Reference Manual

ADVANCING ORGAN AND TISSUE DONATION

A COLLABORATION OF THE CANADIAN CONFERENCE OF CHIEF CORONERS AND CHIEF MEDICAL EXAMINERS, THE CANADIAN TISSUE COMMUNITY AND CANADIAN BLOOD SERVICES

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Canadian Blood Services
Société canadienne du sang

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Contents

Introduction

At the 2010 Canadian Conference of Chief Coroners and Chief Medical Examiners meeting, members unanimously endorsed their commitment to, and support of, organ and tissue donation. This reference manual was developed by Canadian Blood Services in response to this support and in collaboration with the Canadian Conference of Chief Coroners and Chief Medical Examiners. Content was validated and informed by the Canadian tissue community at the 2012 Eye and Tissue Banking in Canada: Leading Practice Workshop.

The manual is focused on improving the donation rates in Canada in order to reduce the unmet need for tissue and organ transplants. To achieve this purpose, we emphasize partnerships between the tissue and organ donation community and the provincial and territorial medicolegal death investigation community.

The manual has been developed to support medical examiners, coroners, pathologists, death investigators, funeral professionals, first responders and eye and tissue banks to advance organ and tissue donation. The objectives of the manual are to:

a. Ensure that the quality of the medicolegal death investigation is maintained;
b. Improve communication between coroners and medical examiners and organ and tissue organizations;
c. Minimize restrictions to organ and tissue donation;
d. Increase awareness in the Chief Coroners (CC)/Chief Medical Examiners (CME) and the organ and tissue donation and transplantation (OTDT) communities; and
e. Advance the identification and referral of potential organ and tissue donors to donation organizations.

Given the significant operational variances in medicolegal death investigation between provinces and territories, this manual focuses primarily on policy and high level processes rather than operational procedures. From a strategic perspective, it is a societal responsibility to respect the donor and donor family's wishes in order to improve the lives of patients, while still meeting the requirements of medicolegal death investigation[iii]. The National Association of Medical Examiners (NAME) has provided a position paper indicating support for OTDT in all but a very limited number of cases investigated by the CC/CME system[iii] (see link below). This reference manual supports the NAME paper and its position.

http://thename.org/index.php?option=com_docman&task=doc_download&gid=89&Itemid=26

In June 2013 the Scientific Working Group for Medicolegal Death Investigation (SWGMDI) published “Standards for Interactions Between Medical Examiner/Coroner Offices and Organ and Tissue Procurement Organizations and Eye Banks”. The link to the SWGMDI website is:

http://swgmdi.org/images/organ1.standardsforme.c.opo.eyebankinteractions.published6-20-13.pdf

These standards provide yet another reference to work from in order to ensure the necessary balance between organ and tissue donation and appropriate medicolegal investigation of death.

Overview of Donation and Transplantation

Health Canada's Cells, Tissues, and Organ Regulations (CTO's) regulate tissue and organ donation and transplantation systems. Additional standards and accreditation requirements may also be incorporated as part of the quality and safety policies and procedures. As a result, OTDT programs have specific operational standards and documentation requirements and CC/CME programs must identify and understand these requirements before they can successfully proceed with a formal partnership with the OTDT community.

Similar to the CC/CME systems in Canada, the OTDT models in each province and territory are different. This document will not provide in depth details of these models. We recommend that members of the CC/CME community review existing documentation on the OTDT systems, available from the Canadian Blood Services (www.organsandtissues.ca). However, this document will provide a brief overview of the common processes associated with OTDT systems. The following diagrams illustrate the basic steps involved with donation:

Diagram 1: Tissue Banking

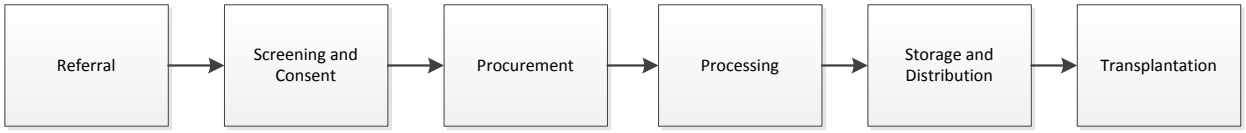
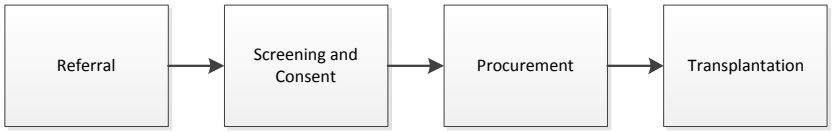


Diagram 2: Organ Donation and Transplantation



Referral

Similar to the requirements of the coroners/medical examiner systems, a fatality must be referred to the OTDT organization responsible for organ and tissue donation in order to initiate the process. The CC/CME systems play a significant role in ensuring that deaths are referred to tissue and organ donation programs. Any donation criteria used to screen a potential donor must be considered carefully in order to optimize donation and ensure an effective referral process.

Screening and Consent

The regulations and standards that govern the OTDT communities provide specific limitations to donation in order to optimize safety and reduce risk to recipients. These safety and quality considerations are the basis for the criteria and processes used to

screen potential donor suitability. Typically a risk questionnaire is used along with a review of the donor's medical history in order to rapidly screen the suitability of the donor. The OTDT organization may include additional limitations to donation that relate to the quality of the tissue or organ for transplantation. Additional tests including infectious disease testing will also be used should initial screening determine the donor suitable for donation.

The donor may have registered intent to donate on a provincial/territorial donation registry. The legal significance of the registry is different across the country. In all cases the donor family is contacted and consent for donation is requested from them. The donor's wish, if indicated in the registry, is often communicated to family with the hope that the family will support their loved one's wishes. Consent often allows for the families to make restrictions to the type of tissues and organs that can be recovered.

Consent is also required from the CC/CME organizations before donation can proceed. Due to the nature of medicolegal death investigation it is imperative that CC/CME organizations are familiar with the donation process. If the medical examiner or coroner cannot grant consent, it is no more than reasonable to suggest that this decision is based on a clearly-articulated set of principles.

Procurement (Recovery)

Tissue procurement (also referred to as recovery) must occur within very strict ischemic time limits. These time limits should be well understood by the CC/CME organizations. Recovery is completed typically in an operating suite or equivalent. The exception is cornea-only donors since there is not as stringent environmental controls required for cornea recovery. Tissues are typically recovered aseptically and packaged. The types of tissues that are recovered depend on the donor and the recovery programs ability and tissue demands and may include corneas, whole eyes, bones, tendons, soft tissue, heart and skin. In donors where both organs and tissues are being recovered, tissue recovery follows organ recovery. In rare cases the tissue recovery could take place after an autopsy. This requires very specific conditions and formal post recovery processing methods to eliminate cross contamination. It is recommended that tissue recovery occurs before the forensic autopsy.

Organ donation occurs in two distinct situations. First, NDD (neurological determination of death, commonly referred to as 'brain death', is defined according the minimum criteria for NDD established by the Canadian Council for Donation and Transplantation[iv]. Organ donation also occurs in DCD (donation after circulatory death) in patients who have no hope of recovery and do not progress to NDD. In these cases organs are recovered immediately following the declaration of circulatory death. A special team of transplant surgeons and their support team conduct organ recovery in an operating suite. The organs must be recovered rapidly and quickly transported to the recipient. Since

interprovincial sharing of organs is common, the recovery team could be from another province/territory.

Processing

Tissues are processed into allografts in order to improve the safety or effectiveness of the tissue for the purpose of transplantation. Some tissues are processed with minimal manipulation while others are modified significantly using advanced processing techniques and proprietary processes in a biological manufacturing environment.

Organs are not processed *ex situ* but the environmental conditions in which they are transported are controlled in order to minimize organ degradation and ensure optimal transplant conditions.

Storage and Distribution

Tissues can be stored for various timeframes, depending on the tissue type, the state in which the tissue is preserved, and the environment that the tissue is stored. Once the tissues have been approved for distribution by the Medical Director they are sent to various transplant centres.

Transplantation

Organs and tissue allografts are transplanted into the recipients. Tracking the organs and allografts from donor to recipient is important, since multiple organs and tissue allografts can be recovered from one donor, and then are transplanted into numerous recipients. Surveillance of the patients and the corresponding organs and tissue allografts reduces the risk of widespread adverse reactions.

Coroner Systems

In a majority of Canadian provinces and territories a coroner system is established. The main complexity to this system as it relates to organ and tissue donation is that it introduces another layer of independent decision-making in the donation process. In cases where an autopsy has been deemed necessary both the coroner and the pathologist must agree to allow the body to proceed with donation. As a result of this additional layer of decision-making there is a risk of deferral to donation for multiple potential reasons. What is important to recognize in these systems is that there are two communities that must be educated about donation and also understand the implications that donation has on the medicolegal process.

Medical Examiner Systems

Medical Examiner systems operate with the leadership of a forensic pathologist. In most medical examiner systems, the decision to complete an autopsy is made by the pathologist who is also the medical examiner; therefore only one individual is involved with the consent for donation from the Medical Examiner Service. This simplifies the process and the communications. The Medical Examiner/Forensic Pathologist provides continuity in decision-making for both the medicolegal investigation and for donation requirements. For example, if an investigation warrants additional examination of the heart then a Medical Examiner can make a decision to restrict the heart from donation. Alternatively, the ME can request that remnants of the heart be forwarded to pathology for examination post-valve recovery.

Potential Collaboration Models

There are a variety of system models that currently exist or could be developed in Canada related to the relationships and interactions among CC/CME, Tissue Banks, Eye Banks and Organ Donation/Transplantation Programs. It is important to appreciate that each model has unique and complex considerations that are not discussed in this document. This document highlights some of the potential models that could be considered.

The resources necessary to successfully realise organ and tissue donation are significant. However, there are a number of steps early in the donation process that overlap with activities completed by CC/CME organizations, for example, medical history investigation. As the role and responsibilities of the CC/CME systems in Canada vary, the level of participation and contribution to the donation process need to be detailed in a memorandum of understanding (MOU) that is specific to each province or territory.

Four models are proposed in this document; they by no means represent all potential models. The level of involvement and participation from the CC/CME organization for tissue and organ donation begins with a minimal level (Model A) of involvement and finishes with a significant level (Model D) of involvement in the donation process. In each model the donor referral is initiated by the CC/CME organization. While these organizations are not the only source of donor referrals, for the sake of clarity no other sources of referral are discussed in the four models.

An Alternative Referral Model: First Responders

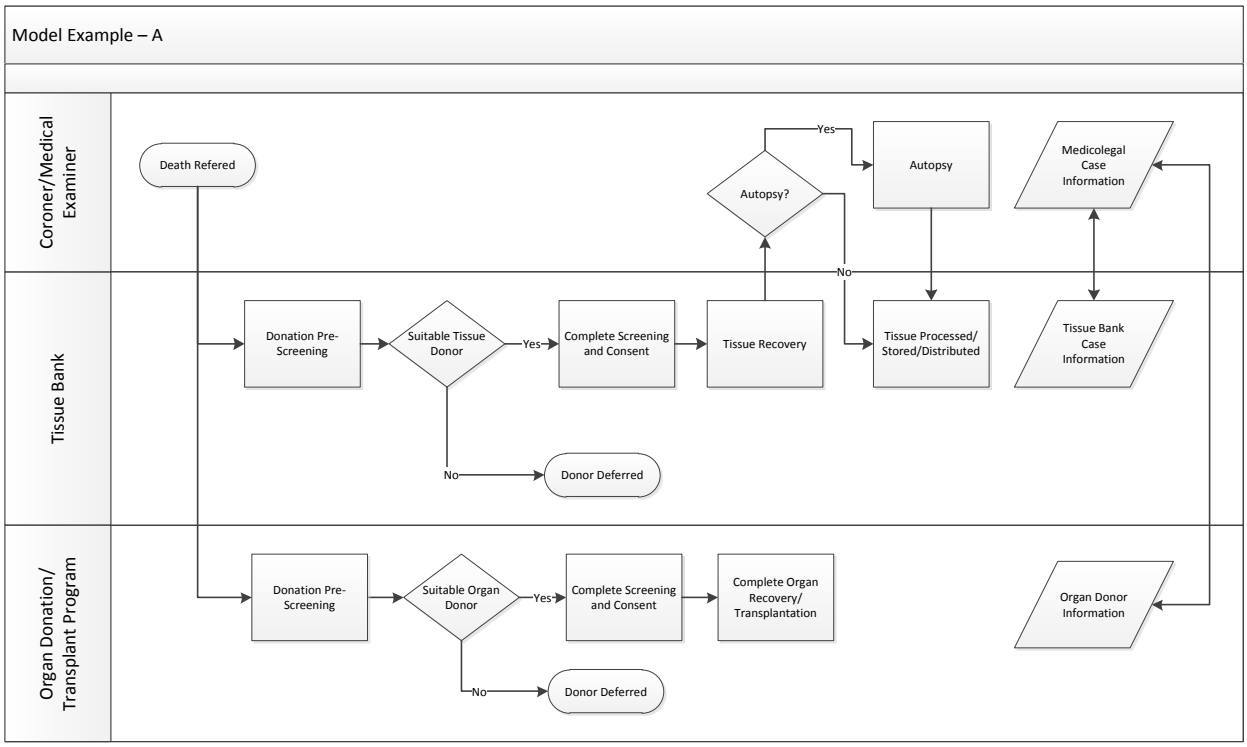
Referral to a tissue bank or organ donation program comes from a first responder (police, fire, or paramedic). If there is any perception of conflict by the C/ME then this example reduces that perception. It also allows for timely referral to the donation organization as the CC/CME may wait until "all" the information is present before referral. This example excludes the CC/CME from the donation process, and provides an alternative referral strategy for consideration.

Chief Coroner / Medical Examiner Referral Models

Model A: Identification to Referral

Highlights:

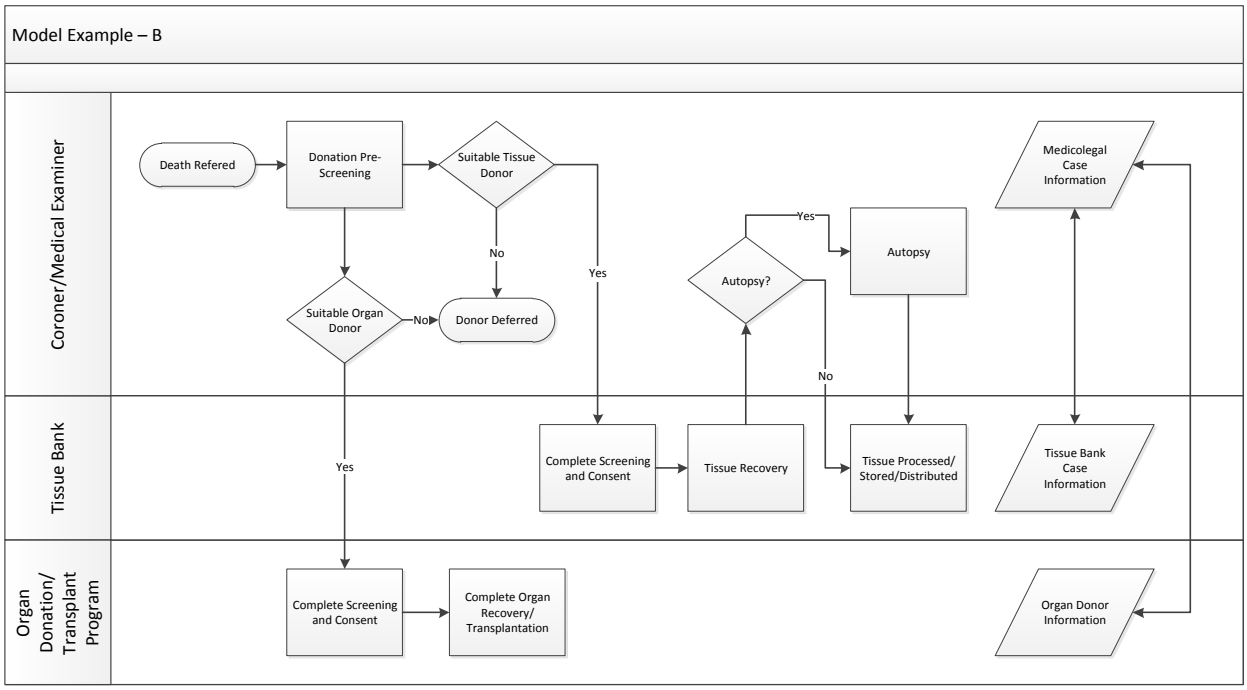
- CC/CME refers the donor with no or limited screening completed;
- The OTDT community is responsible all other activities related to donation and transplantation; and
- Autopsies are the responsibility of the CC/CME organization.



Model B: Identification, Preliminary Screening to Referral

Highlights:

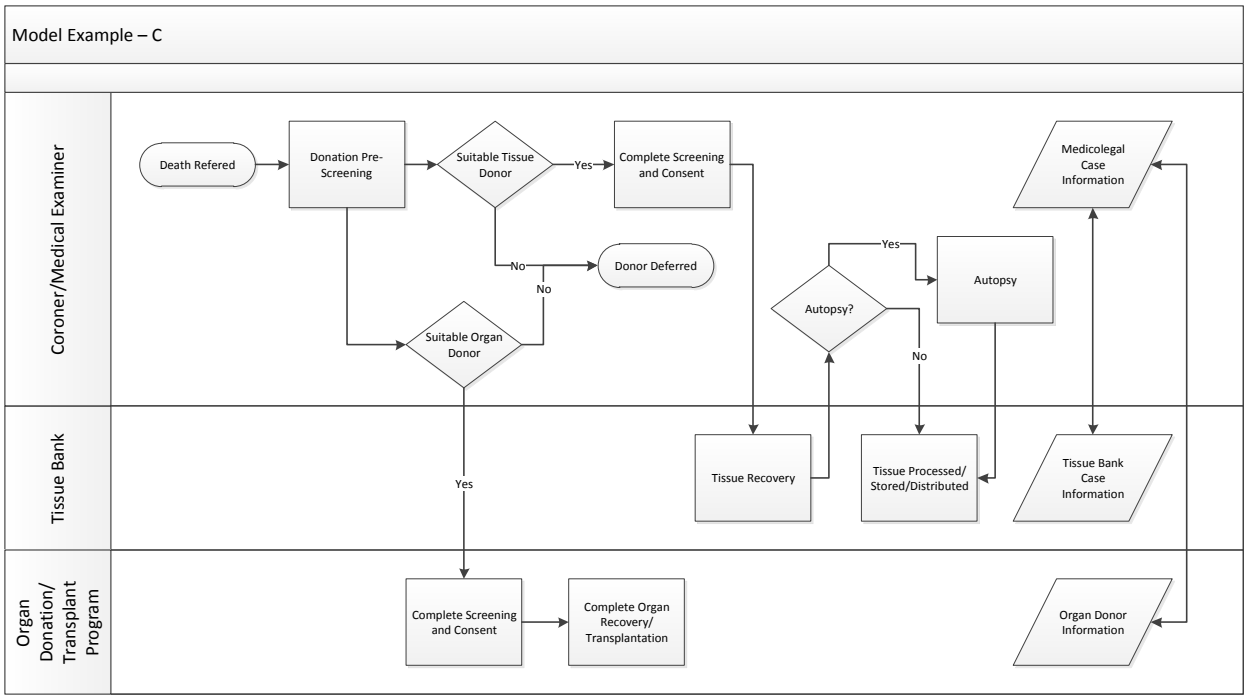
- CC/CME refers the donor with some screening completed;
- The OTDT community is responsible all other activities related to donation and transplantation; and
- Autopsies are the responsibility of the CC/CME organization.



Model C: Identification, Screening, Consent to Referral

Highlights:

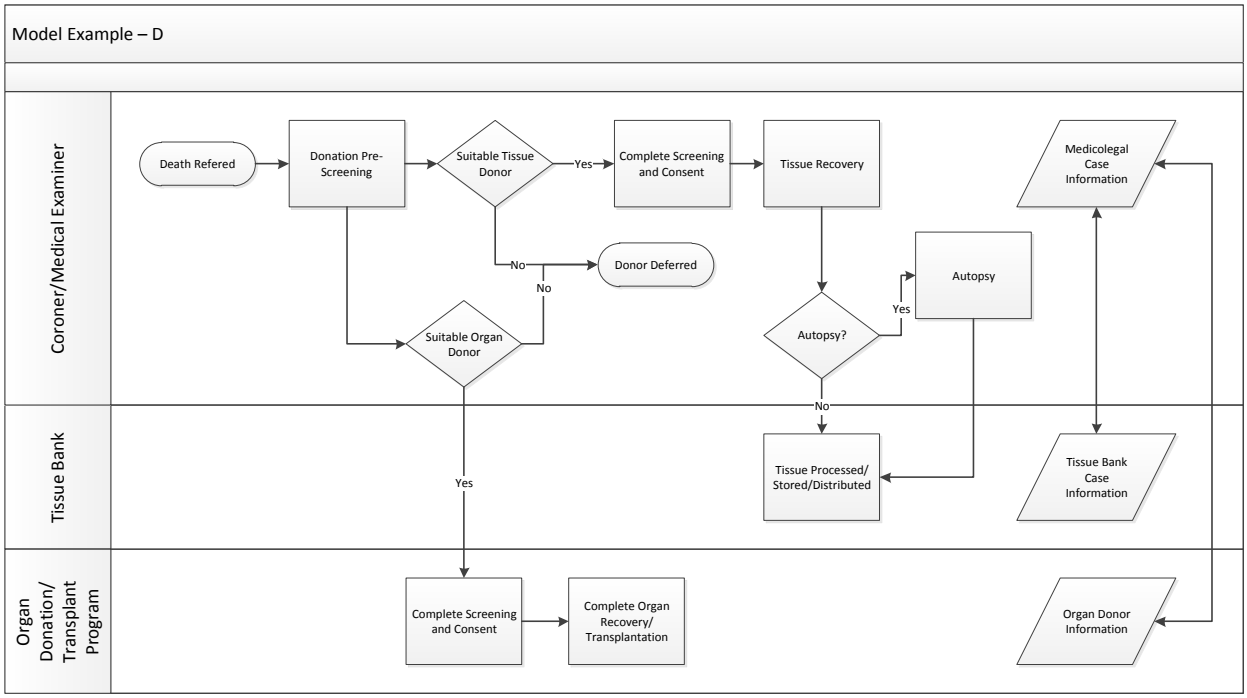
- CC/CME refers the donor with screening and consent completed;
- The OTDT community is responsible all other activities related to donation and transplantation; and
- Autopsies are the responsibility of the CC/CME organization.



Model D: Identification to Recovery

Highlights:

- CC/CME completes the screening, consent and tissue procurement;
- Tissue is processed by a third party tissue bank;
- The OTDT community is responsible all other activities related to donation and transplantation; and
- Autopsies are the responsibility of the CC/CME organization.



Structure and Foundation

In order for successful interaction to occur among the organizations that work in the fields of medicolegal death investigation and donation there must be a strong foundation upon which to base relationships. The recommended format for this foundation is the Memorandum of Understanding (MOU). This approach does not require legislative change, lends clarity to the division of responsibilities, and enables individualized solutions to be developed in response to local challenges.

Memorandum of Understanding (MOU)

The development of a MOU will provide all parties participating in the MOU with a clear understanding of their relationships with other party members and their roles and responsibilities as stated in the MOU, including details of specific operational processes. It is recommended that if operational details are not included in the MOU then standards of practice (SOP) are developed and implemented.

Communication practices must be detailed in the MOU or SOPs. Correspondence and information collected on the decedent by the stakeholders and then shared between stakeholders must be complete, clear, and concise. The risk of a poor communication practice is the loss of the donation opportunity, a compromised investigation, and the loss of public confidence.

Process flow mapping is an important exercise to complete as the MOU is developed. It requires that all stakeholders are identified, the relationships among stakeholders outlined, and activities mapped to a degree of detail that enables the identification of critical processes. For example, the consent process from the coroner or medical examiner needs to be described in detail to ensure this critical activity is captured and understood. Standards of practice can then be generated from the process flow maps, as required.

Key work processes must be developed and then described in the MOU to ensure a successful relationship. Critical areas include:

1. Donor pre-screening criteria;
2. Donor family approach and communication;
3. Consent, both from the family and the coroner/pathologist/ME;
4. Medical, sexual and social history;
5. Information sharing;
6. Body reconstruction and residual tissues;
7. Testing;
8. Complaint/problem resolution;
9. Resources/reimbursement;

10. Performance metrics; and
11. Liability.

Although there may be additional areas and processes that can be included in an MOU, the above are the recommended minimum. Depending on the model used in each province/territory an MOU may be required to include additional critical areas (e.g.: Model D – tissue recovery) or multiple MOUs or contracts (e.g.: Model D – tissue processors) may be required with a variety of OTDT organizations. These additional complexities are not covered in this guideline document.

Donor Pre-Screening Criteria

Pre-screening criteria should be provided to the CC/CME organization from the partnered OTDT organization. Pre-screening criteria are used to include and preclude potential donors based on high level screening demographics such as age, ischemic time (time since cessation of cardiac function), and suspected cause of death. The OTDT organization's medical director establishes the pre-screening criteria within the limitations of CTO regulations. It is critical that the timelines for tissue and organ recovery are understood and that all processes are aligned to expedite the earliest possible timeframe for tissue and organ recovery.

Pre-screening criteria can vary among OTDT organizations and can change with time, so it is important that a process is in place to communicate changes and up-dates. For example, each time a change is made to the criteria, the OTDT organization should provide these changes in writing to the CC/CME office along with a formal training session. It is important that the OTDT organization provides a detailed rationale and explanation for the pre-screening criteria to the CC/CME staff responsible for pre-screening. This interaction also provides an opportunity to discuss donation rates and opportunities for improvement.

The risk of miscommunication or the lack of pre-screening support and training in the CC/CME organization could lead to missed donor referrals. Donation is not included in the legislative mandate of CC/CME systems in Canada; therefore the priority for donation is left to internal policies and the chief coroner/medical examiner leadership. There are many competing priorities with medicolegal death investigation, so the more integrated the donation processes are with the CC/CME investigative methods, the more likely donation will be sustained in the CC/CME organization. If this cannot be achieved then it is recommended that all referrals to the CC/CME organization are directed to the OTDT organizations for pre-screening, and that the CC/CME organization plays no role in pre-screening.

Donor Family Approach and Communication

Both the CC/CME and OTDT organizations contact the families of a decedent in order to collect information for their respective purposes. Medicolegal death investigation is not something a decedent's family can elect to exclude their loved one from, whereas the donor family can exclude their loved one from donation. The approach and corresponding communication with families for donation requires skill, training, sensitivity, and processes that may not be present in the CC/CME organization. Provincial donation organizations as well as eye and tissue banks have trained staff in place to support and manage donation conversations with next of kin.

A number of jurisdictions maintain donation intent registries where individuals register their donation wishes. OTDT organizations access this information ensuring the donors intentions are presented to family members in the consent discussion.

Specific processes should be in place with the CC/CME organizations regarding approaching a donor family for donation. This includes the first mention of donation to the family. How and when to approach the family, and what specifically should be communicated to the family, should be determined by the partnered OTDT organizations. In some cases it may be undesirable to the OTDT community for the CC/CME organization to communicate anything to the family, but instead inform the OTDT organization who will then approach the family.

Leading practices for donor family approach and communication have been developed by a number of organizations in Canada and the United States. It is important to inquire whether the partnered OTDT organization has considered these practices and is applying them to all potential donor referrals made by the CC/CME organization.

All communications with the donor family should be documented accurately. Many details collected from donor families are important to both CC/CME and OTDT organizations and could be used by other organizations to provide a more complete data set of the decedent. It is helpful if each organization has some understanding of each other's methodology for collecting information from the family and the content of information collected.

Consent

Consent for donation given by a donor family should be gained by the organization gathering the donor history from the family. This provides continuity and reduces the burden to the family. The consent for donation must meet all of the regulatory requirements and must be accepted by the legal authority of the organization. In many

jurisdictions telephone consent is the most common approach to consent for donation. Organ donation programs tend to approach families in person as these deaths occur within hospitals with families present. However, it is important that the consent process is discussed and agreed upon by all OTDT and CC/CME organizations involved. Only one organization should be contacting/approaching a family for consent for donation.

Consent must also be obtained from the CC/CME organization before proceeding with donation. In cases where an autopsy is required the consent process must include both the coroner and pathologist. Any restrictions to tissue and organ recovery must be included in the consent process. The documentation of the consent must be clear and concise to ensure no miscommunication and error. There should be very few circumstances when the CC/CME organization cannot provide consent for donation. If consent cannot be provided then the rationale for restrictions to donation must be defensible and documented by both the OTDT and CC/CME organizations.

Donation metrics are important to the improvement of donation rates and associated systems in Canada. One of the initial requirements for donation metrics is documentation for not proceeding with donation and subsequent processes. It is imperative that the CC/CME and OTDT organizations document all deferred donors and the rationale for the deferral. Consent documentation should be kept as part of the case file records and retained for the same duration as the case file.

Medical, Sexual and Social History

Standards and regulations require that a detailed medical, sexual and social history be undertaken to identify and exclude donors at risk for transmissible diseases. OTDT programs have developed detailed questionnaires to standardize this process and ensure a comprehensive history. Interviews are performed by trained staff, in conjunction with, or following consent, with the individual most knowledgeable about a donor's history.

Information Sharing

OTDT and CC/CME organizations should have all information that is shared among them mapped and the details listed. It would be useful to develop standards of practice that detail the process for sharing information, including details that relate to the timing of all information. There are many details about decedents that are relevant to each organization but not necessarily collected by each organization and these should be shared. For example, transmissible disease testing performed by the OTDT organization is not likely performed by the CC/CME organization, but would be useful data to share. Another example is sharing the cause and manner of death with tissue banks in a timely

manner in order to ensure that time sensitive tissues (such as corneas and fresh allografts) can be transplanted.

When an autopsy is required, it is critical that an external exam of the body is conducted in a manner that carefully documents all findings relevant to the medicolegal death investigation that may be lost during the tissue and organ recovery process. Full body "as is" photographs must be requested of the OTDT community. In criminal cases, consideration must be given to pre-donation photography, with special attention to areas of injury. Detailed standards of practice should be developed by OTDT organizations and reviewed by CC/CME partners to ensure that sufficient documentation and processes are in place to satisfy the requirements of the medicolegal death investigation of the body.

It is also recommended that key members from the CC/CME organization, who are responsible for consenting to donation, have a formal understanding of the organ and tissue recovery process. This could be accomplished a number of ways: attending an organ/tissue recovery, attending a presentation on organ/tissue recovery by members of the OTDT community, and independent research and self-study. Increased understanding of tissue and organ recovery will assist in assuring CC/CME organizations that tissue and organ recovery does not diminish the quality or accuracy of the medicolegal death investigation.

The CC/CME organization provides documentation to the OTDT organization that is time sensitive for the release of tissues. For example, cornea tissue has a short expiration window before it is no longer suitable for transplant and any delay to the tissue bank receiving the final cause of death documentation from the CC/CME can jeopardize the chance of a successful transplant. Where possible the timelines for document sharing should be established in the MOU and communicated to all stakeholders. Failure to address this matter could lead to tissue not being transplanted before it exceeds its date of expiry, after which it would be discarded.

Body Reconstruction and Residual Tissues

The tissue recovery occurs in a clean room environment, such as an operating suite, with the exception of cornea only donors. These are tissue donors who are only suitable for cornea donation and no other tissues. In these cases the tissue recovery could occur in an environment such as, a hospital room or the morgue. It is important to consider the limitations on the physical space needed for tissue recovery so that access to the body for autopsy and related logistical issues are taken into account when developing process flow diagrams.

Organ and tissue recovery should occur before an autopsy. Therefore detailed expectations of body reconstruction (e.g.: prosthetics, closure of surgical incision sites, etc.) must be provided in the MOU or in corresponding standards of practice.

Retained tissues and organs are potentially important to CC/CME organizations. Formal communication strategies from OTDT organizations to a CC/CME organization must be established in the MOU. Clinical findings during the subsequent processing or post-transplant outcomes could be vital to the medicolegal death investigation. An additional consideration is the communication to the decedent's next of kin, or whoever has the legal responsibility for the body. If the retained organs and tissues are to be returned to the family then this must be clearly understood and communicated to ensure appropriate final disposition.

Testing

Samples may need to be taken at the time of tissue and/or organ recovery. Collection of samples for medicolegal death investigation (toxicology analysis) may be deferred to the procurement organization. Ensure that the labeling and collection protocols are well understood by the OTDT organization. There are multiple tests that are performed on a tissue/organ donor. Transmissible disease testing, HLA, and microbiology are examples of common tests but there are many more that can be ordered or used as standard screening and matching tests. It is important that OTDT organizations share relevant results with CC/CME partners where indicated or requested. Which details are specifically relevant to any particular CC/CME organization need to be established in the MOU or corresponding standards of practice.

CC/CME organizations should also share toxicology and histology results with their OTDT partners. While these test results are often not relevant to decision-making for organ transplantation (since the timelines of these tests would not satisfy the needs of an organ transplant team), nevertheless they can be relevant to the treatment strategy of the recipient and therefore should be shared. Specific arrangements for sharing the results must be outlined in the MOU. Tissue banking timelines may allow for the inclusion of these results into the data set which the Medical Director(s) use to determine the safety of the allografts for transplant. Similar to organs, the sharing of results must be outlined in the MOU.

Complaint/Problem Resolution

In the event that there is a complaint involving the CC/CME organization from any shared stakeholder group, such as the decedent's family, the resolution mechanism should be described in the MOU. There is a risk of not carefully outlining the

communication plan for such an event. The likelihood of a complaint that impacts on both organizations may be small but the impact could significantly affect the reputation of the organizations and negatively impact on donation.

In the event that a problem arises between an OTDT organization and a CC/CME organization then a reasonable resolution strategy should be described in the MOU. It is important to consider third party mediators in the evaluation of potential strategies so that a rapid resolution can be achieved and not have a prolonged negative impact on donation. It is important to recognize that in most provinces and territories donation programs are funded and operated by public service organizations, and in all provinces and territories the CC/CME systems are public services, so the idea of two publicly funded systems not being able to resolve a dispute between them and potentially jeopardizing donation is unacceptable.

Resources/Reimbursement

Tissue banking functions within a range of reimbursement models. Within the United States all eye and tissue banks operate in a competitive and commercial business model where banks are compensated for the allografts they provide. Canadian hospitals and dentists continue to import allografts from the United States due to lack of Canadian supply.

Within the Canadian system a number of models are currently employed depending on the tissue type and jurisdiction involved. These models vary from “funded” models where provinces or hospitals fund banks to distribute allografts within their region at no direct cost to hospitals to “competitive commercial” models where Canadian banks compete with US banks for Canadian market share.

Depending on the involvement and responsibility that a CC/CME organization has with the tissue banking system, cost recovery for services maybe a reasonable consideration, whether through a funded or commercial model. This is an important consideration if resources are a limitation to the CC/CME ability to participate in tissue donation - to any degree of involvement.

CC/CME organizations’ potential involvement with an organ donor is much less than that of tissue banking. It is less likely that any resources expended on the referral of an organ donor would be reimbursed.

Performance Metrics

Donation metrics are important to measure and track since opportunities for improvement and system changes must be based on definitive evidence. There are numerous ways to measure the number of potential donors, the number of donor referrals and the number of donors realized. In order to ensure consistency among the CC/CME and OTDT organizations it is important that the methodology for donation metrics is detailed in the MOU.

The OTDT community, in collaboration with Canadian Blood Services is developing common metrics and definitions that will enable a national comparison among provinces and territories and assist in the development of evidence-informed best practice. This reference manual can be modified as data demonstrates opportunities for improvements to our systems. The quality and effectiveness of donation related systems would then be evidence-informed and able to maximize donation and improve efficiencies, while reducing risks and errors.

Liability

Although this document does not outline potential liabilities, it does recommend that any potential liabilities identified by the CC/CME risk management and/or legal department are described in MOU, along with mitigation strategies.

References

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