

Canadian Blood
Services

TISSUE EXPERT COMMITTEE: HOW CAN TISSUE DONATION BE INCREASED IN CANADA? (DRAFT SOLUTION DESIGN PAPER)

1. Scope

This paper presents options available within the tissue system to improve tissue donation by assessing options at each stage of the process including donor identification and referral, obtaining consent and tissue recovery. Activities and programs that support the tissue donation but are not part of the core process will not be assessed (e.g. intent to donate registries or public awareness campaigns). Living donors are not included in the scope of this report.

2. Donor Potential

Identification of potential tissue donors and timely referral to tissue banks or Organ Procurement Organizations (OPOs) are critical to increasing the Canadian supply of tissue for processing. Unlike organ donors who are generally identified in emergency departments or intensive care units, tissue donors may be referred from hospitals, medical examiners/coroners (ME/C) or 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 who were identified as medically eligible to donate tissues based on their admitting diagnoses for the hospitalization during which they died were considered potential tissue donors. 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 the acute care setting could serve to meet the gap between allograft supply and demand that has been estimated in the 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 that could be identified outside the hospital environment. The report included a study of potential donors that could be identified by ME/Cs. Unexpected deaths from accidental 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% of accidental deaths (mostly motor vehicle accidents) and 44% of natural deaths (mostly occurring 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

¹ Estimating Potential Tissue Donors in Canada from 1995-2000: An Exploratory Analysis Based on Acute Care Hospital Admission Data, January 2004, Prepared by CIHI for the CCDT.

² Allograft Demand Report 2003.

³ Tissue Donation Potential Beyond Acute Care, Prepared by CIHI for CCDT, 2004.

and referral of tissue donors: paramedics, emergency department staff, coroners/medical examiners, 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 with system/process issues and a lack of infrastructure that fail to achieve a greater benefit from the existing donor pool. The remainder of this report will examine 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.

3. Donor Identification and Referral

3.1 Routine Referral Legislation

In routine referral, all deaths (typically hospital deaths) are required to 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.

Legislation exists governing the required referral of donors 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 health care 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 attitudes and the level of staff support for organ and tissue donation within the hospital environment. A recent Canadian ocular study noted that the initial effectiveness of Routine Notification and Request (RNR) was not sustained over a three year period. Initial increases in cornea availability and decreased wait times for corneal transplantation were not uniformly sustained in the provinces with RNR⁴. It is clear that any legislation needs to be paired with the appropriate processes and structures within a hospital environment to realize donor potential.

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

Strengths and Weaknesses of Routine Referral Legislation

Strengths	Weaknesses
<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Adds extensive costs to the organ and tissue donation process (e.g. communication centres, training and education of hospital staff) • Can frustrate hospital staff that are required to report all deaths including those with no potential for donation. • Increases workload for hospital staff who are required to provide medical information on a large number of potential donors • Long time frames are required when changing legislation • Limited effectiveness if tissue referral and recovery/production processes are not improved concurrently.

3.2 Identification and Referral Responsibilities in the Hospital Environment

The vast majority of tissue donors in Canada are identified within the hospital environment. The majority of OPOs and tissue programs rely on front line health care providers to identify and refer potential tissue donors. Health professional awareness and education programs vary from province to province. In some regions, education about organ and tissue donation is developed and deployed by the OPOs, while in other regions, tissue banks are directly involved with the education of health care providers. Health care professionals are often less informed about tissue donation than organ donation⁵.

Option 1 - Front line health care providers identify and refer potential tissue donors in the hospital setting.

Strengths	Weaknesses
<ul style="list-style-type: none"> • Hospitals can establish a consistent process for organs and tissues • When front line care providers are actively involved with identifying and referring tissue donors it can have a synergistic effect of increasing organ donation⁶ 	<ul style="list-style-type: none"> • Cost and resources required to provide health professional education regarding referral and identification and the tissue donation process. • Adds additional responsibilities to identify and refer donors to front line health care providers.

⁵ Rodriguez-Villar C. et al. Attitude of Health Professionals Toward Cadaveric Tissue Donation. Transplantation Proceedings, 41, 2064-2066 (2009).

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

Option 2 – Departments or functions within hospitals that record deaths within the facility (e.g. Medical Information, Admitting, Death Registration) notify the OPO or the tissue bank. Coordinators from the tissue bank or OPO follow-up with health care providers within the hospital to obtain information on potential donors.

Strengths	Weaknesses
<ul style="list-style-type: none"> Minimizes the inconsistency associated with front line health care providers identifying potential donors. Minimizes the resources required by front line care providers in the donation process; detailed medical information is only required for donors that are identified by the OPO / tissue bank as suitable for follow-up. 	<ul style="list-style-type: none"> A separate process is established for identifying tissue donors; front line health care 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 implemented this approach successfully in alignment with referral legislation, noted that 90% of all deaths are reported to the tissue bank and 80% of these within the first hour of death⁷.

⁷ Personal communication from Chris Snow, 2009-06-29

3.3 Identification and Referral of Potential Tissue Donors in Medical Examiners and Coroners (ME/C) Offices.

Outside the hospital environment, medical examiners and coroners (ME/Cs) offices are the next highest source of multi-tissue donors in Canada. However, there is variability in the level of support from ME/Cs from jurisdiction to jurisdiction. Some tissue programs do not receive referrals from local ME/Cs while one tissue bank indicated that 13% of their deceased donors were referred from ME/Cs.

Strengths	Weaknesses
<ul style="list-style-type: none"> • Greatest potential to influence rates of tissue donation from outside the hospital setting. Data collected in 2007 indicates that in the US, 14.8% of all tissue recoveries from deceased donors were performed in medical examiners' facilities⁸. • ME/Cs cases constitute the single greatest source for healthy tissue donation⁹. 	<ul style="list-style-type: none"> • By focusing resources on defining referral processes with ME/Cs 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 in the hospital setting to the OPO or tissue program? Front line health care providers or departments/functions within the hospital responsible for recording deaths?
- In order to increase tissue donation from donors outside the hospital environment should efforts be initially focused on ME/C offices?

⁸ Robert Rigney. Report on the 2007 Annual Survey, American Association of Tissue Banks 13th Annual Spring Meeting, March 29, 2009.

⁹ Health Resources and Services Administration (HRSA) 2003.

[http://optn.transplant.hrsa.gov/SharedContentDocuments/03printedMECbooklet\(1\).pdf](http://optn.transplant.hrsa.gov/SharedContentDocuments/03printedMECbooklet(1).pdf) Accessed 2009-12-01

4. Consent

In some regions the OPO is involved with 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 - Front line health care providers in the hospital setting or professionals outside the hospital setting establish contact with the families of potential donors and obtain consent (e.g. paramedics, medical examiners or funeral directors)

Strengths	Weaknesses
<ul style="list-style-type: none"> • Health care 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. 	<ul style="list-style-type: none"> • Approaching families to discuss donation is not an activity that health care providers or other professional groups are routinely performing. Lack of experience in providing information on tissue donation and obtaining consent results in a lower consent rate¹⁰. • Training staff to perform activities that are infrequently performed is unlikely to improve performance. • There would be significant costs associated with educating all front line health care providers or other professional groups on how to appropriately discuss donation options with families. • Personal opinions about donation may influence health care providers' discussions with families. • Donor families may perceive a conflict of interest when those who are providing health care also advocate for tissue donation.

¹⁰ Tissue and Cell Donation, An Essential Guide pg 19 – Wiley-Blackwell 2009

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. Health care 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 on the phone)

Strengths	Weaknesses
<ul style="list-style-type: none"> • Research indicates that experience and the comfort level of the requester impacts both the families' experience and their choice to donate tissue.¹¹ • Removes any perception by donor families that there is a conflict of interest with those who are providing health care also advocating for tissue donation. • Aligns well with telephone based consent processes. 	<ul style="list-style-type: none"> • There are costs associated with having dedicated coordinators and requestors with a specialized skill set.

Additional Considerations:

A. Obtaining Consent by Telephone

Many tissue programs and OPOs have established call-based consent processes as an alternative to face-to-face conversations with the potential donor's family. 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 consent rates are comparable to face-to-face approaches telephone^{12,13}. One challenge with obtaining consent by telephone is that it is sometimes difficult to establish contact with the family after they have left the hospital.

B. Donor Registries

Some OPOs have access to "intent to donate" registries to be able relay the donor's wishes during the donation conversation with the family. It has been shown in the literature that the Next of Kin (NOK) are more likely to provide consent if they are aware

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

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

¹³ Rodrigue JR et al. The tissue donation experience: a comparison of donor and nondonor families. Prog Transplant. 2003 Dec 13(4):258-64

of the donor's intent¹⁴. If designated coordinators and requestors have access to donor registries it can inform the discussion with the donor's family and ease the difficult decision making process for the family.

Questions for Consideration - Consent:

Are dedicated coordinators/requestors or front line health care providers best suited to discuss options with families and obtain consent?

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

5. Tissue Recovery

The lack of availability of tissue recovery teams is an issue that requires resolution in each province. Canada's population is widely dispersed and most provinces do not have programs to deal with donation outside of the larger centres. In Ontario, tissue recoveries generally only occur 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 population¹⁵. In some areas, recovery teams will travel to other provinces/regions to recover tissue. The comprehensive tissue banks within Canada use teams of tissue bank specialists.

Option 1 – Physician Recoveries

Currently, physicians performing recoveries are often associated with a specific tissue program's area of focus e.g. 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
<ul style="list-style-type: none"> No technical training required for staff. 	<ul style="list-style-type: none"> Challenges with training and retaining individuals who are often not staff physicians (e.g. residents). Tissue recovery is not a primary responsibility for physicians, impacting their availability for recovery. Individuals recovering tissue may have a specific tissue focus depending on their area of specialty, and multi-tissue recovery opportunities may be missed. Higher labour cost for recovery activities

¹⁵ Preliminary Data Analysis – National Survey for Supply of Allograft Tissue 2009.

Option 2 - Tissue Specialist Teams

Tissue specialists employed by the OPO or tissue bank perform recoveries.

Strengths	Weaknesses
<ul style="list-style-type: none">• 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.	<ul style="list-style-type: none">• No identified labour pool of tissue specialists. There are no education and certification programs currently available within Canada.

Additional Considerations:

A. Multi-Tissue Recoveries

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

B. Ocular Tissue Recoveries

The characteristics of the ocular recovery process has resulted in a wider use of individual physicians (General Practitioners or residents) or other health professionals for ocular tissue recoveries. Eye banks often have a more distributed recovery network that reaches out into smaller health care facilities and communities. In Ontario there are over 200 physicians and nurses that recover ocular tissue. In some jurisdictions there is provision for physician billing for recovery activities. New Brunswick has the highest number of ocular donors per million population due to an effective recovery network¹².

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 the existing eye bank recovery networks be maintained or expanded?