STRATEGIES TO OPTIMIZE ORGAN AND TISSUE DONATION AND TRANSPLANTATION

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Strategies to Optimize Organ and Tissue Donation and Transplantation
(Background Paper)

Publication No. 2020-29-E

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EXECUTIVE SUMMARY

The deceased organ donor rate in Canada is lower than that of top-performing countries, but Canada’s rate has improved in recent years. Although the gap between the number of Canadians awaiting organ transplants and the number of organs available has narrowed, further increases in organ donation are necessary to meet demand. Closing this gap will require implementing initiatives and strategies to optimize the availability of organs and tissues for transplantation, and to improve the matching of available organs with individuals on the waiting list. Jurisdictional considerations and legislation also need to be taken into account. Most of the strategies described in this Background Paper have been implemented in provinces and territories across Canada.

Initiatives to improve the organ donation and transplantation system include organ and tissue donor registries, national wait lists of patients, and the collection and storage of cord blood rich in stem cells. Another initiative that may help to optimize the deceased organ donor rate is the introduction of presumed consent approaches, whereby all individuals are considered for organ donation after death unless they register their refusal during their lifetime. In terms of consent, the issue of mandatory declaration has been considered by a number of jurisdictions. Under this model, all individuals are required to register either their consent or refusal for organ donation, which differs from a passive approach of allowing a means of registering consent but not requiring it.

Consent to donate is of little value if potential donors are not properly identified and referred to specially trained donation specialists. Mandatory referral, which requires that hospital personnel identify and refer potential donors to donation programs, could play a part in optimization efforts. To be successful, this involves training organ donor coordinators to identify potential donors and specially trained physicians to optimize donation practices.

Public awareness campaigns may contribute to improving deceased and living organ and tissue donor rates. In this regard, Canada’s National Organ and Tissue Donation Awareness Week, organized by Canadian Blood Services, takes place during the last full week of April every year.

Finally, a number of initiatives have been established to optimize the matching of donor organs and recipients. These include the Kidney Paired Donation Program, the National Organ Waitlist and the Highly Sensitized Patient Program.
INTRODUCTION

The number of transplant procedures performed in Canada increased 33% between 2009 and 2018. In 2018, 2,782 transplant procedures were performed, resulting in 2,849 organs being transplanted. While the number of donated organs from living donors has remained largely unchanged over that time, organs from deceased donors have risen in number, largely between 2013 and 2018, when a 30% increase was noted. However, despite the increase in available organs for transplant, the waiting list of Canadians in need of an organ continues to outnumber the number of organs available. In 2018, there were 4,351 people on the waiting list, and 223 of those people died before a suitable organ became available for them.1

This Background Paper provides an overview of the jurisdictional considerations in organ and tissue donation and transplantation and lists the related federal and provincial/territorial legislation. It goes on to describe several strategies that can increase the number of organs and tissues available for donation and that improve procedures for matching available organs with people on the waiting list. This publication is a companion to the Library of Parliament Background Paper by the same author, entitled Organ Donation and Transplantation in Canada – Statistics, Trends and International Comparisons.2

FEDERAL, PROVINCIAL AND TERRITORIAL RESPONSIBILITY FOR ORGAN AND TISSUE DONATION AND TRANSPLANTATION

The provinces and territories are responsible for delivering health care to the majority of Canadians,3 including almost all aspects of organ and tissue donation and transplantation. The exception is the safety of organs and tissues donated for transplant, which falls within federal jurisdiction. In this regard, federal regulations pursuant to the Food and Drugs Act for organ and tissue donation and transplantation came into effect in December 2007. The purpose of the regulations is to minimize the potential health risks to transplant recipients resulting from transplantation. The Safety of Human Cells, Tissues and Organs for Transplantation Regulations standardize the screening and testing of potential donors in Canada.4

In addition, the federal government may collaborate with the provinces and territories and interested stakeholders to optimize existing programs. To that end, in 2018, Health Canada created the Organ Donation and Transplantation Collaborative (the Collaborative), which includes provincial and territorial governments (except Quebec), Canadian Blood Services (CBS), patients, families, and clinical,
administrative and research professionals. The federal government has indicated that the activities of the Collaborative include

- creating a pan-Canadian data system that will support decisions, avoid missed opportunities and improve patient care;
- identifying decision-making and accountability mechanisms to ensure that Canadians have access to an organ donation and transplantation system that responds to their needs and those of their families;
- maximizing donor identification in hospitals and referrals to transplantation services across Canada;
- identifying underserved populations and improving patients’ access to post-transplantation care in remote communities;
- improving the efficiency and effectiveness of organ sharing processes across jurisdictions to prevent any missed opportunities for donation;
- increasing living donation as a preferred treatment option (e.g., kidneys, liver); and
- supporting health care professionals through professional education.

Budget 2019 proposed $36.5 million over five years and $5 million annually of ongoing funding to allow the Collaborative to develop the above-mentioned pan-Canadian data system.

All provinces and territories in Canada have legislation on organ and tissue donation. These statutes are set out in Table 1.

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<th>Jurisdiction</th>
<th>Legislation</th>
<th>Year</th>
<th>Comments</th>
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<td>British Columbia</td>
<td>Human Tissue Gift Act, R.S.B.C. 1996, c. 211</td>
<td>1996</td>
<td>–</td>
</tr>
<tr>
<td>Ontario</td>
<td>Trillium Gift of Life Network Act, R.S.O. 1990, c. H.20</td>
<td>1990</td>
<td>The Act is to be renamed the Peter Kormos Memorial Act (Trillium Gift of Life Network Amendment) if Bill 91 becomes law.</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>Human Tissue Gift Act, R.S.N.B. 2014, c. 113</td>
<td>2014</td>
<td>–</td>
</tr>
</tbody>
</table>
### STRATEGIES TO OPTIMIZE ORGAN AND TISSUE DONATION AND TRANSPLANTATION

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<th>Jurisdiction</th>
<th>Legislation</th>
<th>Year</th>
<th>Comments</th>
</tr>
</thead>
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<tr>
<td>Yukon</td>
<td>Human Tissue Gift Act, R.S.Y. 2002, c. 117</td>
<td>2002</td>
<td>–</td>
</tr>
<tr>
<td>Northwest Territories</td>
<td>Human Tissue Donation Act, S.N.W.T. 2014, c. 30</td>
<td>2014</td>
<td>–</td>
</tr>
<tr>
<td>Nunavut</td>
<td>Human Tissue Act, R.S.N.W.T. (Nu) 1988, c. H-6 (CanLII)</td>
<td>2011</td>
<td>Nunavut adopted the legislation of the Northwest Territories. Subsequent amendments contained in S.Nu. 2017, c. 22, s. 8 were not available online at the time of writing.</td>
</tr>
</tbody>
</table>

Source: Table prepared by the author based on provincial and territorial statutes in force at the time of writing.

### 3 INITIATIVES AND POLICIES INTENDED TO INCREASE THE SUPPLY OF DONATED ORGANS AND TISSUES

#### 3.1 REGISTRIES

A national registry containing information about donors and recipients can help authorities to identify who is willing to provide an organ and who requires one. While a registry or database of intended donors can be helpful in identifying greater numbers of donors (described in section 3.1.1), a transplant recipient database of individuals awaiting an organ can help to improve efficiency in identifying compatible recipients. Canada’s situation with respect to a national organ recipient waiting list is discussed in section 4 of this Background Paper.

Some factors may affect the usefulness of a donor registry that helps to identify individuals who have expressed their intention to donate their organs should they become candidates. These include the efficiency of coordinators in recruiting candidate donors who are registered, the administrative burden of maintaining and updating the registry, and the role of family consent.

Another limiting factor for both donor and waiting list registries is geography. The viability of retrieved organs is measured in hours, and the faster an organ can be transplanted, the better the chances are for a successful outcome. For example, transplantation should occur within 12 hours for a liver, six hours for a heart and eight hours for a lung. The time constraint limits recipient possibilities in a large country like Canada. Such a constraint does not apply in most other countries.

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7 The time constraint limits recipient possibilities in a large country like Canada. Such a constraint does not apply in most other countries.
3.1.1 Databases of Intended Donors

Also referred to as a donor registry, a database of intended donors is what most people have in mind when they discuss a national registry. It contains names or other identifying information of individuals who have registered their intent to donate one or more organs and tissues after death. The registry can be set up to register consent to donate only or to register either consent or refusal to become a donor.

While there is no national database of intended organ donors in Canada, all provinces and territories, usually under their respective organ and tissue donation legislation, provide some means of registering intent to donate. These are listed in Table 2 below.

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>BC Transplant’s Organ Donor Registry allows residents to register their intent online, by mail or in person to become donors.</td>
</tr>
<tr>
<td>Alberta</td>
<td>The Alberta Organ and Tissue Donation Registry permits residents to register, edit and update their consent to donate online or in person at registry agent offices. Alternatively, residents can signal their wish to be organ donors by signing the back of their health cards.</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>The province does not operate a registry but has announced that it will establish one in early 2020. In the meantime, residents can request a sticker to place on their health card and sign an Intention to Donate card to identify them as intended donors.</td>
</tr>
<tr>
<td>Manitoba</td>
<td>Through Transplant Manitoba’s SignUpforLife.ca, residents can register to be a donor, as well as check and update their consent to donate, online.</td>
</tr>
<tr>
<td>Ontario</td>
<td>The Trillium Gift of Life Network operates an organ and tissue donor registry. Residents can register, as well as check and update their consent to donate, online or in person at ServiceOntario locations.</td>
</tr>
<tr>
<td>Quebec</td>
<td>There are three ways to register consent to donate in Quebec. Quebec’s Régie de l’assurance maladie du Québec operates a donor registry in which residents can register their intent to donate online or intended donors can affix a signed sticker to their health cards. Thirdly, residents can contact the Chambre des notaires du Québec to register consent or refusal to become a donor.</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>There is no online organ donor registry in New Brunswick. Instead, residents can indicate their desire to become donors when they update or renew their provincial health insurance cards.</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>Residents may register their intent to donate either online or by completing a form and submitting it to the Prince Edward Island Medicare Office.</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>There is no online organ donor registry in the province. Instead, residents can complete a form that can be mailed or faxed to the Nova Scotia health department’s organ donation program. A presumed consent system will be implemented in 2020 whereby residents can register only if they do not wish to donate.</td>
</tr>
<tr>
<td>Newfoundland and Labrador</td>
<td>There is no online registry in the province, but residents can indicate and update their intent to donate on Medical Care Plan applications for health coverage. When residents apply for health coverage, they can indicate intent to donate and the words “organ donor” appear on their newly issued health cards.</td>
</tr>
<tr>
<td>Yukon</td>
<td>Residents can complete a form and submit it to the territorial health insurance office to register their intent to donate. In addition to being added to the registry, intended donors receive a sticker to put on their health cards.</td>
</tr>
</tbody>
</table>
Jurisdiction | Description
--- | ---
Northwest Territories and Nunavut | Residents who wish to register their intent to donate can do so through Alberta’s Organ and Tissue Donation Registry.

Sources: Table prepared by the author using information obtained from BC Transplant, Register Your Decision!; Government of Alberta, Alberta Organ and Tissue Donation Registry; Saskatchewan Health Authority, Organ and Tissue Donation; Transplant Manitoba, SignUpForLife.ca; Trillium Gift of Life Network, beadonor.ca; Government of Quebec, Organ and tissue donation; Government of New Brunswick, “New Brunswick Organ and Tissue Donation Program,” Health; Government of Prince Edward Island, Register as an Organ and/or Tissue Donor; Government of Nova Scotia, Organ and Tissue Donation Act: an overview; Government of Newfoundland and Labrador, “Organ and Tissue Donation,” Service NL; and Government of Yukon, Organ donation program.

A national donor registry could be created through the voluntary participation of the provinces and territories by combining their respective databases into a single registry. Another approach to the matter was proposed in a private member’s bill introduced in the 42nd Parliament. The bill sought to allow the Canada Revenue Agency to collect information on donor intent on federal income tax forms and to pass the information on to the relevant provincial or territorial government.8

Creating a national donor registry in this way would not necessarily result in higher organ donor rates. Without an awareness and education campaign, a database, voluntary or otherwise, might be undermined by such factors as the withholding of family consent and the belief among many that if consent is granted before death, less effort will be put into saving their lives. This latter perception may explain the discrepancy between the high proportion of people who say they support organ donation and the low percentage of individuals who register their intent to donate.9

3.1.2 Living Tissue Donor Registry

CBS operates the OneMatch Stem Cell and Marrow Registry, which is a registry of potential live donors of bone marrow or circulating peripheral blood (both sources of stem cells) for all provinces except Quebec. In Quebec, Héma-Québec operates the Stem Cell Donor Registry.10 Both registries are part of the World Marrow Donor Association, which provides access to over 37 million potential donors around the world.11

3.2 CORD BLOOD BANK

Umbilical cord blood is a rich source of stem cells, which are used in the treatment of blood disorders such as aplastic anemia and leukemia. Stem cell transplants from cord blood result in less tissue rejection than stem cell transplants from other sources. In 2015, the provincial and territorial ministers of health (except Quebec’s minister) announced the launch of a national publicly funded umbilical cord blood bank, created
3.3  PRESUMED CONSENT

An option often suggested as a way to increase organ donor rates is known as “presumed consent,” or the “opt-out” system. Under this approach, consent to donate is presumed unless a person has expressly indicated otherwise during their lifetime. Until recently, all provinces and territories in Canada have operated under the “opt-in,” or “explicit consent” or “required consent,” system, whereby an individual expresses the intention to become a donor. Consent to donate is addressed under the provincial and territorial statutes pertaining to organ and tissue donation. Failure to express a desire to donate during one’s lifetime is not considered a refusal to become a donor: the family becomes the ultimate source for consent. Proponents of the presumed consent approach note that the vast majority of Canadians are in favour of organ donation when asked, but that only a fraction of those who are in favour actually register their intent in a database or through their health cards.14

Many countries have adopted the presumed consent approach, and proponents of this approach note that the majority of countries with the highest deceased donor rates worldwide have presumed consent legislation (see Figure 1).15 In 2020, Nova Scotia will become the first province in Canada to implement presumed consent for organ and tissue donation. The new legislation would still require consent from next of kin, and it also implements a mandatory referral system, described in section 3.5 of this Background Paper.16 Proposed legislation to implement presumed consent models for donation are currently before the Alberta, Ontario and Quebec legislatures.17 British Columbia, however, asserts that other strategies, including some described later in this document, are more effective at increasing the deceased donor rate than presumed consent.18
Figure 1 – Deceased Organ Donor Rates and Consent Regimes in Selected Countries, 2017 (per million population)

Note: * Explicit consent to donate organs is required in the United Kingdom; however, Wales operates a presumed consent system.

Source: Figure prepared by the author using data obtained from International Registry in Organ Donation and Transplantation, *International Registry in Organ Donation and Transplantation: Final Numbers 2017*, December 2018.
At the same time, several countries with presumed consent regimes have donor rates that are lower than some countries that operate opt-in systems. For example, Poland and Sweden, which both have presumed consent legislation, report lower donor rates than Canada under its opt-in approach. Moreover, the United States (U.S.), which has an opt-in system, has one of the highest deceased donor rates.19

A 2009 review of studies that compared donation rates before and after the introduction of presumed consent legislation in three countries found that presumed consent “is associated with increased organ donation rates, even when other factors are accounted for.”20 The review’s authors noted, however, that there was little examination in the studies of any other changes taking place when the legislation was introduced, and that other factors, such as the availability of donors, the infrastructure of the transplantation service, investment in health care, and public attitudes to organ donation may all have played a role in determining donor rates. More recently, a similar conclusion was drawn by the authors of a 2019 study that compared six countries that had changed from an explicit to a presumed consent regime. The authors concluded that

[a]lthough presumed consent alone is unlikely to explain the increase in donation rates, the adoption of such a policy may prove to be a worthwhile risk for countries experiencing consistently low organ donation rates.21

This conclusion is supported by analyses of organ donor rates in both Spain and Brazil that suggest that it was not the introduction of presumed consent legislation per se that brought about an increase in organ donor rates, but rather an increased investment in donation and transplantation infrastructure. Spain, which has had the highest organ donor rate worldwide for several years, did not realize an improvement in the organ donor rate, despite its presumed consent system, until the country invested in the organizational structure for organ donation.22 Brazil abolished its presumed consent law shortly after implementing presumed consent in the late 1990s, when it realized that without the added infrastructure, presumed consent would not produce additional organ donors.23

Other countries have taken different approaches to rendering presumed consent more effective. Singapore, Israel and Chile, for example, have implemented policies whereby individuals who opt out as potential organ donors under their presumed consent systems are given lower priority should they need an organ transplant.24

It has been reported that few countries that have presumed consent legislation actually enforce it.25 Rather, these jurisdictions have brought about improved organ donor rates by addressing family consent and donor identification and recruitment.26 Public awareness campaigns that reinforce the need to voice one’s intentions to family, as well as professional awareness and training programs that ensure donor identification and recruitment occur under a specific set of guidelines and policies, are some of the initiatives put in place by high-performing countries to improve organ donor rates.
A 2012 article about the deceased donation process in 29 countries where explicit consent must be given and 25 countries operating presumed consent systems observed that “deceased donation programs are complex, affected not only by law, administration and infrastructure but also ideology and values. It is improbable that any single strategy or approach will cause a marked improvement on deceased donation rates.” The article contends that the authority of next of kin must be factored into any decision to implement presumed consent.

3.4 MANDATORY DECLARATION

Although not implemented anywhere in Canada, mandatory declaration (sometimes referred to as “mandated choice”) ties consent for organ donation to a regulated program, usually provincial health care coverage, for which every resident applies. This approach requires that, as part of the application process, individuals declare whether or not they consent to organ donation following death.

3.5 MANDATORY REFERRAL

Mandatory referral (or required reporting) is the requirement that health care professionals report all brain deaths (and possibly cardiac deaths) or imminent deaths to their local organ procurement organization. With the exception of Saskatchewan and Newfoundland and Labrador, all provinces that have an organ donation and transplantation program have implemented or are implementing some sort of mandatory referral system in an effort to boost organ and tissue donor rates.

3.6 PROFESSIONAL TRAINING IN DONOR RECRUITMENT

In the past, health care professionals were not given specific training for recruiting organ donors. As a result, they may have felt reluctant to approach the families of potential donors and may not have been adequately informed about organ referral. Over the years, as organ donation and transplantation programs have evolved, specially trained organ donor coordinators and physicians have joined these programs. The coordinators are trained to identify potential donors and approach families for consent. The organ donor physicians are trained to improve donation practices, support donor care, and facilitate education and awareness, all in collaboration with the coordinators and the health care facility. All provinces with an organ donation and transplantation program have implemented or are in the process of implementing donation physician programs. CBS has described the inclusion of donation physicians as the “cornerstone” of Spain’s successful organ donation and transplantation program.
3.7 PUBLIC AWARENESS

Public awareness campaigns about organ donation and transplantation help individuals to make an informed choice about the intent or refusal to donate their organs. As well, the campaigns help to increase public support for and participation in the donation and transplantation process.

In 1997, Parliament enacted the National Organ Donor Week Act, which established the last full week of April of each year as National Organ Donor Week. Since assuming responsibility for organ and tissue donation in 2008, CBS coordinates activities during the week, now called the National Organ and Tissue Donation Awareness Week, together with provincial organizations, health charities and advocacy groups, to raise awareness and encourage Canadians to register their intent to donate organs either after their death or as a living donor.

4 INITIATIVES INTENDED TO OPTIMIZE THE MATCHING OF AVAILABLE ORGANS AND TISSUES WITH INDIVIDUALS ON WAITING LISTS

4.1 NATIONAL REAL-TIME WAITING LISTS FOR PATIENTS REQUIRING TRANSPLANTS

Proponents of real-time waiting lists sometimes point to the registry operated in the U.S. as an example to follow. The U.S. has implemented a system to manage the logistical issues associated with operating a national approach to organ donation and transplantation. The U.S. Organ Procurement and Transplantation Network (OPTN) links all professionals involved in the donation and transplant system by maintaining a national waiting list (operated by a private organization called the United Network for Organ Sharing, or UNOS) and providing “equity in access to transplants.” All U.S. transplant centres and organ procurement organizations are members of the OPTN.

When an organ donor has been identified and consent obtained in the U.S., the procuring organization accesses the national transplant database operated by the OPTN, either online or by contacting the UNOS Organ Center directly. Once donor information is entered, a donor–recipient search for a match is run for each donated organ. The resulting list of potential recipients is ranked according to objective medical criteria (e.g., blood type, tissue type and size of the organ, as well as the medical urgency of the patient’s situation, the time already spent on the waiting list and the distance between donor and recipient). Each organ has specific criteria.

Using the list of potential recipients, the local organ procurement coordinator or an organ placement specialist contacts the transplant centre of the highest-ranked patient and offers the organ. If the organ is turned down, the organ procurement coordinator or
placement specialist contacts the transplant centre of the next highest-ranked potential recipient on the match list, and this is repeated until a recipient is found. Once the organ is accepted for a patient, UNOS assists with the transportation arrangements, and the transplant surgery is scheduled.34

Canada does not have a single, centralized list of all patients waiting for an organ. However, since accepting responsibility for Canada’s organ and tissue donation and transplantation system in 2008, CBS has developed, with the participation of all jurisdictions, including Quebec, the Canadian Transplant Registry. It consists of three national patient registries, described below.

4.1.1 Kidney Paired Donation Program

In 2009, CBS announced the first kidney transplants performed through the Living Donor Paired Exchange, the first registry of its kind in Canada. In 2014, the program was renamed the Kidney Paired Donation (KPD) Program. The KPD, which is both a donor and a recipient registry, aims to optimize the use of kidneys from living donors. If an individual is willing to donate a kidney to a designated recipient, such as a family member or friend, but is not a match for that recipient, the donor may register and possibly be a match for another recipient. The KPD registers pairs of individuals: a donor willing to donate a kidney and a recipient in need of a kidney but who are not a match. However, matches can be made with another donor/recipient pair where tissue type and blood group make such swapping possible. Matching donors to recipients can sometimes involve multiple pairs. As of 1 March 2020, the KPD Program had facilitated 733 kidney transplants.35

4.1.2 National Organ Waitlist

The National Organ Waitlist (NOW) was launched in 2012 by CBS. NOW is a real-time, online listing of Canadians awaiting transplant for all organs except kidneys (heart, lung, liver, pancreas and bowel, or multiple organs). Provincial and territorial donation and transplantation programs can access the secure database to identify patients in the most critical need anywhere in Canada. NOW alerts are also sent regularly to health care subscribers to provide information about wait times and organ availability.36

4.1.3 Highly Sensitized Patient Program

CBS established the Highly Sensitized Patient (HSP) Program in 2013, in cooperation with provincial transplant programs, to provide kidneys for donation to patients whose immune systems are highly sensitized. It provides a registry for kidney transplant candidates who are difficult to match and includes efforts to help find donors for these highly sensitized patients through national sharing. As of 1 March 2020, the HSP Program had facilitated 602 kidney transplants.37
CONCLUSION

Canada has a long waiting list of individuals in need of a transplant. Various strategies could be deployed to increase the number of organs available and optimize outcomes in transplantation. Many countries with the highest deceased organ donor rates also have presumed consent regimes, although other countries with presumed consent regimes have low donor rates. The introduction of such regimes is controversial, and debate continues as to whether presumed consent regimes alone can increase organ donor rates. Initiatives such as improving the training of personnel for identification and follow-up of potential donors in hospitals; requiring individuals to register their intent or refusal to donate; and ongoing public awareness campaigns are essential elements to boost organ donor rates and increase the number of successful organ transplants.

NOTES


5. Government of Canada, Organ donation and transplantation collaborative.


9. This concern is addressed by several provincial organ procurement organizations. See, for example, Government of New Brunswick, Organ and Tissue Donation: Talk about it! Answers to your questions.


18. BC Transplant. *About the Organ Donor Registry*.


29. Ibid.


32. CBS, *Background: National Organ and Tissue Donation Awareness Week*.

33. United States [U.S.], Organ Procurement and Transplantation Network [OPTN], “OPTN Goals,” *Vision & Goals*.

34. U.S., OPTN, *Donor Matching System*.

