

Background Paper for the Tissue Expert Committee

How can tissue donation be increased in Canada?

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Original version: January 2010 Reformatted: October 2011

1. Introduction

A. Background

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

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

Limitations of these documents:

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

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

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

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

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2. Scope

This paper presents options available within the TDT system to improve tissue donation. The paper assesses options at each process stage, including donor identification and referral, obtaining consent and tissue recovery. Activities and programs that

support tissue donation but are not part of the core process (e.g., intent-to-donate registries and public awareness campaigns) will not be assessed. Living donors are not included in the scope of this report.

3. Donor Potential

Identification of potential tissue donors and their timely referral to tissue banks or Organ Procurement Organizations (OPOs) are critical to increase the Canadian supply of tissue for processing. Unlike organ donors, who are generally identified in emergency departments or intensive care units (ICUs), tissue donors may be referred from hospitals, medical examiners and coroners (ME/Cs), and funeral homes.

A study commissioned by the Canadian Council for Donation and Transplantation (CCDT) in 2004 sought to derive estimates of potential tissue donors annually in each province from administrative data on hospital admissions. Patients were considered potential tissue donors if they were identified as medically eligible to donate tissues based on their admitting diagnoses for the hospitalization during which they died. Potential donors were defined on the basis of tissue type and specific inclusion-exclusion criteria by tissue type. The report concludes that even when the consent rate is considered in the analysis, the number of potential tissue donors in acute care settings could address the gap between allograft supply and demand that has been estimated in previous reports.1,2

Deaths among patients admitted to hospitals account for approximately half of all deaths in Canada. CCDT's *Tissue Donation Potential Beyond Acute Care* report examined potential tissue donors who could be identified outside the hospital environment, including those who could be identified by ME/Cs. Unexpected deaths by

accident or natural causes were assessed using ME/C databases in four provinces. Applying inclusion criteria to ME/C data using CSA guidelines for tissue donation revealed that 43 per cent of those people who died accidentally (mostly in motor vehicle accidents) and 44 per cent of those who died naturally (mostly at home) met eligibility criteria for tissue donation.³ The data in the report was not extrapolated to a national estimate of potential tissue donors. The report also summarized information from an environmental scan of four professional groups that can be involved in the identification and referral of tissue donors; specifically, paramedics, emergency department staff, ME/Cs and funeral home directors.

There is a significant opportunity to increase the number of potential tissue donors identified in both hospital and non-hospital settings. Unlike barriers that exist for vital organs, tissue donation appears not to be curtailed by problems with lack of available donors, but rather with system and process issues and a lack of infrastructure that, when combined, fail to optimize the existing donor pool. The remainder of this report examines the various process and infrastructure options that could serve to increase tissue donation. These options will be specifically assessed under the following headings: donor identification and referral, consent and recovery of tissue.

¹ Canadian Institute for Health Information (Jan 2004). Estimating Potential Tissue Donors in Canada from 1995-2000: An Exploratory Analysis Based on Acute Care Hospital Admission Data. Prepared for the CCDT.

 $^{^{\}rm 2}$ Canadian Institute for Health Information (May 2003). Demand for Human Allograft. Prepared for the CCDT.

³ Canadian Institute for Health Information (2004). Tissue Donation Potential Beyond Acute Care. Prepared for the CCDT.

4. Donor Identification and Referral

A. Routine-referral Legislation

In routine referral, all deaths (typically hospital deaths) must be referred to an OPO, regardless of the age of the patient, the cause of death, whether the patient was registered as a donor, or whether the family is willing to consider donation.

Required-referral legislation exists in British Columbia, Ontario, Alberta, Manitoba and New Brunswick. In some legislation, mandatory consideration for donation is required, but it is left up to the discretion of the medical practitioner to determine if the person's tissue or organs may be suitable for transplantation. Similarly, in other provinces without legislation, referral is at the discretion of the attending physician or healthcare providers. In regions where the capacity for tissue recovery does not exist, potential tissue donors are not referred. For example, in British Columbia, potential musculoskeletal, cardiovascular and skin

donors are not referred, as there is no recovery infrastructure.

It is important to note that legislation does not necessarily change either public attitudes or the level of staff support for organ and tissue donation within hospitals. A recent Canadian ocular study noted that the initial effectiveness of Routine Notification and Request (RNR) was not sustained over a three-year period. For example, initial increases in cornea availability, and decreased wait times for corneal transplantation, were not uniformly sustained in the provinces with RNR.⁴ It is clear that any legislation needs to be paired with the appropriate processes and structures within a hospital environment to realize donor potential.

Strengths and weaknesses of routine referral legislation

Strengths	Weaknesses
 Can provide every donor family the opportunity to donate. Can eliminate the need for hospital staff to determine donor suitability. Standardizes the donor referral system and provides the opportunity to integrate tissue donation processes with organ donation. 	 Adds extensive costs to the organ and tissue donation process; for example, through the need for communication centres, and training and education of hospital staff. Can frustrate hospital staff that is required to report all deaths including those with no potential for donation. Increases workload for hospital staff that are required to provide medical information on a large number of potential donors. Enacting new legislation would take time. Limited effectiveness if tissue referral, recovery and production processes are not improved concurrently.

⁴ Lee, K. (2009). Sustainability of Routine Notification and Request on Eye Bank tissue supply and corneal transplantation wait times in Canada. Abstract for World Congress of the Cornea.

B. Identification and referral responsibilities in hospital environments

The vast majority of tissue donors in Canada are identified in the hospitals. The majority of OPOs and tissue programs rely on frontline healthcare providers to identify and refer potential tissue donors. Healthprofessional awareness and education programs vary from province to province. In some regions, education about organ and tissue donation is developed and deployed by OPOs; in other regions, tissue banks are directly involved in the education of healthcare providers. Healthcare professionals are often less informed about tissue donation than organ donation.⁵

Option 1: Frontline healthcare providers identify and refer potential tissue donors in the hospital setting.

Strengths	Weaknesses
 Hospitals can establish a consistent process for organs and tissues. Active involvement of frontline care providers in identifying and referring tissue donors can have a synergistic effect on increasing organ donation.⁶ 	 Costs and resources required to provide health professional education regarding referral and identification and the tissue donation process. Adds additional responsibilities to frontline healthcare providers.

Option 2: Departments or functions that record deaths within hospital (e.g., medical information, admitting, death registration) notify the OPO or tissue bank. Tissue bank or OPO coordinators follow-up with healthcare providers within the hospital to obtain information on potential donors.

Strengths	Weaknesses
 Minimizes the inconsistency associated with frontline healthcare providers identifying potential donors. Minimizes the resources required by frontline care providers in the donation process, since detailed medical information is required only for donors that are identified by the OPO or tissue bank as suitable for follow-up. 	 A separate process is established for identifying tissue donors, yet front line healthcare providers are still required to identify organ donors. The structure and responsibilities of departments or functions that record deaths vary from hospital to hospital.

One health region that has successfully implemented this approach in alignment with referral legislation noted that 90 per cent of all deaths were reported to the tissue bank and 80 per cent of these within the first hour of death.7

⁵ Rodriguez-Villar, C. et al. (2009). Attitude of health professionals toward cadaveric tissue donation. *Transplantation Proceedings*, 41: 2064-2066.

⁶ Anderson, M. (2008). The History of MTF. Edison, NJ: 2008.

Snow, C. (2009-06-29). Personal communication.

C. Identification and referral of potential tissue donors in ME/Cs offices

Outside the hospital environment, ME/Cs offices are the next highest potential source of multi-tissue donors in Canada. There is, however, variability in the level of support from ME/Cs from jurisdiction to jurisdiction. Some tissue programs do not receive referrals from local ME/Cs, but one tissue bank indicated that 13 per cent of its deceased donors were referred from ME/Cs.

Strengths	Weaknesses
 Greatest potential to influence rates of tissue donation from outside the hospital setting. Data collected in 2007 indicates that in the US, 14.8 per cent of all tissue recoveries from deceased donors were performed in medical examiners' facilities.⁸ ME/Cs cases constitute the single greatest source for healthy tissue donation.⁹ 	 By focusing resources on defining ME/C referral processes, there may be little or no focus on other potential sources of tissue donors, such as funeral homes and long-term care facilities. There are some cases where tissue donation is not possible because of the legal and medical mandate to determine cause and manner of death

Questions for Consideration (referral and identification)

- Should routine referral legislation be implemented in all provinces?
- Who should be responsible for identifying and referring potential donors to OPO or tissue programs in hospitals? Should the responsibility lie with frontline healthcare providers or departments within the hospital responsible for recording deaths?
- To increase tissue donation from donors outside the hospital environments, should efforts be initially focused on ME/C's offices?

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⁸ Rigney, Robert (2009). Report on the 2007 Annual Survey, American Association of Tissue Banks 13th Annual Spring Meeting.

⁹ Health Resources and Services Administration (2003). http://optn.transplant.hrsa.gov/SharedContentDocuments/03printedMECbooklet(1).pdf (Accessed 2009-12-01)

5. Consent

In some regions, OPOs are involved in obtaining consent for both organ and tissue donations. In other jurisdictions, OPOs and tissue banks function separately, and tissue bank staff are involved with obtaining consent from donor families.

Option 1: Frontline healthcare providers in the hospital setting or professionals outside the hospital setting (e.g., paramedics, medical examiners and funeral directors) establish contact with and obtain consent from the families of potential donors.

Strengths	Weaknesses
 Healthcare providers in an in-patient hospital setting may have developed a positive relationship with the patient and the family. Additional staffing within a hospital may not be necessary, depending on volume. 	 Approaching families to discuss donation is not an activity that healthcare providers or other professional groups routinely perform. Lack of experience in providing information on tissue donation and obtaining consent results in a lower consent rate.¹⁰ Training staff to perform activities that occur infrequently is unlikely to improve performance. There would be significant costs associated with educating all frontline healthcare providers or other professional groups on how to appropriately discuss donation options with families. Personal opinions about donation may influence healthcare providers' discussions with families. Donor families may perceive a conflict of interest when those who are providing healthcare also advocate for tissue donation.

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 $^{^{10}}$ Wiley-Blackwell (2009) Tissue and Cell Donation, An Essential Guide. pp.19.

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Option 2: Dedicated or trained coordinators or requestors establish contact with the families of potential donors and obtain consent. Coordinators may work for an OPO or a tissue bank, or may be hospital staff designated specifically to coordinate donation activities. Healthcare professionals who have developed a positive relationship with the patient and family can join the family during the conversation with the trained coordinator and requestor (either face-to-face or by phone).

Strengths	Weaknesses
 Research indicates that experience and the comfort level of the requester impacts both the families' experience and their decision to donate tissue.¹¹ Removes any perception by donor families that there is a conflict of interest in which those who are providing healthcare are also advocating for tissue donation. Aligns well with telephone-based consent processes. 	There are costs associated with ensuring dedicated coordinators and requestors have a specialized skill set.

¹¹ Geissler, A (2005) Cornea Donation: Evaluation of a Training Session to Obtain Consent by Telephone, 37: 4634-4636.

A. Additional Considerations

Obtaining consent by telephone

Many tissue programs and OPOs have established call-based consent processes as an alternative to face-to-face conversations with potential donors' families. Discussing donation options and obtaining consent over the telephone is particularly useful when potential tissue donors are identified outside the hospital environment. Literature has shown that requestors are able to communicate with sensitivity and understanding in the absence of a face-to-face interaction, and that telephone consent rates are comparable to face-to-face approaches. ^{12,13} One challenge with obtaining consent by telephone is that it is sometimes difficult to establish contact with a family after they have left the hospital.

Donor registries

Some OPOs have access to intent-to-donate registries to reference the donor's wishes during the donation conversation with the family. It has been shown in the literature that next of kin (NOK) are more likely to provide consent if they are aware of the donor's intent.¹⁴

Questions for Consideration (consent)

Are dedicated coordinators and requestors or frontline healthcare providers best suited to discuss options with and obtain consent from families?

¹² Rodriguez-Villar, C. et al. (2007) Telephone Consent in Tissue Donation: Effectiveness and Efficiency in Post-mortem Tissue Generation. *Transplantation Proceedings*, 39: 2072-2075.

¹³ Rodrigue, J.R. et al. (2003). The tissue donation experience: a comparison of donor and nondonor families. *Prog Transplant*, Dec13 (4): 258-64

¹⁴ Lawlor, M (2006) Consent for Corneal Donation: The effect of age of the deceased, registered intent and which family member is asked about donation. Br J Ophthalmology, 90: 1383-1385.

6. Tissue Recovery

The limited availability of tissue recovery teams is an issue that must be resolved in each province. Canada's population is widely dispersed, and most provinces do not have programs to deal with donation outside of larger centres. In Ontario, tissue recoveries generally occur only in the greater Toronto area, and are most often performed by physicians. Nova Scotia and New Brunswick are the only provinces that provide complete coverage in terms of recovery capabilities. Of all provinces, Nova Scotia has the highest number of musculoskeletal, cardiovascular and skin donors per million population. In some areas, recovery teams will travel to other provinces and regions to recover tissue. The comprehensive tissue banks within Canada use teams of tissue bank specialists

Option 1: Physician recoveries

Currently, physicians who perform recoveries are often associated with a specific tissue program's area of focus; for example, recovery of bone and soft tissue is performed by orthopaedic surgeons for musculoskeletal tissue banks. Physicians can bill provincially for recovery work resulting in lower recovery costs for tissue programs.

Strengths	Weaknesses
No technical training required for staff.	 Challenges with training and retaining individuals who are often not staff physicians (e.g., residents). Tissue recovery is not a primary responsibility for physicians, which affects their availability for recovery. Individuals who recover tissue may have a specific tissue focus depending on their area of specialty; multi-tissue recovery opportunities may be missed. Higher labour cost for recovery activities.

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¹⁵ Canadian Blood Services (2009). Preliminary Data Analysis - National Survey for Supply of Allograft Tissue. Prepared for the CCDT.

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Option 2: Tissue specialist teams

Recoveries are performed by tissue specialists employed by the OPO or tissue bank

Strengths	Weaknesses
 Staff are dedicated to recovery activities and are more readily available when required. Staff are accountable to the OPO or tissue bank. Training and performance. measurement can be more easily carried out. Tissue specialists can be cross-trained to participate in the entire tissue banking process. 	No identified labour pool of tissue specialists. There are no education and certification programs currently available within Canada.

A. Additional Considerations

Multi-tissue recoveries

Most large tissue programs optimize tissue donation by recovering multiple tissues from each donor. In 2008, 83 per cent of all musculoskeletal recoveries and 100 per cent of skin recoveries from deceased donors were performed by teams of tissue bank specialists that had the capability to recover multiple tissue types.

Ocular tissue recoveries

The characteristics of the ocular recovery process has led to a wider use of individual physicians—including general practitioners or residents—or other health professionals in this process. Eye banks often have a more distributed recovery network that extends into smaller healthcare communities and facilities. In Ontario, there are more than 200 physicians and nurses who recover ocular tissue. Some jurisdictions provide for physician billing for recovery activities. New Brunswick has the highest number of ocular donors per million population due to an effective recovery network.

Questions for Consideration (recovery)

- Should tissue recovery activities primarily be performed by teams of tissue specialists?
- Should the number of tissue allografts recovered from each donor be optimized (e.g., musculoskeletal, cardiovascular skin)?
- Should existing eye-bank recovery networks be maintained or expanded?