

ORGAN AND TISSUE DONATION AND
TRANSPLANTATION IN CANADA:

The case for change



PREPARED BY CANADIAN BLOOD SERVICES ON BEHALF OF
THE ORGAN AND TISSUE DONATION AND TRANSPLANTATION COMMITTEES



Canadian Blood Services
it's in you to give

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INTRODUCTION

IN AUGUST 2008, it was officially announced that Canadian Blood Services would assume a new mandate related to organ and tissue donation and transplantation. This included assuming the activities of the former Canadian Council for Donation and Transplantation (CCDT), as well as setting up registries for living donor paired exchange and urgent status and highly sensitized patients. Canadian Blood Services was also given the responsibility to develop a strategic plan for a national integrated organ and tissue donation and transplantation (OTDT) system, in collaboration with the OTDT community. (Note that the scope of these activities does not include organ and tissue donation and transplantation in Quebec).

To develop recommendations for a national integrated OTDT system, Canadian Blood Services is using a defined process based on the following four phases:

- assessment of the current state,
- establishment of strategic direction,
- definition of goals and progress indicators, and
- development of an implementation approach

The process relies heavily on collaboration and input from the OTDT stakeholder community. As part of that collaboration, three committees have been formed: the Steering Committee, the Organ Expert Committee and the Tissue Expert Committee. During the first phase—the assessment of the current state—the two expert committees focused on the need for change and key problems and issues. This Case for Change document is based on those discussions as well as a number of background documents. Its purpose is to identify and explain the elements of the Canadian tissue donation and transplantation system that are most critical to address in order to improve patient outcomes. It is not intended to be a comprehensive description of the current state of all aspects of OTDT in Canada, nor does it focus on any one particular province or program. It is intended to focus on what needs to be remedied from a national perspective and be a baseline to measure progress moving forward. It is expected that this document will be revised as the process evolves and as further input is received from committee members, stakeholders and the public.

- Note that some material in this report is based on data and information provided by the Canadian Institute for Health Information (CIHI). However, the analyses, conclusions, opinions and statements expressed herein are those of Canadian Blood Services, and not necessarily those of CIHI.

TISSUE DONATION AND TRANSPLANTATION CASE FOR CHANGE

TISSUE BANKING in Canada consists of a collection of independent tissue banks that procure, process, store and distribute tissue. In 2008, there were a total of 25 eye, tissue and surgical bone banks (excluding Quebec). As well, there are a number of organizations (including some of those above) that import and distribute tissue products, mainly from the United States. Because of the fragmented nature of the tissue system in Canada, there exists an underlying set of gaps that undermines patient safety and product quality, and system efficiency.

1. THE SAFETY AND QUALITY OF TISSUE PRODUCT IN CANADA CANNOT BE ASSURED.

- There is inconsistent application of standards, regulations and best practices in Canadian tissue banks, resulting in inconsistent quality and safety of tissue product.
- The traceability of transplanted tissue is incomplete.
- An effective surveillance system for tissue related adverse events is not in place nationally.
- There have been several safety incidents involving imported tissue product.
- There is no systematic follow-up of medical outcomes of tissue transplants

In 2007, Health Canada issued safety regulations for cells, tissues and organs (CTO) used in transplantation. These regulations are intended to provide minimum requirements for safe practices in donor suitability assessment, transmissible disease testing, retrieval, processing and labeling, adverse event monitoring and recalls, importation, exportation, as well as general quality and audit requirements. These regulations apply to all establishments that process, import and distribute CTO within Canada. While these regulations are intended to minimize the potential health risks to Canadian recipients of human tissues, there are many gaps in the safety and quality framework.

1.1 There is inconsistent application of standards, regulations and best practices in Canadian tissue banks, resulting in inconsistent quality and safety of tissue product.

- **Inconsistent interpretation and application of regulations.** Although Health Canada's CTO regulations have been in place since 2007, and CSA standards since 2003, they have been interpreted in different ways by different tissue banks. In April 2009, Health Canada issued a document, *Guidance Document for Cell, Tissue and Organ Establishments, Safety of Human Cells, Tissues and Organs for Transplantation*, to provide further clarification on the regulations. It remains to be seen whether this will assist in improving consistency between banks. As well, Health Canada has only recently begun to conduct comprehensive inspections of tissue banks so the level of compliance is not clear. It is known that many recommendations have not been implemented. For example, use of nucleic acid testing for West Nile Virus, Human Immunodeficiency Virus and Hepatitis C Virus, as recommended by Health Canada, has not been implemented by several tissue banks.
- **Voluntary nature of accreditation.** There are accreditation systems available to programs in the Canadian tissue system. For example, the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA) offer accreditation to those tissue banks that meet their requirements. The voluntary nature of this structure leaves gaps in accountability for performance improvement. For example, of the 29 tissue programs in Canada, seven have AATB accreditation and seven have EBAA accreditation. There is no mandated consequence to a tissue program for non-accreditation or loss of accreditation.

Accreditation Canada is currently working to extend the scope of hospital accreditation in emergency and critical care to donation and transplantation programs. While this is likely to prove beneficial, it may not probe deep enough into hospital operations to identify case-level issues, process shortcomings or other more substantive findings that would be necessary to see constant and significant improvements in the system.

- **Uncoordinated policy development and implementation, and limited ability to respond to emerging issues and safety incidents.** Policy development and implementation related to tissue donation and transplantation occurs within many jurisdictions, among them: individual tissue programs, Health Canada, the Public Health Agency of Canada (PHAC) and the Canadian Standards Association (CSA). However, this uncoordinated approach to policy development does not respond well to emerging issues, nor does it ensure that recommendations are quickly adopted or evaluated.

This is especially true for safety issues. For example, when West Nile Virus became a health issue of international concern, the tissue system in Canada responded in a fragmented fashion, with programs acting on their own or waiting for guidance from others. To this day, there is a lack of standardization in testing for West Nile Virus, with some programs testing year round, testing seasonally or not testing at all. In another example, the FDA in the United States recently released a guidance document recommending the screening of all tissue donors for Chagas disease. To date, there has been no policy guidance provided within Canadian jurisdictions.

- **Lack of adoption of best practices.** Currently regulations mandate only minimum requirements and there is no regulatory requirement to follow Good Manufacturing Practices (GMPs), as is required for the blood industry or Good Tissue Practices (GTPs) as is required in the United States. Implementation of best practices is key in improving product safety and quality. Best practices can be applied throughout donation, recovery, processing, and distribution. However, there are several reasons why best practices are not always implemented, even when they can make large improvements.
- **Constraints on health care budgets.** Resources and budgets for staff for donation activities and tissue processing are often part of the larger hospital budget. The hospital may not have or may not provide funding for initiatives that would improve safety or quality. Even for those programs with separate budgets, revenues may not always be reinvested into the tissue bank, instead going back into the general hospital budget. As a result, there may not be enough money to make best practice improvements.
- **Lack of training and awareness.** Tissue banking requires specialized, highly trained people. There are no recognized Canadian training programs available where health care professionals can improve their knowledge and learn about best practices.

1.2 Traceability of transplanted tissue is incomplete.

In order to manage the safety risks associated with tissue transplantation, it is necessary to be able to trace a tissue from the donor to the recipient or vice versa. In the event that a transmissible disease is found or a processing error is discovered, there is a need to prevent further transplantations of tissue and to follow up with recipients who have received tissue. The impact of this could be significant, as one tissue donor may provide as many as 100 allografts. Investigations in the United States have demonstrated severe infections and deaths from transmission of various agents, including Clostridia, West Nile Virus, Group A Streptococcus, Trypanosoma cruzi, Lymphocytic choriomeningitis virus, rabies virus and others.¹

¹ *Surveillance and Traceability in Tissue Transplantation: Discussion Paper*, Canadian Council for Donation and Transplantation, April 2007.

In Canada, there is currently no comprehensive system to ensure complete traceability. There are several areas where issues and barriers exist:

- Individual banks and distributors can generally trace their grafts to end users (hospitals and dentists), however, the capabilities and completeness of ensuring traceability from end user to recipients varies significantly.
- There is inconsistency in obtaining informed consent from allograft recipients. In many cases, tissue recipients may not be aware of their implants or the potential risks. The National Consultation held by Canadian Blood Services in 2008 recognized this gap and recommended that changes be implemented in informed consent practices.²
- As tissue donors are also sometimes organ donors, it is important that information about infections or adverse events be shared between the two systems. Currently, there is no mechanism in place to ensure this happens.
- The use of information technology for traceability is limited and uncoordinated.

1.3 An effective surveillance system for tissue related adverse events is not in place nationally.

Surveillance of transmissible diseases in tissue donors and recipients across the entire country is critical to the safety of Canadian patients. The identification, collection, analysis and ongoing monitoring of safety threats assist in timely responses to emerging issues and provide data for policy and decision making. The Transfusion Transmitted Injuries Section (TTI) of the Public Health Agency of Canada has the responsibility to capture data on moderate and severe adverse events, including the risk of transmission of infectious diseases due to transfusion of blood, blood components and blood products (plasma derivatives) and transplantation of cells, tissues and organs, and assisted reproduction. In 2008, PHAC introduced a pilot for a cells, tissues and organs surveillance system that is to be completed within five years.

1.4 There have been several safety incidents involving imported tissue products.

It has been estimated that Canada imports about 90 per cent of the tissue products used by Canadian patients.³ While the suppliers and distributors are required to register with Health Canada, and certify they comply with the CTO regulations, these requirements may not be sufficient to ensure product safety. There have been several instances of contaminated foreign tissues being imported into Canada. In the United States, both Biomedical Tissue Services Ltd. and Donor Referral Services knowingly violated safety regulations, and sold improperly screened and tested donor tissue to American processors. Product from both these companies was imported into Canada.

While AATB and EBAA accreditation and FDA registration may assist Canadian consumers in choosing reputable companies to purchase from, there is little evidence that auditing or vendor qualification of international companies is performed by Canadian end users. To date, there have been no inspections or audits of foreign manufacturers by Health Canada.

² Canadian Blood Services Organ and Tissue Donation and Transplantation National Stakeholder Consultation, September 2008.

³ *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand, Final Report*, Canadian Council for Donation and Transplantation and Canadian Institute for Health Information, September 2003.

1.5 There is no systematic follow-up of medical outcomes of tissue transplants.

Other than the occasional clinical trial or research study, there is no systematic way to capture and study data on medical outcomes of tissue transplants in Canada. Given the large number and types of tissue products being used, it is important to evaluate the appropriateness and effectiveness of treatments and their side effects in order to improve the success and safety of tissue transplantations.

2. CURRENT CANADIAN TISSUE SUPPLY PRACTICES DO NOT ENSURE SECURITY OF SUPPLY.

- Canada's dependency on imported tissue product exposes patients to supply and safety risks.
- Misalignment between supply and demand means that Canadian tissue banks are not meeting the needs of Canadian patients in terms of either type or volume of product.

2.1 Canada's dependency on imported tissue exposes patients to supply and safety risks.

The Canadian dependency on imported tissue products presents supply risks that could have significant impacts on the health of Canadian patients.

- **Tissue Shortages.** Despite the current availability of tissue product from international markets, there are certain tissue types that are consistently in short supply and for which wait lists exist. These products include heart valves, skin, cornea and tendons. In some cases, this can impact the health of patients.
- **Tissue Safety.** As discussed in section 1.4, there have been several safety incidents involving imported tissue product. Recalls can affect a large number of recipients, as a single tissue donor can provide more than 100 allografts. Tissue disease transmissions (viral, bacterial or fungal) can be severe and can result in the death of the patient.
- **Security of Supply.** Currently, sufficient tissue supply exists internationally to meet Canadian requirements. However, disruption of this supply could occur. For example:
 - Utilization in the United States is projected to increase by 5.4 per cent between 2008 and 2013⁴ and demand could potentially exceed supply.
 - An epidemic in the United States could decrease the number of tissue donors or result in restrictions at international borders, making importation difficult and expensive.
 - In case of disasters, it may be difficult to quickly obtain the amount and type of tissue graft required, e.g. allograft skin to treat burns from wildfires or manufacturing facility fires.

In the event of a supply disruption, Canadians have few alternatives with which to deal with the shortage.

- **Cost Risks.** The volatility of the exchange rate makes it difficult to plan financial budgets for the importation of tissue product. An increase in the rate can significantly impact a budget.

⁴ BCC Research (2008) Market Research Report – Organ and Tissue Transplantation and Alternatives, BCC Research, www.bccresearch.com.

2.2 Misalignment between supply and demand means that Canadian tissue banks are not meeting the needs of Canadian patients, in terms of either type or volume of product.

There is no integration or coordination of Canada's tissue supply, either in Canadian produced tissue grafts or imported products. There are no processes nationally to share inventory information or manage distribution across provincial borders. The impact of this is felt by Canadian end users and patients:

- There have been numerous occasions where there are tissue shortages in one area of the country and surpluses in another.
- There is significant provincial variation in production of, and access to, tissue allografts. The average waiting time for corneal transplantation ranges from seven months to three years.
- Production appears to be a function of donor supply rather than end user demand. As a result, end users cannot consistently rely on their Canadian tissue banks to have the type, quantity and quality of product they need.
- Canadian tissue banks do not yet have the ability to produce highly processed tissue products. Demineralized bone matrix, the most commonly utilized tissue product, must be imported from foreign processors.

3. THE CANADIAN TISSUE SYSTEM OF INDEPENDENT AND UNCOORDINATED TISSUE BANKS RESULTS IN INEFFICIENT TISSUE COLLECTION, PROCESSING AND DISTRIBUTION.

- Most Canadian tissue banks are structured on a hospital service-delivery model, rather than a manufacturing model, making it difficult to implement process improvements and efficiencies.
- Canada is failing to realize its potential for tissue donation.
- Uncoordinated interactions with international suppliers and processors result in lower volume agreements at higher costs.

A survey was conducted in 2007 by the AATB. Data showed that in the 32 American tissue facilities responding to the survey, 49,207 deceased donors were processed (average of 1,538 donors per bank) with an average allograft production of 49 grafts per donor. Four of those tissue banks processed more than 4,000 donors each. In contrast, the Canadian data from the survey showed that the seven AATB accredited Canadian tissue banks processed 400 deceased donors (average of 57 donors per bank) with an average 21 grafts per donor.⁵

3.1 Most Canadian tissue banks are structured on a hospital service-delivery model, rather than a manufacturing model, making it difficult to implement process improvements and efficiencies.

Most tissue can be frozen or freeze-dried, stored for long periods of time and shipped thousands of miles without consequence to quality or safety. Because tissues can be handled in these ways, tissue banks in the United States have evolved using a manufacturing model. They are centralized and deal with large volumes of products. They have a supply chain focus and well established distribution channels. They operate using

⁵ Robert Rigney, Report on the 2007 Annual Survey, AATB Spring Meeting, March 29, 2009.

Good Tissue Practices (GTPs), which are similar to Good Manufacturing Practices (GMPs). In this type of environment, tissue banks tend to optimize the costly investments needed for facilities and equipment, inventory management information systems, and highly trained, specialized staff. In Canada, most tissue banks are run within hospitals, and are structured along a hospital service-delivery model. This model focuses on patient care and service to physicians, deals with smaller volumes and does not operate under GMP/GTP conditions. Not only does this make it more difficult to achieve process efficiencies and expand operations, it also makes it difficult to implement and maintain a GMP/GTP culture.

3.2 Canada is failing to realize its potential for tissue donation.

Although there is a shortage of organ donors in Canada, it has been estimated that there could be enough tissue donors to potentially meet demand for Canadian patients.^{6,7} There are greater opportunities for tissue donation than there are for organ donation. Tissue can be recovered up to 24 hours after death. Not only can potential donors be identified in hospital emergency and intensive care departments, but also from other wards, the medical examiner and funeral homes.

However, there are many difficulties in increasing tissue donation. In appropriate situations, families are not always given opportunities for donation. In most hospitals, discussing the opportunity for donation remains the decision of the treating physician rather than a standard of care. Health care professionals may not always recognize potential donors, especially in the expanded situations available for tissue donation. Families sometimes refuse to consent to donations, many times because they are unaware of the potential donor's wishes, are not approached properly, or do not have enough information about tissue donation.

Tissue banks are not always able to develop or implement strategies to expand their donation pool. They do not always have collaborative processes in place with organ-procurement organizations, medical examiners or with other tissue banks, and miss opportunities for donation. Others simply do not have the budgets to expand or support their programs. In other situations, even if the family is willing to consent to donation, there may not be sufficient capacity in the system to recover and process tissue. There are significant geographical areas where tissue recovery is not supported. For example, there is no deceased bone, skin or cardiac recovery occurring in British Columbia or Newfoundland. In other cases, a recovery team may only retrieve a particular type of tissue, or may only recover from a defined geographical area. There may be difficulty in securing the hospital operating room environments needed for tissue retrieval, as well as having enough highly specialized recovery teams available.

3.3 Uncoordinated interactions with international suppliers and processors results in lower volume agreements at higher costs.

In Canada, some organizations have centralized tissue purchasing and have developed preferred supplier agreements. Others have agreements to provide tissue in exchange for preferred pricing. However, in other jurisdictions purchases are generally made by individual surgeons, dental surgeons, hospitals or tissue banks. It is probable that the contracts negotiated by individual end-users are not optimal and are more expensive compared to a more integrated national contract approach. As much of the product is paid for by governments, either directly or indirectly, these costs are borne by the Canadian public.

⁶ *Tissue Donation Potential Beyond Acute Care*, Canadian Council for Donation and Transplantation, August 2006.

⁷ *Estimating Potential Tissue Donors in Canada from 1995 – 2000: An Exploratory Analysis Based on Acute Care Hospital Admissions Data, Final Report*, Canadian Council for Donation and Transplantation, January 2004.

4. THE CURRENT TISSUE SYSTEM LACKS THE MEASUREMENT AND ACCOUNTABILITY MECHANISMS TO DRIVE CONSISTENT, SYSTEM-WIDE PERFORMANCE IMPROVEMENTS.

- Inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to make system wide, evidence-based improvements.
- Unclear and uncoordinated accountability diminishes both incentives and mechanisms for effecting improvement.

4.1 Inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to make system wide, evidence-based improvements.

Data collection and analysis occurs in many Canadian tissue banks and programs, generally with different standards and data definitions. However, at the national level, consolidated data are virtually non-existent, even for basic donation and transplantation activities. The Canadian Institute for Health Information maintains information on organ but not tissue donation and transplant activity. There is no incentive or requirement for tissue banks to share information.

The lack of comprehensive, timely, consistent, accurate national data limits the ability to fully understand and describe the performance of the current system: How many tissue donors are there in Canada annually? How much tissue is processed in Canada? How much are governments spending on imported tissue from other countries? Are there wait lists for specific tissues and how long are they? What products and transplantation practices are associated with better patient outcomes? The lack of data also makes it difficult to identify evidence-based, national-level improvement opportunities, including improvement in system accountability.

4.2 Unclear and uncoordinated accountability diminishes both incentives and mechanisms for effecting improvement.

While individuals have their own accountabilities—to their boards, to their professional organizations and to their funders—there is no accountability across the supply chain to improve performance by delivering on agreed outcomes and targets. Each organization or component does not always coordinate its efforts or performance targets with others in the system. There are no consequences for not implementing best practices. There are no incentives or pressures to improve performance. There is no linking of resources invested to performance results. There is little motivation to be collaborative. These issues are particularly complex because of the fragmented and geographically dispersed nature of the programs and organizations involved.

ORGAN DONATION AND TRANSPLANTATION CASE FOR CHANGE

ORGAN TRANSPLANTS have proven to be the most cost effective treatment for end-stage renal disease, and the only life-saving option for many heart, liver and lung patients. Patient survival rates and outcomes have improved significantly over the last decade. However, in Canada, there is a significant shortage of organs available for transplantation. As of December 31, 2008, there were 4,380 patients on wait lists for organ transplants across Canada.⁸ During 2008, 215 Canadians died while waiting for organ transplants, while many others were in advanced stages of illness and died without being included on wait lists.

Future demand is only expected to make the existing gap wider. The need for organs is predicted to increase by 152 per cent over the next two decades.⁹ Canada's aging population will become increasing consumers of organs, as well as smaller contributors to the organ pool. Advances in medicine will mean more patients will benefit from transplantation. New organ support and bridging technologies will enable patients with end-stage organ failure to live longer, as they wait for organs to become available. As well, increases in the prevalence of Hepatitis C and diabetes rates will significantly increase the need for organs.

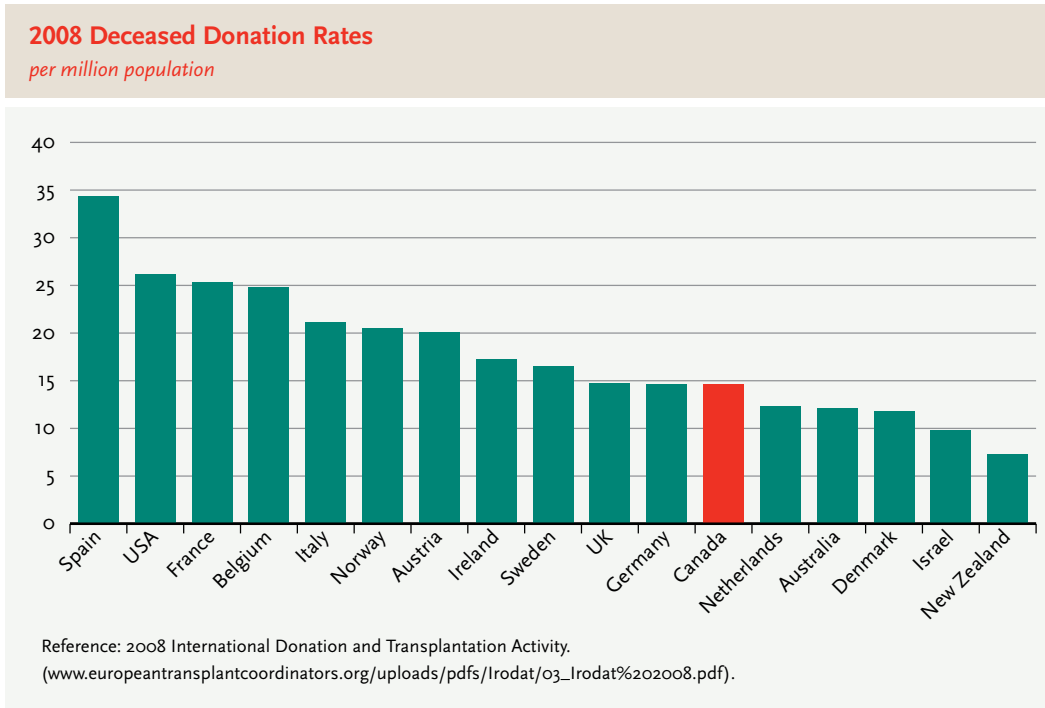
The Canadian organ donation and transplantation system is unable to cope with current demand and unable to plan for and meet future demand. There are a number of major problems needing to be fixed and while solutions are available to improve the situation, there are many road blocks in implementing them. This document describes the most critical problems and issues that need to be addressed to improve the situation for Canadian patients waiting for organ transplants.

1. CANADA IS FAILING TO REALIZE ITS POTENTIAL FOR ORGAN DONATION.

- Families are not always given the opportunity for donation; it remains the decision of the treating physician rather than a standard of care.
- Request for donation to the families is not always done in an effective way, resulting in lower consent rates.
- Donation after cardio-circulatory death (DCD), a practice with potential for increasing organ donation, is under-utilized

⁸ 2008 CORR Data.

⁹ Baxter D and J Smerdon, *Donation Matters: Demographics and Organ Transplants in Canada, 2000 to 2040*, June 2000 (<http://www.urbanfutures.com/UF1%20Reports/Report%2046%20-%20Donation%20Matters%20-%20Demographics%20and%20Organ%20Transplants.pdf>).



Compared with other countries, Canada's deceased donation rate is unacceptably low: less than half that of the best-performing countries. Even provinces with the highest donation rates are far behind comparable countries.

The majority of organs for transplantation in Canada come from donors who die in Canadian hospitals under specific conditions. The donation process involves multiple players and a series of complex steps: identification of a potential donor in the hospital, referral to the organ procurement organization (OPO), assessment of the donor, consent from the family, clinical management of the donor, arrangement of hospital operating rooms and staff, and ultimately organ recovery. Unfortunately, in Canada, too many donations are lost because not every step is optimized or executed effectively.

1.1 Families aren't always given the opportunity for donation; it remains the decision of the treating physician rather than a standard of care.

It is recognized that consistently identifying every potential donor at the hospital and referring them to the provincial or regional OPO is a major driver of organ donation. However, practices for donor identification and referral vary across Canadian provinces. In British Columbia, Manitoba, Ontario and Alberta, referral of potential organ donors to OPOs is a legal requirement. In other provinces, it is up to the individual hospitals and health care professionals to determine whether a potential donor is referred or not. Even when mandated, not all potential donors are referred. Because organ donation is a relatively rare event in smaller hospitals, potential donors are not always recognized in a timely manner by health workers.

In other cases, health care professionals feel unsure of the process or are uncomfortable approaching families, and decide not to ask them about organ donation. For most hospitals, there is no obligation or incentive to do so. In many instances, access of potential donors to intensive care units where donation

proceedings typically occur is restricted due to unavailability of donation services or bed capacity limitations. Even when the family approaches the hospital about donation, they are not always supported. In these cases, the opportunity for donation is lost.

1.2 Request for donation to the families is not always done in an effective way, resulting in lower consent rates.

In Canada, it is standard practice to ask the deceased's family for consent to donate before proceeding with organ donation, even if the intent of the donor is known. Conversations with families are difficult. Proper training is required to ensure that the family is approached in a sensitive, ethical and culturally appropriate manner. Unfortunately, health care professionals trained in dealing with donor families are not always available, even in those hospitals where donor identification and referral are standard practice. This can negatively impact the consent rate of families.

Discussions with families are also easier when the family or the health care providers are aware of the donor's wishes. Many provinces have registries where people can indicate the intent to donate. Unfortunately, these 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 it is on a database, not all hospitals or not all 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.

Although public awareness and support for organ donation in Canada is relatively high (greater than 90 per cent), only about half of all Canadians have taken the action of indicating their intent to donate, either by telling a family member, signing a donor card or registering online.¹⁰ People often do not know how or where to register their intent or consent to donate. They are not aware that they need to talk to their families about their wishes with respect to donation. As well, families of potential donors are not aware of all situations where donation is possible. As a result, many organs are lost when families choose not to pursue the donation opportunity.

1.3 Donation after cardio-circulatory death (DCD), a practice with potential for increasing organ donation, is under-utilized.

Most organ donations come from patients who have been declared brain dead based on neurological criteria. However, there are many patients with catastrophic brain injury who are not brain dead, but who are on life support and for whom there is no chance of recovery or survival. Organs can be recovered from these donors. While this practice, known as donation after cardio-circulatory death (DCD), is a recent development for the Canadian system, it is common and well advanced in many other countries. In the United States, DCD can account for about 20 per cent of deceased organ donors while in Canada, in 2008, they accounted for approximately eight per cent. While Ontario has advanced implementation of DCD, it is only rarely offered in British Columbia, Quebec, Nova Scotia and Alberta. While this type of donation has potential to increase the number of organs for transplants, it is still not available in most hospitals.

¹⁰ *Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death*, Canadian Council for Donation and Transplantation, 2005 (http://ccdt.ca/english/publications/surveys-pdfs/Public_Survey_Final_Report.pdf).

2. THE CANADIAN ORGAN DONATION AND TRANSPLANTATION SYSTEM IS NOT EQUITABLE NOR TRANSPARENT.

- Not all people who could benefit from transplants are being referred to wait lists.
- The likelihood of receiving a transplant varies widely across the country.
- Organ allocation practices are not transparent, which erodes trust in the system.
- Some patient groups receive a disproportionately small share of available organs

2.1 Not all people who could benefit from transplants are being referred to wait lists.

For patients with end-stage organ failure, an organ transplant is the best long-term treatment option. To obtain access to a transplant, a patient must be identified as a potential transplant candidate, assessed for transplant suitability and placed onto a wait list for the appropriate organ. In Canada, it is unclear whether all patients who meet the criteria for transplantation are being placed on wait lists.

There are inconsistencies in how practitioners in different provinces refer patients to specialists for assessment and how specialists add patients to wait lists. There are national criteria available that guide physicians in determining whether patients are suitable candidates for transplantation. Unfortunately, some of these guidelines are not widely available and there is a lack of awareness of these criteria among health care professionals. As well, in some provinces, patients are excluded from wait lists by physicians who know that the chance of their patient getting an organ is extremely small. As a result, patients who may be eligible for transplantation are not on wait lists.

2.2 The likelihood of receiving a transplant varies widely across the country.

While some inter-provincial differences in transplant rates are to be expected, the variation that is currently seen is very marked and concerning. A 2006 Canadian Medical Association Journal article reported large variations among the seven provincial regions studied. For example, patients in Alberta were 3.74 times more likely than those in Ontario to receive kidney transplants from deceased donors.¹¹

Transplants Rates (PMP)*	BC	AB	SK	MB	ON	QC	NB	NS	NL	NAT AVG
Kidney	13.4	22.1	20.8	16.3	20.0	26.3	24.9	27.3	24.1	21.1
Heart	5.1	7.5	5.0	3.1	4.9	4.5	5.8	5.9	5.9	5.1
Lung	3.2	8.5	5.7	2.8	5.4	3.7	3.6	5.0	11.1	5.0
Liver	9.3	15.1	7.0	6.8	11.7	12.1	10.7	14.6	4.6	11.5

* (per million population, organs from deceased donors only) CORR data, averaged from 2005 - 2007

¹¹ Tonelli et al, *Residence Location and Likelihood of Kidney Transplantation*, CMAJ, August 29, 2006; 175 (5).

There are a number of factors that can cause regional differences, including donation rates, variations in listing practices and availability of transplant programs within the provinces. However, while some provincial differences in these areas are unavoidable, the size and scope of these differences indicate a significant inequity in access to organ transplantation in Canada.

2.3 Organ allocation practices are not transparent, which erodes trust in the system.

Patients in need of organ transplants are understandably in anxious situations. They want to know how likely they are to receive organs, how long they will need to wait, or why they have not yet received a transplant. In the current state, there is no systematic or easy way for patients to better understand their status. The lack of public, standardized criteria for wait list referral and allocation, along with the complexity of the system, make it difficult not only for the public, but also for health care professionals to understand. The public has very limited say into what values should be considered in the development of wait listing and allocation rules. In general, the wait listing and allocation rules are not publicly available. All this contributes to a system that is not understood or trusted, and can lead to frustration for patients and families.

2.4 Some patient groups receive a disproportionately small share of available organs.

Highly sensitized patients, the majority of whom are women, have developed strongly reacting antibodies to specific, common HLA markers through previous blood transfusions, transplantations or pregnancies. Sensitized patients make up about 30 per cent of kidney transplant wait lists, but receive less than five per cent of all deceased donor kidneys. Approximately 75 per cent of highly sensitized patients are women who have had children and who are waiting for their first organ transplants.¹² For highly sensitized patients, only a limited fraction of available organs are compatible. As a result, these patients wait much longer than non-sensitized patients for a transplant offer, and are more likely to die while waiting for transplants. Because kidney allocation is limited to provincial donation pools, these patients effectively have a much lower likelihood of transplantation than other patients.

Another group of disadvantaged patients is Aboriginals. While Aboriginals have more than twice the prevalence of end-stage renal disease compared with Caucasians, their likelihood of receiving transplants was significantly lower and they had significantly higher overall median wait times.¹³

¹² *Canadian Highly Sensitized Patient and Living Donor Paired Exchange Registries Task force Discussion Document*, Canadian Council for Donation and Transplantation, Oct 28–30, 2005.

¹³ Yeates et al, *Indigenous people in Australia, Canada, New Zealand and the United States are Less Likely to Receive Renal Transplantation*, *Kidney International*, June 24, 2009.

3. THERE ARE SYSTEM INEFFICIENCIES ASSOCIATED WITH PATIENT ASSESSMENT AND ORGAN ALLOCATION THAT CAN IMPACT PATIENT WAIT TIMES AND HEALTH.

- The current allocation process for urgent status patients is inefficient and can result in sub-optimal matching and lost transplantation opportunities.
- Patient assessment for referral to wait lists can take too long.

3.1 The current allocation process for urgent status patients is inefficient and can result in sub-optimal matching and lost transplantation opportunities.

While organs generally remain in the provinces in which they were donated, there is organ sharing between provinces for urgent status heart, liver and small bowel patients. National agreement on the determination of patient status has been developed for heart and liver recipients but accountability mechanisms to comply with the agreed-to policies are limited. The national urgent status wait list is maintained by the London Health Sciences Centre. Weekly updates are made by fax or phone. When an organ becomes available, offers are made by phone based on the list. It is estimated that an average of 100 to 200 telephone calls are required to coordinate organ procurement and distribution. If the process takes too long, some organs lose viability and cannot be transplanted. Because data is added manually, there is a high potential for errors. Because updates are made only on a weekly basis, patient data and status are often outdated. There have also been concerns about the system related to security, privacy, transparency, traceability and accountability.

Stakeholders have also expressed concern that, with the current system, organs are declined that could have been used, and retrieved organs are not always allocated appropriately to the person at the top of the list. This results in mistrust in the system by many health care professionals.

3.2 Patient assessment for referral to wait lists can take too long.

Patients with end-stage organ failure can be placed on wait lists only after an extensive assessment and work up. This process includes medical examinations, laboratory testing, imaging (CT scans, ultrasound) and consultation among various specialists. Processes are not always well integrated, especially when tests and consultations are across different departments, hospitals and data information systems. The typical work up takes many months and in some jurisdictions is substantially longer than in others.

4. THE CURRENT ORGAN SYSTEM LACKS THE MEASUREMENT AND ACCOUNTABILITY MECHANISMS TO DRIVE CONSISTENT, SYSTEM-WIDE PERFORMANCE IMPROVEMENTS.

- Inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to make system-wide, evidence-based improvements.
- Patient safety is being compromised by uncoordinated and fragmented policy development and implementation, and the limited ability to respond to emerging issues and safety incidents.
- Best practices and national guidelines are not adopted quickly and consistently.
- Unclear and uncoordinated accountability diminishes both incentives and mechanisms for effecting improvement.

The problems previously discussed are related to specific areas of the organ donation and transplantation supply chain. However, there are also many over-arching issues that apply to all aspects of the system and that need to be corrected to see transformational improvement in performance.

4.1 Inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to make system-wide, evidence-based improvements.

Data collection and analysis occur in many Canadian organ donation and transplantation programs, generally with different standards and data definitions. However, at the national level, the reporting of data is limited to summary activity submitted to the Canadian Organ Replacement Registry (CORR), a national database managed by the Canadian Institute for Health Information. Data submission is voluntary, often late, not comprehensive, and there is minimal auditing of the quality of the data. There is no national data collection on donation activities such as donor identification, referral rates or consent rates. Because of the issues with the current system, there is lack of faith in the data collected.

The lack of comprehensive, timely, consistent, accurate national data limits the ability to fully understand and describe the performance of the current system: How many potential donors are not being identified or referred to OPOs? How many families refuse consent to donate? What are the average wait times for the different organ types by different provinces? How often are organs refused by transplant programs and for what reasons? What allocation practices are associated with better patient outcomes? The lack of data also makes it difficult to benchmark Canada against other countries, and identify evidence-based, national-level improvement opportunities.

4.2 Patient safety is being compromised by uncoordinated and fragmented policy development and implementation, and the limited ability to respond to emerging issues and safety incidents.

Policy development related to organ donation and transplantation occurs within many jurisdictions, among them the Canadian Standards Association, the Canadian Society of Transplantation, Health Canada and the Canadian Critical Care Society. However, this uncoordinated approach to policy development does not respond well to emerging issues, nor does it ensure that recommendations are quickly adopted or evaluated.

This is especially true for safety issues. When West Nile Virus became a health issue of international concern, the organ system in Canada responded in an uncoordinated fashion, with programs acting on their own or waiting for guidance from other healthcare authorities. To this day, there is a lack of standardization in testing not only for West Nile Virus, but also Hepatitis C, Human Immunodeficiency Virus, and other transmissible diseases.

Another example is transplant tourism. Canada still has no policies in place to respond to the increasing practice of patients' paying for organs and receiving transplants in third-world countries.

4.3 Best practices and national guidelines are not adopted quickly and consistently.

The implementation of best practices is considered to be a successful strategy in improving organ donation rates. The success of Spain, which has the highest deceased donor rate in the world, is largely attributed to the way it has organized and implemented organ donation processes. After implementing elements of the Spanish model, Italy increased its organ donation rate from 12.3 donors per million population in 1998 to 21.1 in 2004.¹⁴ Likewise, in the United States, the experience of the Organ Donation Breakthrough Collaborative (which promotes implementation of best practices) contributed to that country's significant increase in donation rates.¹⁵ In Canada, there is no requirement or incentive to implement best practices to improve donation rates and no coordinating body to facilitate the implementation.

There are many reasons why best practices are not always implemented, even when they can make large improvements:

- **Constraints on health care budgets.** Resources and budgets for staff for donation activities are often part of the larger hospital budget and are not segregated. These resources are particularly vulnerable during budget cuts, as there are no incentives for the hospital to promote and encourage organ donation, which does not generate revenue. In most cases, organ donation and transplantation is in competition with other services: ICU beds, operating room time, and operating room staff. Specialized recovery teams, generally from the transplant hospital, are required to retrieve organs from a donor. These teams are not always available when required.
- **Financial disincentives exist which discourage organ donation.** There are some disincentives that actively discourage organ donation in hospitals. For example, to maintain a donor in an ICU bed until organs can be recovered is very expensive. Not all hospitals are reimbursed for this cost. Therefore, the hospital must pay for this from its operating budget. In many situations, ICU and operating resources are over capacity and there is no financial incentive to make room for the donor, especially if it disrupts other patients or surgeries.
- **Lack of training and awareness.** The activities for organ donation and transplantation require specialized, highly trained people. There are very few training programs available, either in medical schools or in hospitals, where health care professionals can learn about this area, including best practices.

¹⁴ International Registry of Organ Donation and Transplantation data (IRODaT), www.tpm.org, downloaded Aug 2009.

¹⁵ Tuttle-Newhall et al, *Organ Donation and Utilization in the United States: 1998–2007*, American Journal of Transplantation, 2009: 9(Part 2) 879-893.

4.4 Unclear and uncoordinated accountability diminishes both incentives and mechanisms for effecting improvement.

While individuals have their own accountabilities, to their boards, to their professional organizations and to their funders, there is no accountability across the supply chain to improve performance by delivering on agreed outcomes and targets. Each organization or component does not always coordinate its efforts or performance targets with others in the system. There are no consequences for not implementing best practices. There are no incentives or pressures to improve performance. There is no linking of resources invested to performance results. There is little motivation to be collaborative. These issues are particularly complex because of the fragmented and geographically dispersed nature of the programs and organizations involved.

APPENDIX 1: OTDT COMMITTEE MEMBERS

Steering Committee	Organ Expert Committee	Tissue Expert Committee
Dr. Graham Sher (Chair)	Dr. Peter Nickerson (Chair)	Dr. Locksley McGann (Chair)
Dr. Andrew Baker	Dr. Ian P. J. Alwayn	Mr. Michael Bentley
Dr. John F. Hamm	Dr. Stephen Beed	Dr. Brian Berry
Commodore Hans W. Jung	Dr. Tom Blydt Hansen	Mr. Scott A. Brubaker
Dr. Maurice McGregor	Dr. Michel Carrier	Ms. Mary Gatien
Honourable A. Anne McLellan P.C., O.C.	Dr. Noel Gibney	Dr. Michael Gross
Dr. Brian Postl	Dr. David Grant	Dr. Frank I. Hohn
Dr. Judith Shamian	Dr. Gregory A. Grant	Dr. David Howarth
Dr. Michael Strong	Dr. Debra Isaac	Mr. Dermot Kelly
Dr. Simon B. Sutcliffe	Dr. Anthony Jevnikar	Dr. Sarvesh Logsetty
Dr. William J. Wall	Dr. Shaf Keshavjee	Ms. Janet MacLean
	Dr. Norman Kneteman	Mr. Sean Margueratt
	Dr. Greg Knoll	Dr. Hassan Moghadam
	Dr. Adeera Levin	Dr. Jutta Preiksaitis
	Dr. Robert D. Levy	Mr. Christopher Snow
	Dr. Frank Markel	
	Ms. Raylene Matlock	
	Mr. Scott McIntaggart	
	Dr. Guiseppe Pagliarello	
	Ms. Deanna Paulson	
	Dr. Sam D. Shemie	
	Dr. John M. Tallon	
	Ms. Kimberly Young	