not available |
| California | <ul style="list-style-type: none"> • Registry implementation and promotion: ~\$177,288* • Integration with DMV system: ~\$1.3M* | <ul style="list-style-type: none"> • Once built, operating costs of system are low | <ul style="list-style-type: none"> • 25% of driver's license population |
| Florida | <ul style="list-style-type: none"> • \$648,974* | <ul style="list-style-type: none"> • \$162,244 - \$216,325* | <ul style="list-style-type: none"> • 21% of driver's license population |
| Philadelphia – Gift of Life | <ul style="list-style-type: none"> • \$327,211 - \$490,816* | <ul style="list-style-type: none"> • Little to no operating costs • Donations from license renewal raises about \$908,564/year* | <ul style="list-style-type: none"> • 44% of driver's license population (Pennsylvania only) |

United Kingdom • Not available

- Registry team: \$463,328*
- Call centre: \$102,205 (handles 80-100 calls/day)*
- 38%

* All figures in 2009 Canadian dollars. Low operating costs in California and Philadelphia may be due to partnership and collaboration with Department of Motor Vehicles. Original development costs were not available for BC, resulting in lower apparent costs.

Enabling Legislation

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.

Environmental Scan

The Process of Providing Intent/Consent

The first important element to leading a person to donation begins with 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 in the process is to take action, which can take many forms, ranging from registering to be a donor, to telling your family about your decision, depending on the call to action and the availability of donor registration. If the opportunity to donate occurs, 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 their use in the donation process.



Figure 1: Process flow indicating the steps an individual takes before donation.

Difference between Intent and Consent

Generally registries collect either intent or consent to donate. Expressing intent is a way for a person to indicate their wish to be a donor to family members. Consent, in contrast, provides legal protection for health professionals to obtain organs without necessarily consulting with next-of-kin. However, most jurisdictions report that they will consult with the family or next of kin and usually will not overrule their wishes. More details about the legislation of consent are provided in Table 5 and Table 6, below.

Tissue Considerations

Methodologies for the designation of “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 will need to consider strategies and approaches required for locations where recovery systems are not in place.
- The public is generally unaware of the extent that tissues are used today and are unaware 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 the association ethical considerations.

Expressing Consent

There are multiple ways to express consent:

1. Presumed consent (legislated or not)
2. Registries: intent, consent, opt-out, both opt-in and opt-out
3. Organ donor cards
4. Designation on health cards, motor vehicle license or other identification card
5. Through discussions with family/next of kin
6. Expression in a will or other legal document

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

Canada

In Canada, mechanisms for indicating consent vary province to province. Three provinces (Alberta, Saskatchewan and New Brunswick) rely solely on the signing of a health care card, two provinces (Manitoba and Newfoundland) use an organ donor card system, independent of any other mechanism, one province (Prince Edward Island) provides an option to indicate intent using either a health care card or driver's license, three provinces (Ontario, Quebec and Nova Scotia) use a combination of registries and health care cards and one province (British Columbia) 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/family before donation, regardless of the existence of an individual's consent/registration. A comparison of registries in across Canada is presented in Table 3, below.

Table 3: Comparison of Registry Types across Canadian Provinces

| Province | Organ DPMP* (2008) | Tissue DPMP* (2008) | Registry | Mechanism to indicate intent | Performance | Access to Information |
|------------------|--------------------------|---------------------|------------------|---|---|---|
| British Columbia | 12.3 | 116 | Opt-in & 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. |
| Alberta | 11.4 | 92 | No | Sign health care card - sign either "yes" or "no". Can designate specific organs or tissues. | Unknown | Information is kept by the individual. Not usually accessed by OPO. |
| Saskatchewan | 12.0 | 30 | No | Apply a sticker to health card. Stickers mailed with health card when renewed and only indicate willingness to donate, not consent. No form is completed. | Unknown | Information is kept by the individual. Not usually accessed by OPO. |
| Manitoba | 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. |
| Ontario | 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. |
| Quebec | 19.4 | N/A | No | Sign and affix a sticker to the back of a health card. Independent registry maintained by notaries. | Unknown | Unknown |
| New Brunswick | 16.5 (Atlantic combined) | 234 | No | Sign health care card with either "yes" or "no" 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 |

| Province | Organ DPMP* (2008) | Tissue DPMP* (2008) | Registry | Mechanism to indicate intent | Performance | Access to Information |
|----------------------|--------------------|---------------------|-------------|--|--|--|
| | | | | | | to identify communities to target for education/awareness. |
| Nova Scotia | | 152 | Opt-in only | Register via health care 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. |
| Prince Edward Island | | 0 | No | Affix a red sticker on health card or have a red heart engraved on driver's license at renewal. | Unknown | Unknown |
| Newfoundland | | 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

In all provinces, the practice is to acquire next of kin/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 health care 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.

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 4, below.

Table 4: Comparison of Registry Type across International Jurisdictions

| Country | DPMP (2008) | Presumed Consent | Opt-in Registry | Opt-out Registry | Combined Registry | Number of registrants | Comments |
|---------|-------------|------------------|-----------------|------------------|-------------------|---|--|
| Spain | 34.2 | ✓ | | | | | In practice, family consent is obtained when NOK available (17% of families refuse donation). Use the Donor card approach which bridges 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 (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, |

| Country | DPMP (2008) | Presumed Consent | Opt-in Registry | Opt-out Registry | Combined Registry | Number of registrants | Comments |
|----------------|-------------|------------------|-----------------|------------------|-------------------|--|---|
| | | | | | | | designation on health card, etc.). |
| United Kingdom | 13.5 | | ✓ | | | 16.743 million (28% of total population) | Opt-in registry launched in 1994 It is 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

An important component to the success of a registry is 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 the provincial Human Tissues Gift Act (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 5, below.

Table 5: Comparison of Consent Laws across Canadian Provinces

| Province | DPMP (2008) | Legislation | Authority to Act |
|------------------|-------------|---|--|
| British Columbia | 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 is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 3(4) Act) |
| Alberta | 11.4 | <i>Human Tissue and Organ Donation Act</i> .S.A. 2006, c.H-14.5 | Consent is binding and authorizes: 1. any medical practitioner to make any examination necessary to assure medical acceptability of the donation; and 2. the use of the body or the removal and use of the specified tissue or organ for the specified purpose (s. 8(1)) |
| Saskatchewan | 12.0 | <i>The Human Tissue Gift Act</i> , R.S.S. 1978, c. H-15 | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 4(3)) |
| Manitoba | 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 |
| Ontario | 13.6 | <i>Trillium Gift of Life Network Act</i> , R.S.O 1990. c. H.20 | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 4(3)) |
| Quebec | 19.4 | Civil Code of Québec (C.C.Q.), S.Q. 1991, | No provision |

| Province | DPMP (2008) | Legislation | Authority to Act |
|----------------------|--------------------------|---|--|
| | | c. 64 | |
| New Brunswick | | <i>Human Tissue Gift Act</i> , S.N.B. 2004, c. H-12.5 | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 3(3)) |
| Nova Scotia | 16.5 (Atlantic combined) | <i>Human Tissue Gift Act</i> , R.S.N.S. 1989, c. 215, | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 4(3)) |
| Prince Edward Island | | <i>Human Tissue Donation Act</i> , R.S.P.E.I. 1988, c. H-12.1 | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 10(1)) |
| Newfoundland | | <i>Human Tissue Act</i> , R.S.N.L. 1990, c. H-15 | Consent is full authority for any physician to: 1. Make any exam necessary to assure medical acceptability of the tissue; and 2. remove such tissue (s. 4(3)) |

While the law is clear that in most provinces next of kin/family consent is only required 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.

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 higher donors per million than Canada have presumed consent laws. Countries with higher donors per million without presumed consent laws include the United States, Ireland, the Netherlands and Germany. A comparison is summarized in Table 6, below.

Table 6: Comparison of Consent Laws in International Jurisdictions

| Country | DPMP | Law | Source | Practice |
|---------------|------|---|------------------------------------|--|
| Spain | 34.2 | Presumed consent | | Families are approached to understand the wishes of the individual if they are not known. |
| 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 2 witnesses (one of whom is a disinterested witness). An individual may refuse to make an anatomical gift using similar methods to the 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 during their lifetimes. A family | Uniform Anatomical Gift Act (2006) | Historical practice has been to obtain family consent however, states are moving toward honouring the Uniform Anatomical Gift Act and acting on first person consent where registries exist. |

| Country | DPMP | Law | Source | Practice |
|----------------|------|---|---|--|
| | | member may make an anatomical gift on an individual's behalf in the absence of donor designation. | | |
| Canada | 14.6 | Under the legislation of the provincial Human Tissues Gift Act (or equivalent), a person who meets the statutory age requirement has the authority to consent to post-mortem donation. This consent is 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 individuals 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, from now on 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, forty-six 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 one's 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% of total organ donors and 27.2% of tissue donors in 2008 had joined a registry before their death. This is an increase from the previous year in which 19.1% of organ donors and 26.7% of tissue donors had joined a registry prior to their death.

The donor designation registries in the United States, combined with their 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. Using this information, the donor management can begin without family consent which results in conversion rates equal to the percentage of population registered and additionally reduces the time from identification to donation.

Costs and Benefits of Registries

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

- Encouraging discussion about wishes with family members
- Informing health care providers/requestors

- Potentially reducing the stress of health care providers in approaching families
- Measuring success of marketing/public awareness activities
- Potentially reducing the stress of family in knowing/following the wishes
- 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, as well as any evidence for their effectiveness at increasing donation rates. Associated capital investments and operational costs were solicited and lessons learned were also collected. Table 7, below, provides a summary of the reported costs, benefits and lessons learned from various jurisdictions. Complete results are available in Appendix A.

Table 7: Comparison of Reported Costs, Benefits, and Lessons Learned for Various Jurisdictions

| Jurisdiction | Operations | Estimated Costs | Evidence for Effectiveness | Insights* |
|---|---|---|--|---|
| British Columbia | <ul style="list-style-type: none"> • Online consent registration • Backed by paper registration | <ul style="list-style-type: none"> • \$100K to upgrade online registry • Annual license fee of \$20K - \$30K | <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 key • Awareness marketing campaign was key • Be careful of language used to “sell” registry (avoid promises of encouraging donation rates) |
| Nova Scotia | <ul style="list-style-type: none"> • Intent registered with health card • Providers have 24 hr access to database | <ul style="list-style-type: none"> • None available | <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 5 years) to promote |
| Ontario Ministry of Health and Long Term Care | <ul style="list-style-type: none"> • Registry attached to health card and drivers’ license renewal • No online access yet • Phone lookup for providers | <ul style="list-style-type: none"> • Costing to add online development to existing system: \$700K to build, \$300K/year to operate | <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 |
| Trillium Gift of Life | <ul style="list-style-type: none"> • Not applicable (promotes Ontario registry) | <ul style="list-style-type: none"> • Not applicable | <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: recommending that doctor approaches with coordinator for higher content rate • Mail-in form does not yield a good response • Best practice: affirmative action registry, easy link transaction, online access and robust public campaign |
| Donate Life Alaska | <ul style="list-style-type: none"> • Shared database with driver’s licensing | <ul style="list-style-type: none"> • Original cost ~\$100K + \$10K-15K annually | <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 |

| Jurisdiction | Operations | Estimated Costs | Evidence for Effectiveness | Insights* |
|---|--|---|--|--|
| Donate Life California | <ul style="list-style-type: none"> Shared database with driver's licensing | <ul style="list-style-type: none"> Development, build and promotion of registry: \$150K Integration with DMV: ~\$1.1M | <ul style="list-style-type: none"> Purpose is to help gain consent Current proportion in CA: 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 |
| Gift of Life Donor Program – Pennsylvania | <ul style="list-style-type: none"> Shared database with driver's licensing | <ul style="list-style-type: none"> Initial investment: \$200-300K | <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, 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 |
| Donate Life Florida | <ul style="list-style-type: none"> Shared database with driver's licensing 24/7 access for providers | <ul style="list-style-type: none"> Annual costs: \$250K Projected cost for online registration: \$600K | <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 |
| Eurotransplant | <ul style="list-style-type: none"> Information on systems not available | <ul style="list-style-type: none"> Information not available | <ul style="list-style-type: none"> Rates in Netherlands (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 |
| Spain | <ul style="list-style-type: none"> Presumed consent, but donor card approach used for discussion with family | <ul style="list-style-type: none"> No registry (no cost) | <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 |
| UK NHS Blood and Transplant | <ul style="list-style-type: none"> Online registration Call centre Paper registration Partnered with gov'ts and commercial orgs (largest is driver) Oracle database | <ul style="list-style-type: none"> Registry costs £272K (\$450K) per year (£80K pay, £12K stationery, £90K postage and £90K for the "Welcome" letter service) Call centre budget: £60K (\$100K) per year Communications budget is separate | <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.

Conclusions

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

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 family/next of kin. Even in jurisdictions recognizing 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.

Interviews also provided specific insights into the most effective approach to implementing a registry, the most common recommendation for which was a partnership with existing government organizations. This 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.

Appendix A – Interview Findings

The following pages contain the complete results of interviews with several jurisdictions:

- British Columbia
- Nova Scotia
- Ontario (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
- United Kingdom (NHS Blood and Transplant)

Information was collected in seven areas:

1. Type of registry and information collected
2. Systems and operations
3. Usefulness in encouraging intent to donate
4. Effectiveness in increasing donation
5. Lessons learned
6. Costs
7. Enablers (policy, legislative, governance, etc.)

Intent to Donate – Environmental Scan

Final Draft, February 2010

Objectives

Proposed objectives of the Environmental Scan are:

1. Provide deeper or broader understanding of the following areas, with a particular focus on international experience:
 - Existing systems to document intent to donate (e.g., registries, donor cards, utilization of driver's license or health care insurance cards, etc.) and mechanisms to operationalize the systems (e.g., stand-alone databases, jurisdiction-wide registries, etc.)
 - Usefulness of existing systems in encouraging and supporting donor intent/consent, and in supporting the identification/referral and consent processes within the donation process flow (e.g., accessibility to the public, designed for use by health care professionals, OPOs, etc.)
 - Effectiveness of existing systems in increasing donation (using measures such as percentage of population registered, percentage of actual donors who had registered, percentage of donors who had registered)
2. Document costs of developing, maintaining and operating intent to donate registries, nationally and internationally

Canada – British Columbia

| Website | Description of Register | Key Contact |
|---|---|---|
| https://www.transplant.bc.ca/onlinereg/bcts.asp | Individuals may register on the Organ Donor Registry online or by mail; brochures can be obtained by mail, via download from the internet or form ICBC Claim Centres, ICBC Autoplan Branches, Driver Service Centres or physicians' offices. | Ken Donohue BC Transplant Society Tel: 604-877-2240 |
| Subject Area | Key Findings | |
| Type of registry and information collected | <ul style="list-style-type: none"> The registry is based on a first person affirmative consent based on the Human Tissue Gift Act; they are using special digital signature software to make the donor's consent legal | |
| Systems and operations | <ul style="list-style-type: none"> Initially, the registry was a paper based process where individuals completed registration forms that were scanned into the registry data base In 2000, an on line form was introduced, which needed to be printed and faxed or mailed into the registry Online registration was implemented in May 2008, with digital signature technology. The online registry is backed by a traditional paper based system. During a critical event, if someone has been registered in the registry with an affirmative consent, clinicians and or transplant workers will talk to the family and ask if they think the patient may have changed their mind since they registered | |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> 300-400 registrations received every day, an increase from the 150/day that were received prior to launch of the new system 50,000-55,000 new registrations are expected annually. Currently there are 742,986 (January 2010) total registrants Donor families report that the existence or a registry helped them through the donation process in a time of great grief 20-30 % of people who actually become donors are on the registry which indicates that registry is having an impact. The percentage of people prior to the introduction of the system is not clear. Conversion rates pre and post registry are not available Viewed as more secure and timely than past processes which involved a phone in process that would result in a fax being sent to the hospital Health care providers like having the registry as it provides an entry point to a conversation about donation | |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> 16% of population overall on registry. BC has the oldest demographic in Canada. Large immigrant population with cultural challenges toward OTDT. Low-cost transition to online. Moving to online had a moderate effect on conversion rates, though actual numbers are not available. | |
| Lessons learned | <ul style="list-style-type: none"> User's (primarily critical care nurses and physicians) tested the registry before implementation and were part of the piloting of the system Key implementation step is a marketing campaign to leverage the technology / increase awareness of online registry Don't oversell the registry; be careful of language used to "sell" the value of the registry – avoid statements that it will improve organ donation rates First and most important steps in donation process relate to clinical identification of donors at the front end. The registry will not help this, it will help to close the opportunity. | |
| Costs | <ul style="list-style-type: none"> \$100,000 was invested to upgrade registry in 2008. These funds were to replace dated hardware and old technology within existing system and would have been required regardless of the online registry <ul style="list-style-type: none"> Estimated \$20K for online registry portion National online organ donor registry estimated cost less than \$500K Software group absorbed development costs but developed intellectual property as a result of the process Annual license fees are about \$20K, \$25K and \$30K for year 1, 2 and 3 | |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> None noted | |

Canada - Nova Scotia

| Website | Description of Register | Key Contact |
|---|--|--|
| http://www.legacyoflife.ns.ca/about_us/ | <p>Donor wishes are recorded on health cards only, not on driver's licenses or provincial identification cards.</p> <p>Transplant staff now has 24-hour access online to donor information stored on the provincial health card database.</p> | <p>Corinne Corning RN Program Manager, Legacy of Life Nova Scotia Department of Health</p> |
| Subject Area | Key Findings | |
| Type of registry and information collected | <ul style="list-style-type: none"> From Medical Services Insurance (MSI) office - the intent to donate is just part of the health card There is a 1 800 number that goes directly to coordinators where people can ask questions The website also has educational materials and registration form In Halifax, there is a core team of trained requestors -- this team approaches the family -- they also have an end of life consultant that talks to the family At time of death, health card number is the key identifier - aboriginal or military people have a different health card due to their services being covered by Federal government. Linkage to intent to donate has not been fully transitioned. Privacy and Confidentiality are significant issues for any type of registry and a constant concern for organization | |
| Systems and operations | <ul style="list-style-type: none"> The data is currently stored as part of the health care database (not a separate database) 3 organ donor coordinators access the database via computer Currently looking at a website for the public to register | |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> Organ donor coordinators find the registry invaluable -- they bring the consent to the family and 9 times out of 10, the family goes along with the family's wishes 10 year trends could show the impact of moving from DMV to health card First year, about 300,000 people signed up -- year over year has been increasing over 10-20 thousand per year Trying to discover data around whether people who donate are people who register their intent Difficult to determine if donation rates have been impacted | |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> 50% of the population is registered | |
| Lessons learned | <ul style="list-style-type: none"> Were supplying a brochure with educational information, which has been seen as too dense for people. Recently changed it to include a case study of a donor and a recipient to make more of an emotional appeal. Were concerned about telling the public they can donate when in reality, for many causes of death, they won't be able to donate -- for this reason, have targeted provider education first Now, looking at possibly targeting the public -- going to rely heavily on the health card renewal process (every 5 years) to send brochures | |
| Costs | <ul style="list-style-type: none"> None available | |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> None noted | |

Canada – MOHLTC Ontario

| Website | Description of Register | Key Contact |
|---|--|---|
| | <p>Registry began as part of Health Card information. Recently the registry has been transferred to Service Ontario under the Ministry of Government Services to enable “One Stop Shopping” for Ontarians. Through this service they can renew healthcare cards and driver’s licenses. Registry is an affirmative registry. There is currently no on line access.</p> | <p>Tess Palatino MOHLTC Ontario</p> |
| Subject Area | Key Findings | |
| <p>Type of registry and information collected</p> | <ul style="list-style-type: none"> • Currently, public can register at time of Health Card renewal, and make their donation preferences known • When drivers’ licenses are sent out, a green and white donor card is inserted. It is a way to promote awareness. This card only stays in the individual’s wallet. Individuals who do not need to renew their Health Card are not registered. • About 50% of ON have photo health cards and all of these people would have been asked about whether they would like to be an organ donor. Also possible to download form, and mail it in. • Using registry is “24-7 Lookup Initiative”. Trillium can call the Help Desk, using a dedicated line. They provide the health number, and the Help Desk searches the database, and if it is found, they send an encrypted email to Trillium. Only a set number of individuals with a pass code can access that feature. This to validate if the person has been an affirmative for donation. | |
| <p>Usefulness in encouraging intent to donate</p> | <ul style="list-style-type: none"> • Collection of affirmative decisions to donate has increased public awareness. • Provides the care providers with a baseline to facilitate discussion. • Increases chances of a donor being identified at time in hospital. | |
| <p>Effectiveness in increasing donation</p> | <ul style="list-style-type: none"> • This number is always changing, however at this time it is between 16-20% of the population that has been registered as affirmative. | |
| <p>Lessons learned</p> | <ul style="list-style-type: none"> • There needs to be a strong, transparent consultations and communications about the development of a registry. • A survey on what the public wishes is critical. Especially an affirmative registry, it needs a strong public communication. • In provinces where there is a registry already, the question will be how to leverage them and ensure on a national level there is not duplication. | |
| <p>Costs</p> | <ul style="list-style-type: none"> • Preliminary costing for on-line development to an existing system: <ul style="list-style-type: none"> – \$700,000 to build – \$300,000 for operating, per year | |
| <p>Enablers (policy, legislative, governance, etc.)</p> | <ul style="list-style-type: none"> • Need legislation that organ donation wishes should be respected, or whatever direction is taken. • Trillium Gift of Life Act | |

Canada – Trillium Gift of Life

| Website | Description of Register | Key Contact |
|--|---|--|
| | Trillium's role is not to manage or maintain any part of the registry. Their role is to work to fill it up through promotion of the registry, public education and then downstream to access it when a potential donor presents. | Versha Prakash Vice President, Operations |
| Subject Area | Key Findings | |
| Type of registry and information collected | <ul style="list-style-type: none"> As of December 2001, moved to affirmative registration only, meaning they only collect yes responses. This was based on best practices. No registration online. Public is required to go into a Service Ontario location, or download form from website. Have recently submitted a Business Case to create an on-line option. Partnering with Service Ontario for this. Currently, a hotline and secure email for TGLN to contact the ministry via phone line, then the response is transmitted back to the TGLN coordinator via secure email. When the response comes back, shared with the healthcare professional and the family to confirm person's affirmative response to donation. Using email allows hard copies of the deceased decision, including types of donations. Website is encrypted, with PIN numbers for access | |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> Over a 7 month period there was a 5% increase in affirmative records Public education is key Launching a major public campaign in Spring 2010 Deliver education programs for youth, volunteers and the media on an ongoing basis | |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> Actions have been positive, related to increasing donations and with the upcoming public campaign there is hope this will further increase awareness and ultimately registrations | |
| Lessons learned | <ul style="list-style-type: none"> How the family is approached is critical. Physician and coordinator go together to the family, which is when they have the highest consent rate, higher than when only one professional approaches the family. Best practice for setting up a registry includes the following: affirmative action registry, easy link transaction, on-line access and robust public campaign Mail in form does not yield good response | |
| Costs | <ul style="list-style-type: none"> Cost to create on-line registry will be minimal as it will be built into current functionality Other costs might be related to changes in the legacy systems to update the system | |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> In the TGLN Act there is one loop hole where if there is "reason to believe" that the potential donor has changed their mind, donation will not proceed and there is no requirement to provide evidence related to the conversation. First person consent language in legislation would be helpful | |

US – Donate Life Alaska Registry

| Website | Description of Register | Key Contact |
|---|---|---|
| https://webapp.state.ak.us/AlaskaDonorRegistryPublic/app?service=page/Home | Anyone at least 18 years of age and with a State of Alaska issued driver's license or identification card can use myAlaska to sign up to be a tissue and organ donor in the Alaska Donor Registry | Life Alaska Donor Services at 907.562.LIFE (5433) |
| Subject Area | Key Findings | |
| Type of registry and information collected | <ul style="list-style-type: none"> Alaska is a first-person consent (FPC) state, from 1987 Unified Anatomical Gift Act (UAG), updated in 2006 in Alaska. 2004 legislation allowed consent, and allowed people to do this at time of license renewal. The registry from that point grew from 1-2000 per week. License renewal cycle is five years, so everybody will have been issued a new license by 2009. Education of hospital personnel has been as significant as educating the public. "Call us early, and we will work with you and the physician" is the message. It is orchestrated carefully to not prematurely approach the family, and not to have inappropriate people approach the family. | |
| Systems and operations | <ul style="list-style-type: none"> No linkages to EHR or CIS repositories – for reasons of privacy, optics, and discouraging clinical personnel from approaching family. Records are determined to be unique by using the following fields: Name, address, phone, birth date, date of event (consent in DMV), subsequent changes (degree of donation, types of organs); SSN, Drivers license, and unique record number. DMV infrastructure has been leveraged for the online registry (shared DB); this data is sent to Life Alaska daily | |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> As of September 2009, seeing that 35% of referrals (deaths called in) are people on the registry. Before 2003 it was around 10%. Of those who go on to be donors, 55% of them were on the registry. Before 2003, it was around 5%. | |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> 55% of the population is registered | |
| Lessons learned | <ul style="list-style-type: none"> Family refusal statistic is about 6% of the time. Utah, for example, is closer to 30%. This indicates the way the coordinator is approaching the family is different, and also that the family has a different understanding of what FPC means. Anybody who is a child, so ineligible for driver's licenses, cannot provide FPC, so the parents are approached for consent. This is practice for any person not on the registry – they are presumed to not have given consent, and next of kin are approached. Underage being licensed, the parent must sign for the license, and so in effect parents are also involved in that donor consent provision. The UAG, recognizing that this happens with underage people, in the 2006 version of UAG allows a person under 18 to consent to being a donor if they have received a license, and if they do not reverse at 18 are considered to be FPC. | |
| Costs | <ul style="list-style-type: none"> Original implementation rollout was around \$80K. Subsequent enhancements, SQL improves, +\$20K. We use the state's servers, security, backup, etc. We piggy-back on an existing system. Annual maintenance maybe \$10-15k. | |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> Legislature of Alaska approved the bill that allowed the creation of the Alaska Donor Registry. | |

US - Donate Life California

| Website | Description of Register | Key Contact |
|---|---|--------------------------|
| http://www.donatelifecalifornia.org/ | <p>“Donate Life California is a nonprofit Organ and Tissue Donor Registry dedicated to saving the lives of thousands of Californians awaiting life-saving transplants.”</p> <p>“Officially formed in 2004 after being authorized by the state, California’s four federally designated non profit organ procurement organizations (facilitating the donation process across California), are committed to giving every person waiting for a transplant a second chance at life.”</p> | Bryan Stewart, President |

| Subject Area | Key Findings |
|--|--|
| Type of registry and information collected | <p>Opt-in, consent</p> <p>Only ‘yes’ is collected via DMV</p> <p>On website, users can set up a more specific profile, customized with exceptions for specific organs and tissues (about 10% have chosen a donation limitation in the past)</p> |
| Systems and operations | <p>Registry system integrated with DMV</p> <p>People are asked whether they want to be designated as a donor, only collect yes donors</p> <p>Executive director and an administrative assistant manage the registry day-to-day</p> |
| Usefulness in encouraging intent to donate | <p>Ultimate goal of system is to help gain consent</p> <p>Current proportion of population in California: 14% (5.1M people)</p> <p>US national average: 27.5%</p> |
| Effectiveness in increasing donation | <p>Currently 17% of organ donations were assisted by the registry (34/205)</p> <p>US average: 28.1% (580/2066)</p> <p>Similar rates for designated tissue donors: 13% (94/731), US avg: 31.9%</p> |
| Lessons learned | <p>Key message: use the “turn style” aspect of DMV license renewal and identification cards to gain donors (so-called because almost all adults have to pass through)</p> <p>Generally recommend following the lessons learned of other past registries</p> <p>Do not recommend relying on website for collecting consent (98% will come from DMV)</p> <p>Biggest barriers were in clinicians, who weren’t used to notifying families, as opposed to asking families for consent</p> <p>Recommend using radio to advertise (allows targeting of demographic)</p> <p>States seem to have some ‘intrinsic’ donation rate that is difficult to increase past a certain point. Theory: Higher rates of consent in states/regions with better community group cohesion (i.e. where they feel more ‘neighborly’), and lower rates in more diverse, urban areas with higher crime rates</p> |
| Costs | <p>Development, build, and promotion of registry: ~\$150K in 2005</p> <p>Integration with DMV system: ~\$1.1M (one time)</p> <p>Once built, system is not very expensive</p> <p>There are providers out there who have already built the systems: such as iNet and TransplantConnect</p> |
| Enablers (policy, legislative, governance, etc.) | <p>Joint Commission has mandated a timely referral of all deaths in the state to assist in identifying potential donors</p> <p>In most states, family cannot override consent once the person is 18</p> |

US - Gift of Life Donor Program - Pennsylvania

| Website | Description of Register | Key Contact |
|---|---|----------------------------------|
| http://www.donors1.org/ | <p>Gift of Life Donor Program, the non-profit agency serving the eastern half of Pennsylvania, southern New Jersey and Delaware, is responsible for recovering and distributing organs and tissues used in life-saving and life-enhancing transplants</p> <p>Founded in 1974, Gift of Life is one of the oldest and largest of 58 non-profit, organ and tissue procurement organizations in the United States. Gift of Life is part of the nationwide organ and tissue sharing network run by the United Network for Organ Sharing (UNOS)</p> | Howard Nathan, President and CEO |

| Subject Area | Key Findings |
|--|---|
| Type of registry and information collected | <ul style="list-style-type: none"> Consent to donate in all three registries (PA, DE, NJ) Since 1994, information collected is a single field in the driver's license data Yes-only answer to "Do you wish to organ donor designation on your driver's license?" Organ definition includes tissue. Information is collected on a regular basis along with license renewal (every four years) No distinction for specific organs The State collects and provides OPO's with analysis of sex, age, county, etc. in order to help target education |
| Systems and operations | <ul style="list-style-type: none"> System consists of an extra field in the driver's license system Supported by posters and brochures in the DMV office Mail-out of brochure three months before license renewal OP staff have a security code to access the DMV system, which has the 'yes' field |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> About 44% are registered (about 55-60% for younger people, less for older) |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> In 1993: only around 200 organ and 200-300 bone donors Since then, has increased by 150% About 44 donors per million |
| Lessons learned | <ul style="list-style-type: none"> Key message: Link it to something people have to do routinely (i.e. driver's license renewal) Costs can be minimized by attaching to existing government system Attaching to government also represents a better trusted way to collect data Advise against mass mailing of donor cards (expensive to sort through upon return) Advise giving access online Strongly recommend consent, not intent |
| Costs | <ul style="list-style-type: none"> Little to no costs to run system, because it piggybacks on DMV licensing Initial investment of \$200-300k There is a check-off in the license renewal, to allow optional donations, which raises about \$840,000/year (15-20% of people check off) The states manage these funds (through a trust fund committee appointed by governor) |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> Routine referral of death laws (hospital informs OPO, which checks to see if patient is a registered donor) Family is informed of consent, rather than having to ask them for it Motor Voter – after being asked to register to vote, asked about organ donation Hero Act in NJ – mandating high school, nursing, medical school education Provide educational materials for high school teachers Recommends against intent to donate |

US – Donate Life Florida

| Website | Description of Register | Key Contact |
|---|---|--|
| http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Organ_Donors/become_donor.shtml | The Florida Organ, Tissue and Eye Donor Registry is available only to authorized users through the Internet. This is a confidential computerized database that records a person's decision to be a donor. The Registry is designed to be available on a 24-hour day, 7 days per week basis. | Phone: (850) 414-0359 otdonors@ahca.myflorida.com |
| Subject Area | Key Findings | |
| Type of registry and information collected | <p>Florida has an “opt-in” consent model that recognizes first person consent as being the final voice for donation. Legally, physicians do not have the option of overlooking the donor consent; however, in practice objections from family members are often followed due to the potential negative publicity that may result from ignoring the wishes of family members</p> <p>Potential donors can register:</p> <p>At the DMV by giving verbal consent that is then documented, witnessed by two witnesses then entered in the DHSMV database</p> <p>By mailing in a completed donor registration form, available state wide at different locations or can be downloaded from the internet</p> <p>Consent can be revoked, but it does not expire and therefore does not need to be renewed</p> <p>Registry can be accessed 24/7 by hospitals, OPOs, tissue banks and eye banks. In most cases, hospitals contact OPOs or tissue/eye banks to assist with approaching the family of a potential donors whose death is imminent</p> | |
| System and operations | <p>The registry is housed within a relational Oracle database</p> <p>Registry information from the DHSMV is provided via a biweekly data dump, which is then uploaded to the stand alone donor registry database. Uploads from the DHSMV are supported by an MTP via the AHCA web-site and an application is used to validate data</p> <p>Donors uniquely identified in the donor registry using the following data fields: driver’s license number, social insurance number, name, address, date of birth</p> <p>The registry is not linked to a clinical information system or electronic health record system</p> <p>Approximately 1/3 of registrants (i.e., those who registered by mail) have a digital image of their donor registration form attached to their record. Providing evidence of consent / witnesses and preferences/restrictions on organs / tissues to be donated. The preferences or restrictions of the 2/3s who register at the DHSMV are not recorded.</p> <p>The lineage of the form is accomplished through a combination of manual and electronic processes</p> | |
| Usefulness in encouraging intent to donate | <p>Observed annual increases in the number of potential donors on the registry; noted that 6,000 – 7,000 new registrations are received monthly</p> <p>Perception exists that Florida leads the country in number of potential organs/tissues recovered and transplanted</p> | |
| Effectiveness in increasing donation | <p>29% of population is registered</p> | |
| Lessons learned | <p>Clinicians were not involved in the design of the current registry</p> <p>Past experience and history of inclusiveness exists as advisory committees that included representatives from clinicians, OPOs, tissue/eye banks, donor community and recipient community were formed to support development of the legislation for the donor registry</p> <p>Work to release the RFP for the online registration process has built on this history of inclusiveness, by consulting with the same types of stakeholder group through the development process</p> <p>Critical partners in the development and operation of the registry include the DHSMV is and the Florida Coalition on Organ Donation.</p> | |
| Costs | <p>Annual operating costs for the registry are estimated at \$250,000</p> <p>Projected costs associated with the RFP for the online registration process are as follows: \$600,000 for development and implementation</p> | |
| Enablers (policy, legislative, governance, etc.) | <p>The Florida Organ, Tissue and Eye Donor Registry was authorized by the Legislature in 1995</p> | |

Eurotransplant

| Website | Description of Register | Key Contact |
|---|---|--|
| http://www.eurotransplant.nl/ | <ul style="list-style-type: none"> The Eurotransplant International Foundation has been responsible for the allocation of all organs donated after death for transplantation in Germany, Austria, the Netherlands, Belgium, Luxembourg, and Slovenia Several member countries have national organ donor registries (e.g., Austria, Belgium, the Netherlands) – information not accessible due to language barriers | Verena Diepeveen-Huijsman Axel Rahmel |
| Subject Area | Key Findings | |
| Type of registry and information collected | <p>Germany and Netherlands have legislated laws around requiring consent for donation. The other countries have presumed consent.</p> <p>Austria has the strictest presumed consent. The law is that after death there is no longer ownership of the body - not even by the family. The state does an autopsy so there is less opposition to donation.</p> <p>Belgium has a very clear presumed consent law. There is a registry, but with limited numbers. In Germany almost no autopsies are being granted, and there is no registry.</p> | |
| Systems and operations | No information available | |
| Usefulness in encouraging intent to donate | <p>Netherlands has a registry, with about 25% of population. It has been difficult to increase that number. There was a live TV show of a kidney transplant, with the hope of increasing awareness and registrants. It had almost no impact on the registry.</p> | |
| Effectiveness in increasing donation | <p>Rates of transplantation within Netherlands have not been affected by the use of the registry</p> <p>With laws which require consent of kin before donation, being registered on an IDR makes it likely that the family would know what the person's wishes were. If they don't know then they may not agree to donation. The statistics should likely be the same, with or without a registry.</p> | |
| Lessons learned | <p>The donation rates between some countries are almost twice as high with presumed consent. This is heavily debated in Austria (presumed) and Germany (informed consent required from family). Denmark switched from informed to presumed with no change in rates.</p> <p>Personal contact has been the key within Europe. Changes in legislation – no impact. Public information – no impact. What you need is onsite support for the hospitals with coordinators in extreme close contact with the ICUs</p> <p>Germany looked at consent rates from hospitals with and without coordinator involvement. Coordinator involvement yields a higher yes rate for donation. The Spanish model has the coordinators in the hospitals.</p> <p>The key issue is identifying the donors. Having a coordinated approach in the hospital is most effective.</p> | |
| Costs | Information not available | |
| Enablers (policy, legislative, governance, etc.) | Information not available | |

Spain

| Website | Description of Register | Key Contact |
|---|--|---------------------------|
| http://www.ont.es/Home?id_nodo=124 | <ul style="list-style-type: none"> Primary mandate is to coordinate donation, extraction, preservation, distribution, exchange and transplantation of organs and tissues within the Spanish Health Care System Has a number of registries, including: recipients and waiting lists for organs and tissue; brain death; consultations to the Bone Marrow Expert Committee; and tissue in-flow and out-flow | Beatriz Domínguez-Gil, MD |
| Subject Area | Key Findings | |
| Type of registry and information collected | <ul style="list-style-type: none"> Spain has a presumed consent where the belief is that every person is suppose to be a donor They use the Donor card approach to express volunteering to donate They use the card as a way to bridge the discussion with families at time of death Not legally binding as they would always ask the family what the wishes of the person are | |
| Systems and operations | <ul style="list-style-type: none"> Not applicable | |
| Usefulness in encouraging intent to donate | <ul style="list-style-type: none"> The presumed consent and donor card is used as an awareness method Donation rate is 34.2 DPM | |
| Effectiveness in increasing donation | <ul style="list-style-type: none"> Rates of transplantation have not been affected by the lack of a registry With the approach of consent of kin before donation, they continue to strive for increasing numbers related to awareness | |
| Lessons learned | <ul style="list-style-type: none"> Mass media of reaching public for opinion on donation is critical The moment of approaching the relatives is crucial and getting consent or decline is an important part of donation Working with the OPO coordinators and the staff at the hospital is paramount to successful discussions | |
| Costs | <ul style="list-style-type: none"> No registry/No cost | |
| Enablers (policy, legislative, governance, etc.) | <ul style="list-style-type: none"> Spain has presumed consent legislation The country now has Last Will legislation which is related to how people want to be cared for if their health deteriorates. The questions on this registry are related to end of life. Of the 17 regions in Spain only a few ask about organ donation. It is a parallel system to the Organ Donation organization. Has not changed numbers. Authorization by kin for the donation is not a legal requirement. However, social attitudes, including of some judges, has made the practice imperative. Spanish law would require the family be satisfied about the will of the deceased regarding organ donation. In 2004 17.8% of families did not give consent to the donation Methods of approach to the family show marked differences in results between teams who are well trained vs. those who are not. The latter may exceed 50% of families who do not provide consent. The skills and approach of the coordinator is simply vital. | |

UK - NHS Blood and Transplant

| Website | Description of Register | Key Contact |
|--------------------------|---|---------------------------------------|
| www.organdonation.nhs.uk | NHS Blood and Transplant (NHSBT) was established as a Special Health Authority in England and Wales in October 2005 with responsibilities across the United Kingdom in relation to organ transplantation. Its remit is to provide a reliable, efficient supply of blood, organs and associated services to the NHS. Registry was established 10 years ago. | Andy Maxwell Head of Data Services |

| Subject Area | Key Findings |
|--|--|
| Type of registry and information collected | 24 fields collected in database, including name, DOB, sex, address, donate organs, signature, ethnicity |
| Systems and operations | Register via website and a call centre Call centre can also answer questions about donation Paper registration forms in libraries, pharmacies Have partnerships with governments and commercial organizations who add registration information to their pre-existing forms that already collect name, address, DOB, etc. Largest number of registrations come from Driver and Vehicle Licensing Agency (also through doctors, passport, local councils, Boots the Chemist stores) 3 million transactions per year (1M duplicates, 1M change of info, 1M new registrations) Oracle database |
| Usefulness in encouraging intent to donate | No information reported |
| Effectiveness in increasing donation | No information reported |
| Lessons learned | Active in making partnerships with a variety of agencies and organizations to add registration to their forms |
| Costs | £300 per 1000 Welcome messages to new members Managed by 3 staff who receive and load the electronic data, process paper forms, answer emails and letters about donation Budget for the registry team: £272,000 per annum (£80,000 pay, £12,000 stationery, £90,000 postage and £90,000 for the "Welcome" letter service) Call centre is a separate budget – they handle 80-100 calls per day and an annual cost of £60,000 Communications budget not included here – falls under the Communications and Public Affairs Directorate |
| Enablers (policy, legislative, governance, etc.) | No information reported |