Tissue Banking in the Province of Ontario: Review and Analysis

(A Report Commissioned by Trillium Gift of Life Network)

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1.0 Executive Summary

The use of human allograft tissue is a well-established part of modern medicine that benefits Ontario patients in virtually every surgical specialty. Corneal transplants in ophthalmology, ligament repair in orthopedics, and spinal fusions in orthopedics are three examples in which human allograft tissue contributes to restoration of sight, reestablishment of strength, and mobility and relief from chronic pain. Donated human skin literally helps save the lives of the severely burned who might otherwise die from infection. While alternative materials have been introduced over the years, demand for human tissue allografts is high and continues to grow. It is essential, therefore, for Ontario to have a reliable, safe, and effective tissue system to enable its citizens to have access to optimum medical care.

The Ontario Tissue System has received scrutiny in recent years. Ontario wait times for corneal transplant patients have received a great deal of the media's attention, and the inadequacy of tissue donation levels at local tissue banks throughout Canada is well documented. Estimates have shown that as much as 80% of the human allograft tissue used in Canada is imported from the United States. Yet, we know from examples of tissue systems in other parts of the world that communities similar in many ways to Ontario are self-sufficient with respect to tissue donation and are able to process and provide allograft tissue in the manner and volume desired by their health care systems.

In 2013, Trillium Gift of Life Network was asked by the Ontario Ministry of Health and Long-Term Care to provide recommendations for an integrated and effective tissue donation, banking and transplant system for Ontario. Subsequently, the GJC Consulting Group was engaged to perform an assessment of the Ontario tissue and transplantation system.

a) Strengths of the Ontario Tissue System

There are presently many positive aspects of the tissue donation and transplantation system in Ontario. The most notable are the following:

- There are no patient safety issues such as disease transmission, patient infections, or adverse surgical outcomes attributed to the use of human allograft tissue.
- There are no shortages or rationing of human tissue allografts with few exceptions, due in large part to importation of tissue from providers outside of Ontario (largely the United States).
- The surgeons, operating room managers and others responsible for sourcing that we interviewed expressed a strong preference for obtaining allograft tissue from Ontario based providers.
- Tissue donation, consent and recovery activities have a well-established foundation.
- Provincial outreach efforts to improve donation include the BeADonor registry. 25% of eligible Ontarians are currently enrolled, and hospitals routinely refer potential donors with 93% compliance.
- TGLN's Provincial Resource Centre handles over 25,000 donation referrals per year which contribute to the recovery of over 2,000 eye donations.
- Ontario tissue banks possess good tissue processing methods. The Eye Bank of Canada is the nation's largest eye bank; Mount Sinai Allograft Technologies operates the only fresh tissue program in Canada; the Hospital for Sick Children's Tissue Laboratory is one of four human heart valve providers in Canada.

- Surgeons report that the quality of tissue allografts obtained from the provincial tissue banks is good and often preferred to tissue received from providers outside Ontario.
- Three of the five tissue banks are accredited by the American Association of Tissue Banks or the Eye Bank Association of America and many of the staff have technical certification from these organizations.

b) Shortcomings of the Ontario Tissue System

The assessment of Ontario's Tissue System also identified the following shortcomings:

- The supply and demand needs are not met through the existing system, although Ontario's population of 13.6 million people would suggest a foundation for a high level of tissue donation. We estimate that to meet the current demand, the number of donations needs to rise significantly in all categories: eyes by 10%; musculoskeletal (MS) by 300%; skin for burns by 150% and hearts for valves by 200%.
- Much of this untapped potential is already "in the system" in the form of referred potential donors that are not converted into consented or recovered donations.
- There is no formal program to screen potential donations at the Ontario Coroner's Office which handles over 16,000 cases per year, the majority of which do not come from hospitals.
- The practice of relying on whole eye enucleation for corneal tissue recovery precludes as many as 10% of eye donations from yielding transplantable corneas because of timing issues.
- Tissue processing in Ontario is hospital-based, fragmented and small scale. Some of the scale problem is related to donation volume, but shortcomings include limited capacity, lack of essential equipment, and modest staffing.
- There are numerous examples of inefficiencies and redundancies including multiple tissue recovery teams, donation screening interactions with TGLN, serology testing, quality assurance and record keeping.
- Most of Ontario's tissue banks are reactive and not proactive as evidenced by the lack of formal operating or strategic plans, and only basic processing of traditional allografts.

c) Tissue System Costs

Our analysis estimates the current level of spending to provide tissue allografts in Ontario to be approximately $22 million. Provisional costs related to tissue donation, recovery and processing represent almost 40% of that amount or $9 million with the balance of spending estimated at $13 million for imported allograft tissue. Imported tissue allografts are invariably more costly for Ontario hospitals to obtain than allografts provided by the provincial tissue banks. There is an opportunity for Ontario to redirect funding for much of the imported tissue toward a provincial tissue system with the enhanced capability to provide for its own needs.

d) Recommendations for Tissue System Re-design

The proposed redesign is intended to promote a more self-sufficient Ontario Tissue Donation and Transplantation system. Central to the redesign are interventions to improve donation volumes, eliminate redundancies and inefficiencies, and attain greater processing economies of scale. Specifically, the recommendations are as follows:

1. Focus on increasing tissue donation volumes:
    a. *Act on existing opportunities to convert "in the system" donation potential (e.g., missed recoveries and missed medically eligible referrals due to failure to contact deceased's families).
    b. *Establish a Coroner's screening, consent and recovery program.
2. Consolidate all tissue recovery under TGLN:
    a. *Establish a TGLN Tissue Recovery Department.
    b. *Move the existing multi-tissue recovery teams under TGLN management.
    c. *Implement corneal excision recovery technique to improve transplant yields.
3. Consolidate processing of musculoskeletal, skin and cardiac tissue:
    a. *Select and communicate consolidated tissue model to tissue stakeholders.
    b. Establish or contract with a single processing entity.
    c. Create a new, Toronto based facility.
    d. Provide for contract processing of specialty tissues.
4. *Implement precut corneal tissue processing at the EBC.
5. Establish linked data management systems: Utilize TGLN's Donor Management System as the foundation, add Eye Banking Module for EBC, then link new system for Consolidated Processing Center for multi-tissue processing.
6. Use standard per allograft processing fee and pricing structure – both provisional and import.

** Denotes initiatives meeting criteria to be highly impactful with lower cost and lower capital requirements in years one and two.*

It is our hope that the information and recommendations in this report will help the Trillium Gift of Life Network and the Ministry of Health and Long-Term Care in their efforts to continue to advance the Ontario Tissue System's capability to serve their patient, surgeon, and hospital constituencies. Interventions, such as the ones put forward in this redesign of the Ontario Tissue System, provide a workable framework for the provincial system to meet most, if not all, of Ontario's tissue needs and afford greater self-sufficiency in a relatively short amount of time.

2.0 Introduction

2.1 Background

Tissue banking in Ontario began in 1955 with the opening of the Eye Bank of Canada – Ontario Division (EBC), the nation's first eye bank. Seventeen years later, in 1972, the Rubinoff Bone Bank, now known as Mount Sinai Allograft Technologies (MSAT), began their fresh musculoskeletal tissue donation program. The 1970's also saw the establishment of smaller, less formal surgical bone programs at other hospitals with active orthopedic departments. This was the model of early tissue banking programs which were typically associated within large ophthalmology, orthopedic or burn centre departments at academic medical centres.

Similar to other hospital-based tissue banks at that time in North America, the pioneering work by the Eye Bank for Sight Restoration in New York City and the U.S. Navy Tissue Bank in Bethesda, Maryland, tissue was shared and emulated by this new wave of eye and tissue banks such as the EBC and MSAT. The early tissue banks generally operated independently, each with their own donation, referral, consent and recovery programs as well as processing and distribution.

The 1970s also saw the formation of the Eye Bank Association of America (EBAA) and the American Association of Tissue Banks (AATB), in whose activities the EBC and MSAT participated. By the mid-1980s each association had established its first medical standards for the fast growing field of tissue banking. By 1986, it is estimated there were more than 400 eye and tissue banks in Canada and the United States. The AATB and EBAA established accreditation programs for its member organizations and later established a certification programs for Certified Eye Bank Technician (CEBT) or Certified Tissue Bank Specialist (CTBS) designation.

With the 1990s and the beginning years of the new decade, changes to the stand-alone hospital-based approach to tissue banking started to emerge, first in the U.S. and later in Canada as evidenced by:

- The formation of multi-bank, tissue bank networks (e.g. Tissue Banks International; Community Tissue Services; and AlloSource).
- An increasing level of sophistication and the use of correspondingly more advanced and costly equipment in the preparation and processing of allograft tissue. Tissue banks started to fashion tissue into predetermined and specifically designed allografts instead of supplying large segments of tissue for surgeons to shape and prepare in the operating room. Early examples were Cloward dowels and pre-ground cortical and cancellous bone. Later examples are precision cut spinal implants and precut corneal endothelial allografts for DSAEK.
- The consolidation of the donor consent function with those of other tissue and organ banks into a consolidated effort (e.g. TGLN).
- The consolidation of smaller, mostly hospital-based eye & tissue banks into larger, regional banks
- The advent of tissue banks (and organ banks) specializing in the recovery of all eyes and tissues (e.g. TGLN's recovery of eye tissue).

That time period also saw the emergence of for-profit specialty processors in the field of tissue banking, an area that, prior to that point, had been the sole province of non-profit organizations. For-profit

companies such as CryoLife, Osteotech, LifeCell and RTI were largely established around innovative, patented processes and designs. Government regulation of tissue arrived in the late 1990s in the U.S., followed by Health Canada's regulations and guidelines in 2003. Increasing demand, more stringent regulation, and proprietary products and processes fueled further consolidation of tissue banking.

Continuing advances in technology, science, and health care necessitated a more sophisticated, responsive eye and tissue banking sector. Innovation in communications, overnight shipping, and computer automation have changed the traditional early tissue banking roles and procedures utilized by the smaller, hospital based tissue bank structures.

The pace of consolidation in the field of tissue banking has continued in recent years. Larger tissue bank organizations demonstrated abilities to develop more sophisticated and specialized allografts. Hospitals that had once turned to local tissue banks for their surgical tissues discovered that these newer allografts were not available, and had to be obtained from other suppliers. Larger, U.S. based tissue processors emerged, both for-profit and nonprofit, to provide more reliable supplies, sometimes at lower cost, and/or proprietary grafts that made it increasingly difficult for smaller tissue banks to offer competitive levels of service. Surgical bone banks, in particular, found it increasingly difficult to cost effectively comply with new Health Canada and FDA regulations, which resulted in their slow, steady disappearance. Many hospital-based and other smaller tissue banks merged or were absorbed, resulting in the larger banks becoming even greater in size. Most of the aforementioned changes occurring in the last 30 years did not take place in Ontario.

The Ontario Tissue System has notable challenges. As currently structured, provincial tissue banks are struggling to meet the demand for allograft tissue. Wait times for corneal transplant patients have received a great deal of the Canadian media's attention in recent years, and the inadequacy of tissue donation levels at local tissue banks throughout Canada is well documented. Some people have estimated that as much as 80% of the human allograft tissue used in Canada is imported from the United States. Yet, we know from examples of tissue systems in other parts of the world that communities similar in many ways to Ontario are self-sufficient with respect to tissue donation and are able to process and provide allograft tissue in the manner and volume desired by their health care systems.

The Ontario tissue banking system is at a crossroads. Without meaningful change, the system will continue to struggle and Ontario will rely on non-provincial sources, largely tissue providers from the U.S., to meet its surgical and medical needs. It is essential, therefore, for Ontario to have a reliable, safe, and effective tissue system to enable its citizens to have access to optimum medical care.

2.2 Tissue System Review & Analysis

In 2013, Trillium Gift of Life Network was asked by the Ontario Ministry of Health and Long-Term Care to provide recommendations for an integrated and effective tissue donation, banking and transplant system for Ontario. Subsequently, the GJC Consulting Group was engaged to perform an assessment of the Ontario tissue and transplantation system.

The methods used to gather data, conduct a detailed review and analysis and provide recommendations included:

- Interviews and site visits with each tissue bank, high volume tissue transplant hospitals, key donation hospitals, surgeons, coroner's offices, TGLN and other key stakeholders
- Information requests from tissue banks and key stakeholder groups to support the analysis
- Analysis of costing data using OHIP, DAD, OCCI and NACRS data
- Surveys to North American Tissue and Eye Banks registered with Health Canada
- Literature and data reviews

The focus of GJC Consulting Group's review and analysis concentrated on the recovery, processing and transplantation of ocular, musculoskeletal, cardiac and skin tissues. Excluded from the scope of our review were organs, blood, cord blood, cells for cell therapy, bone marrow and whole body donation associated with comprehensive medical research and education programs.

3.0 Tissue System Overview

3.1 Stakeholder Analysis

The provision of human allograft tissue for patients in need depends on the actions of many individuals and their organizations. Presented below are profiles of the primary stakeholders and stakeholder groups involved in the tissue donation and transplantation continuum of care in the province of Ontario. A more detailed presentation of Ontario tissue banks' and Trillium Gift of Life Network's tissue related activities is presented in subsequent sections of the report.

3.1.1 Trillium Gift of Life Network

The overall scope of TGLN is to plan, promote, coordinate and support organ and tissue donation and transplantation throughout Ontario. In addition to their status as the designated organ procurement organization for the province of Ontario, TGLN's mandate encompasses human tissue donation and transplantation.

TGLN's outreach in the promotion of anatomical donation includes public education in the form of advertising, media events, online web-based promotion (including the BeADonor registry promotion) and other educational activities. TGLN performs focused advocacy and promotion, specifically concentrating on hospital medical education and the facilitation and management of potential donors. ServiceOntario is the custodian and operator of the donation registry but the promotion of the registry and registration process is a joint effort by TGLN and ServiceOntario. The registry web-site is maintained and updated by TGLN.

Additionally, TGLN manages and operates the Provincial Resource Center (PRC) which is TGLN's twenty-four hour per day donor referral and consent call and information center. Upon obtaining consent, arrangements for tissue recovery and the associated logistics are coordinated with the hospital, coroner's office (if applicable), tissue recovery personnel, participating tissue banks, and the funeral home. The PRC staff also recovers eye tissue (enucleations) within the Greater Toronto Area (GTA), East Ontario and Southwest Ontario for the Eye Bank of Canada, Ontario Division.

3.1.2 Sources of Tissue Donors

Stakeholder	Description
Ontario Hospitals	• Ontario's tertiary care hospitals, particularly the acute care and emergency departments within those facilities, represent a primary nexus of organ and tissue donation potential. • Hospitals are responsible for calling and notifying TGLN when a patient has died, or prior to death according to their established referral indicators. • 51 provincial hospitals (referred to as Class A and Class B hospitals) actively refer all deaths to TGLN for initial assessment. 21 of these hospitals are classified as "Tier 1" Hospitals because they have been identified as having a

	higher potential for organ and tissue donation, and are equipped to maintain and manage organ donor cases. • Another 15 provincial hospitals are in the process of fully establishing the policy of routine referral of patient deaths. These "Class C Hospitals" were selected because of their size, specialized services, and potential to allow for additional donors, particularly tissue donors (refer to Appendix A for a list of all provincial hospitals providing routine referral of deaths to TGLN).
Ontario Coroners	• All potential donors that are identified as actual or potential coroner's cases must be cleared with the Office of the Chief Coroner to ensure the completion of the mandated coroner's death investigations and inquests, and compliance with the wishes of the donor and donor families. • The Ontario coroner offices located throughout the province represent a significant source of potential additional tissue donation, but to date, there is no organized program in place to routinely identify and pursue these potential donations and, as a result, tissue donation from coroner cases occurs infrequently. • In 2013, there were 16,586 coroner cases in Ontario, with only 3 percent of the associated deaths occurring in hospitals. Additionally, the Provincial Forensic Pathology Unit in Northwest Toronto contains a dedicated tissue recovery suite which can be utilized to support tissue recovery operations.

3.1.3 Ontario Tissue Providers/Processors

Stakeholder	Description
Eye Bank of Canada (Ontario Division)	• The EBC operates under the auspices of the Department of Ophthalmology at the University of Toronto. • As the sole eye bank in Ontario, the EBC evaluates, processes and distributes donated ocular tissue for ophthalmic surgery throughout the province, primarily corneal tissue for sight restoring corneal transplant procedures. The eye bank also coordinates eye tissue referral and recovery activity that is outside the current scope of TGLN's eye recovery coordination. • Other tissues provided for patient use include sclera for tectonic applications; amniotic membrane for the healing and treatment of severe eye inflammation; and various ocular tissues for use in eye research and medical education.
Hospital for Sick Children Tissue Laboratory (HSCTL)	• The HSCTL heart valve program is located at The Hospital for Sick Children (Sick Kids), Department of Paediatric Laboratory Medicine in Toronto. • The HSCTL also processes pericardium, the outer layer of fibrous tissue surrounding the heart. The HSCTL is one of only four heart valve programs located in Canada.
Lake Superior Centre for Regenerative Medicine (RegenMed)	• Located in Thunder Bay, RegenMed is the only freestanding tissue bank in Ontario. • RegenMed is a not for profit tissue bank that has operated with financial support from fee for service revenue, grants, and loans. • Their operating structure more closely resembles the independent tissue banking model found in the U.S. in that it is not organizationally part of a hospital or hospital department. • RegenMed processes, stores, and distributes primarily musculoskeletal tissue. • RegenMed received tissue bank designation from the Ontario Ministry of Health/Trillium Gift of Life Network in 2011. Additionally, it is the only tissue

	bank with the capacity to process freeze-dried musculoskeletal allografts in Ontario.
Mount Sinai Allograft Technologies (MSAT)	• MSAT is a department of Mount Sinai Hospital in Toronto. MSAT, formerly known as the Rubinoff Bone Bank, has been in continual operation since 1972. The program is renowned for its "fresh" musculoskeletal (osteochondral) tissue program which is the only such program in Canada. • As part of Mt. Sinai Hospital, MSAT's program includes research and education as well as an international fellowship program which includes a tissue donor recovery curriculum. • MSAT's scope of tissues includes processed bone, ligaments, tendons and other soft tissues as well as osteochondral, fresh tissue allografts. • MSAT has processed tissue in-house for many years but in more recent times has arranged for other organizations to process musculoskeletal tissue to MSAT's specifications. It currently contracts with an AATB accredited tissue bank in San Antonio, Texas.
Ontario Professional Firefighters Skin Bank (OPFSB)	• The Ontario Professional Firefighters Skin Bank is located in the Clinical Pathology/Blood Bank Department of Sunnybrook Health Sciences Centre in Toronto. • Skin obtained by the OPFSB is provided for the treatment of patients at the Sunnybrook Hospital Ross Tilley Burn Centre. In the past, when donor volumes were higher, OPFSB was able to share skin with The Hospital for Sick Children.
Other Ontario Tissue Banks	• The surgical bone banks process, sterilize, and provide femoral head tissue for future surgical use, typically when cancellous bone is required. Surgical bone banks may also store cranial flaps in hopes of returning them to patients who have experienced significant head trauma and swelling. The surgical bone banks in Ontario are: o Hamilton Arthroplasty Bone Bank – femoral heads o London Health Sciences – cranial flaps o Queensway Carlton Hospital – femoral heads o St. Michael's Hospital – femoral heads o Sunnybrook Hospital – femoral heads and cranial flaps • In 2013, two smaller, hospital based tissue banks discontinued their operations. The Kingston General Hospital Bone Bank and the National Capital Region Bone Bank had both recovered and provided musculoskeletal tissue.
Tissue Importers	• Most of the human allograft tissue utilized by hospitals and surgeons in Ontario is provided by tissue banks located in other Canadian provinces or the United States. • Distribution is provided directly by the tissue banks or through the medical device companies or independent medical distributors. Of the more than 80% of the allograft tissue used for surgery in Ontario that is imported, 70% comes from the United States and 10% from the other Canadian provinces. • The Canadian tissue banks most often providing tissue to Ontario hospitals are Hema-Quebec and the Regional Tissue Bank (Halifax). Tissue Banks providing tissue for use in Ontario last year included most of the top providing tissue bank processors in the United States including AlloSource (Colorado); Bone Bank Allograft (Texas); Community Tissue Services (Ohio), CryoLife (Georgia); DCI (Tennessee); LifeCell (New Jersey); LifeNet (Virginia); MTF (New Jersey) and RTI (Florida).

3.1.4 Users of Tissue

Stakeholder	Description
Ontario Hospitals	• Human allograft tissue is utilized in a wide variety of surgical specialties including ophthalmology, orthopedics, neurology, podiatry, oncology, pediatrics, burn care, emergency medicine, cardiology, urology and general surgery. • The use of human allograft tissue can be found in the operating rooms of virtually any tertiary care hospital in Ontario, depending on their surgical specialties.
Kensington Eye Institute (KEI)	• KEI is one of the very few ambulatory surgery centres in Canada that provide outpatient surgical procedures. • Located in Toronto, the KEI provides a scope of services which include outpatient cataract surgery, glaucoma surgery, retina surgery and corneal transplants. • In FY 2013/14, KEI was provided funding to perform 400 corneal transplant surgeries and funding has been approved for 500 corneal transplants in FY2014/15.
Dentists	• Dentists, periodontists and oral and maxillofacial surgeons treat patients needing extraction grafting, bone augmentation with dental implants, repair of bony jaw defects, ridge and sinus augmentation, and periodontal regeneration. • The majority (75%) is performed in private dental facilities on an outpatient basis using DBM, both traditional in the form of granules and cubes, and proprietary in the form of injectables, putties and gels. • Certain soft tissue allografts such as traditionally processed pericardium and proprietary ADM are also utilized.

3.1.5 Other Key Stakeholders

Stakeholder	Description
Cancer Care Ontario (CCO)	• CCO operates the Ontario government's Access to Care program in support of the Ontario Wait Time Strategy where data is collected to enable the measurement and reduction of wait times for certain surgical procedures in Ontario. • In 2010, CCO began collecting data for corneal transplant procedures in Ontario. No other surgical procedures that exclusively incorporate allograft tissue are tracked by CCO.
Canadian Blood Services (CBS)	• Canadian Blood Services is a not-for-profit organization established in 1998 to manage the provision of blood and blood products throughout Canada with the exception of Quebec. • In 2008, CBS was tasked to work with the Organ and Tissue Donation and Transplantation communities to develop and propose a Canadian solution for the shortfalls in the country's transplantation system, including tissue transplantation. • In 2011, CBS presented A Call to Action, which included a proposal for a national, coordinated approach to increase donation, coordinate the importation of tissue and establish tissue processing centres of excellence. More recently, CBS proposed to provincial governments the following: a Tissue Procurement Strategy; Tissue Quality and Standardization; and a focused strategy for corneal tissue.

Clinical Laboratories at Mount Sinai Hospital	• The Clinical Laboratories at Mount Sinai Hospital in Toronto perform much of the cadaveric donor testing for Canadian tissue banks; reportedly more than 50% of the tests in Canada • The hospital lab is ISO/CAP/CLIA/OLA and U.S. FDA compliant. • The Mount Sinai Hospital Clinical Laboratories also performs microbiological/bacteriological services. These services include analysis of cultures obtained during tissue recovery and sterility cultures which are usually obtained during and/or after processing of tissue. • The lab has advanced bacteriological testing capability including mass spectrometry which is state of the art in bacterial identification accuracy and speed.
Health Canada	• As part of its responsibility for national public health, Health Canada's scope of oversight expanded in 2003 to include human cells, tissues and organs. • In accordance with the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations), all source establishments and establishments that distribute or import cells, tissues and organs for further distribution (CTOs), must register with Health Canada. Health Canada maintains a list of registered CTO establishments for public reference. • Health Canada issues ongoing directives outlining safety requirements for tissue establishments and their donor screening and tissue processing programs. Should a significant health risk be identified, the establishment can be ordered by Health Canada to cease further manufacturing and distribution of tissues. In addition, Health Canada requires CTO establishments to report any suspected or unexpected adverse reactions involving the transmission of an infectious disease or disease agent to Health Canada.
Ontario Ministry of Health and Long-Term Care (MOHLTC)	• The Ministry of Health and Long-Term Care is the branch of the provincial government responsible for the administration of the health care system and services throughout Ontario. • The MOHLTC scope of services and programs includes the Ontario Health Insurance Program, prescription drug programs, and other long term and home care programs. Additionally, the MOHLTC funds and regulates Ontario's hospitals, medical laboratories and emergency health services. • The oversight and funding of Ontario's tissue banking activities are provided by the MOHLTC through various programs and management structures.

3.2 Overview of Tissue System in Ontario

Tissue transplantation relies on a three phase system. The first phase begins with outreach to individuals and families to encourage donation of tissues and organs. The ultimate goal of Phase1 is the recovery of tissues. The second phase is "tissue processing", where the donated tissue is evaluated and prepared into surgical allografts and stored until needed for transplantation. The final phase encompasses hospital sourcing of allograft tissue, preparation of allografts in the operating room, the surgical implantation or transplantation of tissue allografts and monitoring tissue related patient outcomes.

3.2.1 PHASE 1: Tissue Donation, Consent and Recovery

DONOR IDENTIFICATION AND REFERRAL

Part II.1 of the Trillium Gift of Life Network Act states "8.1 (1) A designated facility shall notify the Network as soon as possible when a patient at the facility has died or a physician is of the opinion that the death of a patient at the facility is imminent by reason of injury or disease". TGLN gives specific guidance and instructions to Ontario hospitals to call the Provincial Resource Center (PRC), preferably within one (1) hour of death, for all patients under eighty years old. The initial call to the PRC is to determine if the patient meets the age eligibility criteria to donate tissue and assure timely referrals for organs donors when a patient meets a set of clinical indicators.

"Call-Screen-Connect" is TGLN's strategy for tissue donor identification (Call), qualification (Screen), and consent (Connect). The PRC operates a twenty-four hour toll free number at the TGLN office in Toronto that is staffed with trained health care professionals who screen all referrals to determine if the patient might be eligible to donate organ and tissue. The PRC received 11,399 organ and tissue referrals in FY 2011/12 and 17,084 in FY 2012/13 from all Tier 1 Hospitals, almost a 50% year-to-year increase.

REFERRAL OF POTENTIAL DONORS

TGLN's hospital development staff has the primary responsibility for working with the "Newly Designated" hospitals to assist in complying with the Routine Notification Requirement, while the Organ and Tissue Donation Coordinators (OTDC) work with the Tier 1 institutions. TGLN is currently publicly reporting hospitals' performance on tissue referrals.

Two resource manuals have been developed and distributed to all provincial referring hospitals: a 'Tissue Donation Resource Manual' and a 'Donation Resource Manual - A Tool to Assist Hospitals with the Process of Organ and Tissue Donation'. These manuals provide consistent guidelines for organ and tissue donor identification and referral. Hospitals have been instructed to have a completed 'Routine Notification Worksheet' and the patient's chart with them when they call TGLN's PRC with a tissue referral. The Worksheet captures the Ontario health card number which is used to check the registry database for all registered donors. Currently, TGLN requires referrals be made only by a physician or a registered nurse or other TGLN approved healthcare professional. The 'Routine Notification Worksheet' is designed to expedite the call time to either fifteen minutes if the patient is considered eligible or as little

as three minutes if a patient is not eligible to donate tissue. TGLN's PRC will assign each referral a unique number which is recorded on the Worksheet and in the patient's hospital chart.

Health Canada standards preclude individuals with certain diseases from donating tissues for transplantation to minimize the risk of disease transmission. If the information provided by the caller does not exclude the patient based on the established criteria, the patient is deemed medically eligible and the referral is considered preliminarily suitable. The PRC staff will continue to screen the potential donor using the 'Next Steps Worksheet', which is used to further assess donor suitability. It is important to note that final eligibility for tissue donors will be determined by, and is the responsibility of, each tissue bank (the Source Establishment as defined by Health Canada) not by TGLN staff. If any questions arise, the PRC staff may contact the local tissue bank for clarification or further assessment of the medical suitability of the potential donation case.

When a ventilated patient might be an organ and tissue donor, a similar Routine Notification Worksheet is used. If it is later determined that a ventilated referral is not a suitable organ donor, the hospital is instructed to call the PRC back when the patient expires for potential tissue donation.

DONOR ELIGIBILITY AND CONSENT

Once the patient is deemed medically eligible by the PRC staff, the focus shifts to consent (Connect). The process for obtaining consent is as follows:

1. The Ontario health card number, obtained from the 'Routine Notification Worksheet', is used to determine if prior consent has been registered by the decedent in the donor registry database. If the patient has registered their consent to be a donor, the information is communicated during the conversation with the legal next of kin or the person authorized to give consent.
2. For all medically eligible patients, PRC staff ask the referring hospital staff if the family is still present and if so, to speak with them. If the family plans to leave the hospital prior to completion of the of the PRC's assessment of the patient, the hospital staff informs the family to expect a call from TGLN and obtains contact information for the legal next of kin.
3. A PRC staff member, usually a Tissue Coordinator (TC), calls the family (between 8AM and 11PM) on a recorded line to obtain telephone consent and complete a medical social history questionnaire. The current practice is: if the patient is a Coroner's case, TGLN staff must contact the Coroner's office to obtain clearance to pursue the donation.
4. Once consent has been obtained, a 'Hold Body Form - Potential Tissue Donor' and 'Telephone Consent Form' are faxed to the referring hospital.

TISSUE RECOVERY

Once consent has been given by the family, a complete set of the donor file and the planned recovery logistics are faxed to the responsible Ontario tissue bank and their tissue recovery teams. The following outlines the process for recovering each tissue type:

- Ocular Recovery: TGLN Tissue Recovery Coordinators (TRCs) recover most whole eyes within the GTA. At certain hospitals, primarily outside of the GTA, per diem enucleators (physicians, nurses, and other trained staff) are dispatched to recover whole eyes for the EBC. Under an

arrangement with the EBC, TGLN is responsible for donor referral and coordination in Ontario except when certain, non-hospital donation opportunities, such as those originating at funeral and nursing homes are coordinated directly by the EBC. The enucleator, be it a TRC or other health care professional, gathers any necessary paper work, performs a body exam, collects blood samples for testing, and completes the eye recovery procedure. Eye tissue recovery does not require the use of an operating room and is frequently performed in the hospital morgue. The donor's eyes are transported to the office of the EBC by hand delivery within the GTA or by other means of transport when recovered elsewhere.

- Musculoskeletal Tissue Recovery: Consented donation opportunities are directed to MSAT or RegenMed depending on the hospital, geographical area, and other logistical factors. As is the case with eye donors, bone bank recovery teams (typically three people), receive a copy of the donor's TGLN record and detailed logistical information, including a designated time frame to perform the tissue recovery. Tissue recovery teams make their own travel arrangements to the donor hospital. Unlike eye recovery, musculoskeletal tissue procurement requires two to four hours of hospital operating room time. Upon completion of the tissue recovery procedures, the recovery teams ensure that the operating room is returned to pre-recovery condition and the deceased is returned to the hospital morgue, and report the completion of the donor recovery to TGLN. Recovered musculoskeletal tissue typically accompanies the recovery team back to the bone bank facility.

- Heart Tissue Recovery: Donated hearts for valves and pericardia are processed by the Hospital for Sick Children Tissue Laboratory. The recovery of hearts for valves, however, is typically performed by MSAT recovery staff on behalf of the HSCTL. This occurs most often in conjunction with a musculoskeletal tissue donation. TGLN provides a copy of the donor's record and other detailed logistical information to both the HSCTL and the recovery team. Upon completion of the tissue recovery, the recovered hearts for valves and pericardium are either hand delivered or shipped to the HSCTL.

- Skin Recovery: The recovery of skin has been limited to the GTA due to the limited geographical availability of the recovery teams from the OPFSB. Skin recovery is currently limited to split-thickness skin (a very thin layer of skin including the epidermis and part of the dermis) intended for the treatment of severely burned patients. If a donation involves multiple tissues, skin recovery typically follows the procurement of eyes and precedes the recovery of musculoskeletal tissue. Split thickness skin requires the use of a special surgical instrument called a dermatome. Upon completion of the skin recovery, the skin is placed into a liquid holding media and typically returns with the recovery team to the skin bank for refrigeration until processing of the tissue can commence.

The Office of the Chief Coroner, a division of the Ontario Ministry of Community Safety & Correctional Services, also plays a key role in the donation process. All potential donors that are identified as actual or potential coroner's cases must be cleared with the Office of the Chief Coroner to ensure the completion of the mandated coroner's death investigations and inquests, and compliance with the wishes of the donor and donor families. While typically not an impediment to anatomical donation, the completion of coroner

case investigations sometimes conflict with tissue recovery and prevent anatomical donation from proceeding (i.e. coroner restrictions).

3.2.2 PHASE 2: Tissue Processing

Users of the allografts processed by the tissue banks in Ontario consider them to be of good quality. There were no reports of quality issues by the surgeons or hospital professionals interviewed during this assessment of the Ontario Tissue System. Our review discovered no adverse outcomes or disease transmissions related to allograft tissue provided by the tissue banks.

OCULAR TISSUE

The EBC currently provides approximately 97% of all corneas transplanted in Ontario from local donations and imports the balance of corneas transplanted from other eye banks in Canada and the U.S.

Despite having the highest rate of tissue processing in proportion to provincial demand, there is a waitlist backlog of corneal transplant patients. Approximately 65% of the corneas distributed by the EBC are used in anterior and posterior lamellar surgery where only certain layers of the cornea are implanted. Currently, the EBC does not provide pre-cut tissue to Ontario surgeons as the surgeons extract the layers they intend to implant immediate prior to surgery in the operating room.

MUSCULOSKELETAL TISSUE

There is a wide range of allografts processed by tissue banks from donated musculoskeletal (MS) tissue. Bone tissue allografts may be prepared in the form of shafts, wedges or be ground and morselized. Soft tissue allografts are also prepared from fascia lata, ligaments and tendons. Graft preservation varies too, as MS tissue may be presented frozen, lyophilized (freeze dried), in media, or as fresh grafts. Grafts may also be aseptically prepared; processed subsequent to a sterilization step; or undergo post processing sterilization. Adding size and weight selection and other popular processing techniques (such as demineralization) can result in literally hundreds of allografts being offered by a MS tissue bank. Allografts processed using techniques such as gamma irradiation sterilization, lyophilization, and demineralization, which have been utilized for twenty or more years, are commonly referred to as "traditional MS allografts".

The advent of specialized techniques, often related to patented allograft designs with precision computer guided cutting or proprietary processing methods, has resulted in the production of tissue referred to as "proprietary MS allografts". Primary examples are demineralized bone within a gel or putty delivery system and precisely designed and fashioned bone implants used in spinal fusions. Ontario musculoskeletal tissue banks (MSAT and RegenMed) do not process or offer proprietary MS allografts. Virtually all of the tissues offered are considered "traditional MS allografts".

CARDIAC TISSUE

Hospital for Sick Children Tissue Laboratory – The HSCTL is the processor and distributor of human cardiac tissue, primarily human heart valves (HV), in Ontario. HSCTL prepares pulmonary and aortic heart valves, conduit grafts, and pericardium for distribution to Sick Kids and other Ontario hospitals (depending on size and supply). Donated and recovered hearts for valves are aseptically trimmed and processed under a bio-flow hood, frozen in a control rate freezer, then stored in liquid nitrogen until needed. More so than other tissues, the size of the HV allograft is of utmost importance because so many of the patients are children who need smaller HVs while heart-for-valve donations are typically larger and from donors older in age. Combined with a typical processing yield of 50%, many donations are required to provide enough HV allografts in Ontario.

SKIN TISSUE

Ontario Professional Firefighters Skin Bank – The OPFSB is located at Sunnybrook Hospital, the site of Ontario's largest burn unit, and is focused entirely on providing split-thickness skin for the treatment of patients with severe burns. Similar to the processing of human HVs, donated and recovered skin is aseptically trimmed and processed under a bio-flow hood, frozen in a control rate freezer then stored in liquid nitrogen until needed. Most skin banks frequently mesh the skin (making lengthwise rows of short, interrupted cuts) during processing to allow for wound drainage and for the graft to both stretch and cover a larger area. The OPFSB does not pre-mesh the skin during processing; the burn surgeons do so at the time of treatment.

The OPFSB only focuses on skin for burns. Another useful allograft obtained from human skin is acellular dermal matrix (ADM). Widely processed and available from skin banks in the United States, ADM is prepared from full-thickness skin that includes more of the dermal layer. ADM grafts are used in a wide range of soft tissue applications such as burn site reconstruction, post mastectomy reconstruction, wound care, and orthopedic surgical site containment. ADM allografts are often, but not exclusively prepared with patented processes and are considered a proprietary tissue.

3.2.3 PHASE 3: Tissue Transplantation (and Follow-up)

Hospitals in Ontario are allowed to obtain tissue from any source listed on Health Canada's list of registered Organ, Tissue and Cell establishments. During the course of our interviews with the hospital staffs responsible for sourcing tissue (surgeons, hospital purchasing agents and operating room managers), with all other things being equal, there was an expressed preference for working with Ontario based tissue banks, Ontario tissue distributors, or other Canadian tissue banks. Currently, electing this preference is often not possible as the supply and availability of certain allografts from the tissue processors within the province is limited. Listed below is more detail on how various allografts are supplied and used in Ontario:

Allograft Type	Use in Ontario
Corneas & Other Ophthalmic Tissues	• All of the hospitals performing cornea transplants (and the Kensington Eye Institute) obtain 100% of their tissue from the EBC. Most of the tissue (97%) is locally sourced coming from eyes donated by Ontarians. • The EBC will source and obtain corneas from outside the province when needed, in essence, providing the hospitals a single, reliable source for ocular tissue.
Skin for Burns	• The Ross Tilley Burn Centre prefers to use the skin allografts processed by the OPFSB but that accounts for only half of its needs. The OPFSB secures and stores skin from the Hema-Quebec tissue bank to make up for the shortfall. However, the cost of the skin from Hema-Quebec is paid for from the burn unit's budget. • The Sick Kids Hospital has only occasional need for burn skin allografts. There have been instances of OPFSB sending tissue to Sick Kids Hospital but not routinely. Our review found Sick Kids Hospital securing skin on occasion from other Canadian tissue banks outside Ontario. • The Burn Unit at Hamilton Health Sciences reports ten to twelve cases per year of severely burned patients, but prefers to use porcine skin. Since their source of porcine skin has discontinued Canadian distribution, human allograft skin is now a consideration for them.
Skin for ADM	• Acellular Dermal Matrix is a soft tissue allograft with many potential surgical applications. Some of ADM's known uses include dermal scaffolding in burn patients, breast reconstruction, abdominal wall repair, and wound healing. • Since ADM is not an allograft offered by Ontario based tissue banks, hospitals must obtain this tissue from U.S. processors such as LifeCell, LifeNet or MTF or their respective distributors. • ADM is considered a proprietary tissue in that the largest providers utilize patented processing systems.
Heart Valves	• Most of the pediatric heart valves distributed by HSCTL are used at their own Sick Kids Hospital. HSCTL does distribute adult heart valves to other Ontario hospitals when they are available. • Because there is a shortage of locally processed human HVs, Ontario hospitals, including Sick Kids Hospital, often obtain HV allografts directly from two large U.S. providers, CryoLife and LifeNet.
Traditional MS Tissue	• The two Ontario based tissue banks distributing MS tissue, MSAT and RegenMed, provide an estimated 35 to 40% of the traditional MS allografts used in Ontario. Therefore, Ontario hospitals have secured additional traditional MS allografts directly from other Canadian or U.S. tissue providers or their Ontario distributors. • The Canadian tissue banks most often utilized are the Regional Tissue Bank in Halifax or Hema-Quebec. The U.S. tissue banks frequently utilized include MTF, Bone Bank Allografts, Community Tissue Bank, RTI and LifeNet.
Proprietary MS Tissue	• All proprietary MS allografts utilized by Ontario hospitals are supplied by U.S. tissue providers or their distributors. • Two families of tissue allografts dominate the Ontario market: precision cut bone implants for spinal fusions and carrier delivered DBM. Bone for spinal implants is typically precision cut to certain patented designs for use with specific insertion instruments. • In Ontario, these tissues are offered by Medtronic, MTF, Osteotech, RTI, Zimmer and others. DBM in granules has been a traditional MS allograft for over two decades, but when combined with a delivery agent or carrier in a syringe, gel, or

Allograft Type	Use in Ontario
	moldable putty form it becomes a proprietary MS allograft. Many of the aforementioned U.S. tissue providers will also provide a proprietary form of DBM.
Dental Market	• MS tissue, particularly morselized cancellous and cortical bone, is used by dentists, periodontists and oral and maxillofacial surgeons to treat patients needing extraction grafting, bone augmentation with dental implants, repair of bony jaw defects, ridge and sinus augmentation, and periodontal regeneration. • Some of these procedures are performed in hospitals but the majority (75%) is performed in private dental facilities on an outpatient basis. • The primary tissue used for dental applications is DBM, both traditional in the form of granules and cubes, and proprietary in the form of injectables, putties and gels. • Certain soft tissue allografts such as traditionally processed pericardium and proprietary ADM are also utilized. The majority of this tissue emanates from U.S. based tissue providers and is largely distributed via their Canadian distributors.

Human allograft tissue is utilized in a wide variety of surgical specialties including ophthalmology, orthopedics, neurology, podiatry, oncology, pediatrics, burn care, emergency medicine, cardiology, urology and general surgery. Therefore, the use of human allograft tissue can be found in the operating rooms of virtually any tertiary care hospital in Ontario. Tissue utilization in Ontario hospitals is not specifically measured in that there is no coding that encompasses all surgical procedures using tissue allografts.

There is currently no centralized tracking of surgical outcomes for procedures using allograft tissue. Due to the volume of procedures, using allograft tissue tracking of surgical outcomes, whose utilization exceeds 10,000 grafts per year, is more analogous to the tracking of medical devices and other surgical implants than it is to organ transplants in Ontario (that number in the hundreds). Adverse surgical events are reportable, however. Health Canada regulations require the reporting of any tissue related disease transmissions or adverse reaction. Furthermore, any tissue provider that is accredited by the American Association of Tissue Banks or the Eye Bank Association of America is required to solicit reports of tissue related adverse outcomes.

4.0 End-to-End Tissue System Assessment

4.1 TGLN Assessment

4.1.1 Background

TGLN was established on April 1, 2002, as a not-for-profit agency of the Government of Ontario, by way of the 'Trillium Gift of Life Network Act subsection 8.7. (1)', under the Ministry of Health and Long-Term Care. TGLN's mission is saving and enhancing lives through the gift of organ and tissue donation and transplantation in Ontario. Consistent with the legislative mandate TGLN has provided an increasingly expanded role in tissue donation and transplantation. TGLN is a vital link between the tissue donor and potential recipient of tissue. The scope of tissue services provided by TGLN includes educational support to hospitals; donor identification; qualification and screening; consent; recovery of eyes; and coordination of Ontario tissue banks for recovery of bone (associated soft tissue), skin, and heart for valves.

A statement in the 'Auditors General 2010 Report,' said, "…less than 8% of Ontario's tissue needs are being met from Ontario's tissue…" and went on to state that that was "due to the lack of resources to recover, process and store tissue". While TGLN performs an important provincial role in the recoveries of eyes for the Eye Bank of Canada, other aspects of the tissue donation and transplantation continuum, such as multi-tissue recovery, processing and distribution of final products are not part of TGLN's current scope of activities.

TGLN's geographical service area is organized into four regions of Ontario: Central/GTA, Eastern, Northern and South Western. Hospitals are categorized as either "Tier 1 Hospitals" or "Newly Designated Hospitals" (see Appendix A for list of hospitals). Our interviews with Tier 1 hospitals' key leadership and staff revealed strong support for TGLN and its expanded effort to increase tissue donation.

TGLN captures the most comprehensive data on tissue donation in Ontario, particularly since TGLN's implementation of the iTransplant system in April of 2013. Our detailed analysis of tissue related data focused on the subset of TGLN's "Tier 1 Hospitals". This dataset was chosen because it represents more than 73% of all organ and tissue donation activity and makes year to year analysis involving newly added hospital data and data elements more consistent. Additionally, the new system's ability to provide meaningful data elements is more robust than TGLN's previous data system. The data encompasses the nine month period from April 2 to December 31, 2013, the most recent data available at the time of the review. Unless otherwise indicated, for presentation purposes, these nine months of data is annualized to represent a projection of the full TGLN fiscal year of 2013-14 and to enable the comparison of annual data.

4.1.2 Tissue Donor Potential

One of the primary shortcomings related to tissue processing in Ontario is the low number of tissue donations, especially for musculoskeletal, skin and heart valve donations. Based on our analysis of tissues in demand and the processing capabilities of the Ontario tissue banks, a targeted number of

donations needed to meet the demand in Ontario for each tissue category are estimated in Table 1 with comparisons to the current rate of donation in Ontario.

Table 1: Donation Shortfalls in Ontario

Tissue Type	Current Level of Annual Donations	Estimated Donations Needed	Shortfall
Eye/Cornea	**2,000**	**2,275**	**275**
Musculoskeletal	**150**	**750**	**600**
- MS traditional grafts	150	500	350
- MS specialty grafts	0	250	250
Skin	**40**	**200**	**160**
- for burns	40	100	60
- for acellular dermis	0	100	100
Hearts for valves	**50**	**150**	**100**

In comparing donor referrals, medically eligible donors, donors approached for consent, consented donors and actual donors over the past 3 years, referrals have increased year-to-year by 49.8% between FY 11/12 and FY 13/14 (see Table 2).

Table 2: Referrals, Approaches and Consents – Tier 1 Hospitals (FY 2011/12-2013/14)

Fiscal Year	Referrals	Eligible	Approached	Consented Donors	Actual Donors
2013/14*	16,272	6,303**	3,791	1,571	1,264
2012/13	17,084	15,714	3,705	1,459	1,189
2011/12	11,399	10,211	4,467	1,696	1,436
**FY 2013/14 projected on nine months April through December 2013.*					
***2013 impact of age criteria change for eye donation.*					

On the surface, it appears the number of medically eligible donors declined dramatically from 15,714 in FY 2012/13 to 6,303 in FY 2013/14. However, a significant change occurred with respect to referrals of eye donors in early 2013. The age criterion for eye donation was lowered to seventy-nine years of age, primarily because there were already sufficient donor volumes used for research and teaching applications. While the change is resulting in lower overall medically eligible case numbers, it is not having a negative effect on the numbers of transplantable eye tissue or patient waiting times. At this time, tissues available for research and teaching are still sufficient.

As Table 2 shows, the number of donors approached for donation increased for Tier 1 hospitals by 2% to 3,791 and the number of donors from which consent was obtained increased by 8% to 1,571. While the 1,264 actual tissue donors in FY 2013/14 reflects a projected 6% increase over the prior fiscal year, the percent of actual donors from those consent remained relatively stable from 81.5% in FY 2012/13 to 80.5% in FY 2013/14.

TGLN is making progress in narrowing the shortage of tissue donations by engaging with the hospitals to improve compliance in making donor referrals to TGLN. Most of the progress has been in the Central & GTA and Eastern Ontario regions (see Table 3).

Table 3: Aggregate Data by Region– Tier 1 Hospitals (FY 2011/12-2013/14)

Fiscal Year	Central & GTA	Eastern Ontario	Northern Ontario	Southwestern Ontario	TOTAL
REFERRALS					
FY 2013/14*	7,884	2,011	1,389	4,988	16,272
FY 2012/13	8,039	1,750	1,484	5,811	17,084
FY 2011/12	4,755	1,797	986	3,861	11,399
ELIGIBLES					
FY 2013/14*	3,459	767	425	1,652	6,303
FY 2012/13	7,456	1,622	1,373	5,291	15,742
FY 2011/12	4,342	1,589	905	3,375	10,211
APPROACHES					
FY 2013/14*	2,243	463	220	865	3,791
FY 2012/13	1,934	459	274	1,038	3,705
FY 2011/12	1,843	731	401	1,492	4,467
CONSENTED					
FY 2013/14*	812	201	119	439	1,571
FY 2012/13	710	173	142	434	1,459
FY 2011/12	651	279	180	586	1,696
DONORS					
FY 2013/14*	660	168	83	353	1,264
FY 2012/13	594	143	95	357	1,189
FY 2011/12	543	241	146	506	1,436
**FY 2013/14 projected based on for the nine months April 2 to Dec 31 2013*					

As Table 4 indicates, the vast majority of the projected 1,264 tissue donors from Tier 1 hospitals in Ontario for FY2013/14 are eye donors. Over 95% of all donations include eyes. Other donated tissues are significantly less numerous, with bone donors at 7% followed by hearts for valves and skin. While there is still room for some improvement in the number of eye donors in Ontario, the very low numbers of bone, skin and heart valve donors represent the greatest potential for improvement.

Table 4: Tissue Donors Recovered by Region– Tier 1 Hospitals (FY 2013/14 Projected)

Type of Tissue	Central & GTA	Eastern Ontario	Northern Ontario	Southwestern Ontario	TOTAL
All Tissue	660	168	83	353	1,264
Bone Donors	35	11	4	43	93
Eye Donors	641	167	80	347	1,235
Skin Donors	8	0	0	0	8
Cardiac Donors	16	3	0	10	29
****FY 2013/14 projected based on for the nine months April 2 to Dec 31 2013***					

Overall, several strong foundational pieces are in place that link TGLN to the supply side of the Ontario tissue system. TGLN's role of working with Ontario hospitals to bring them into compliance with Routine Notification Requirements is functioning well and the expanding inclusion of the Class C Hospitals will increase referrals. A communication strategy designed to reach the public is underway utilizing a number of tactics focused on driving traffic to the BeADonor registry and bringing more attention to the need for organs and tissues. The projected numbers of tissue donors who were registered for FY 2013/14 are listed below in Table 5.

Table 5: Consented, Actual & Registry Tissue Donors by Region– Tier 1 Hospitals (FY 2013/14 Projected)

	Central & GTA	Eastern Ontario	Northern Ontario	Southwestern Ontario	TOTAL
Consented Donors	812	201	119	439	1,571
Actual Donors	660	168	83	353	1,264
Registry Donors	376	140	111	297	924
FY 2013/14 projected based on for the nine months April 2 to Dec 31 2013					

The assimilation of tissue donation functions under TGLN creates a foundation for building an integrated provincial tissue transplant system which will augment its organ donation efforts. Many similar sized organ procurement programs in the United States are connected to strong tissue programs that have not hindered their organ donation numbers in any way (see Table 6 for OPO comparisons). In fact, TGLN's involvement in tissue donation and recovery offers more visibility in their donor hospitals. Because the number of potential tissue donors far exceeds the number of organ donors, there is reason to expect that further improvements in tissue donation with a solid tissue donor referral recovery model will improve organ donation.

Table 6: TGLN Comparison to High Performing U.S. OPOs

	TGLN	**High performing East Coast U.S. OPO**	**High performing West Coast U.S. OPO**
Numbers of Hospitals*	150+	130	205
Population (millions)	13.6	10.4	19.5
Numbers of employees	186	197	300
Numbers of referrals	25,000	44,000 all hospitals	50,752
Bone Donors	150	1,193	1,455
Skin Donors	40	1,093	1,124
Eye Donors	2,000	2,324	1,189
Heart for valves	50	201	256
**** 54 hospital corporations comprised of 150+ hospitals***			

It is also evident from the data in Table 6, which compares TGLN to two similarly sized Organ Procurement Organizations in the U.S. whose scope of tissue activity resembles that of TGLN, that there is a great deal of potential for an expanded number of tissue donors. In particular, these comparisons indicate:

- The numbers of eye donors in Ontario compare favourably with the U.S. West Coast OPO. The data demonstrates that there is still room for improvement based on the number of eye donors obtained by the comparable U.S. East Coast OPO.
- The potential number of bone donors in Ontario is greater than 1,000 and the current Ontario rate is 15% of that amount.
- The potential number of skin donors in Ontario is greater than 1,000 and the current Ontario rate is 4% of that amount. Ontario needs only 100 skin donations for its skin for burn program. Additionally, the donor potential exists for skin recovery for the processing and provision of acellular dermal matrix (ADM) allografts should these grafts be processed locally in the future.
- The potential number of heart-for-valve donors in Ontario can reach approximately 200 per year; a fourfold increase over the current level of donation for heart valves.

It should be noted that the two U.S. donation agencies presented above have more mature programs with the benefit of many years of experience to advance donor outreach initiatives. Their donor registries were established more than ten years ago, and the routine referral of all hospital deaths has been in place for twenty or more years.

When comparing the Ontario system, the unconverted tissue donor potential in Ontario can be separated into:

1. Potential tissue donors already in the system; and,
2. Potential tissue donors not yet in the system

With almost 17,000 donor referrals from Tier 1 hospitals and over 25,000 referrals from all the hospitals in Ontario projected for FY 2013/14, TGLN is capturing a large segment of the potential tissue donors in Ontario. This represents donation potential already "in the system". Further evidence of this penetration of the Ontario donation potential is the number of eye donor recoveries occurring on an ongoing basis (a projected 1,235 from Tier 1 hospitals and approximately 2,000 overall). However, the same level of donor conversion is not occurring for bone, skin and hearts for valves. A review of the data presented in Table 7 indicates a significant number (2,512) of referrals deemed medically eligible are not being converted into tissue donations. Furthermore, over 300 referred cases for which consent has been obtained are not being recovered.

Table 7: Missed Opportunities for Donation by Region – Tier 1 Hospitals (FY 2013/14 Projected)

	Central & GTA	Eastern Ontario	Northern Ontario	Southwestern Ontario	TOTAL
Missed Eligible Referrals	1,216	304	205	787	2,512
Consented Not Recovered	152	33	36	85	307
FY 2013/14 projected based on for the nine months April 2 to Dec 31 2013					
At Least one tissue is suitable					

4.1.3 Consented Cases Not Recovered

From the 1,264 projected tissue donations recovered from Tier 1 Hospitals for FY 2013/14, eyes will be obtained in an estimated 95% of the cases, musculoskeletal tissue in 7% of the cases; heart valves in 2% of the cases and skin in less than 1%. A projected 307 of the total 1,571 projected consented cases will not be recovered during the same time period (see Table 8).

Table 8: Reasons for Consented Cases Not Recovered – Tier 1 Hospitals (FY 2013/14 Projected)

Not Recovered Reasons:	Cases
Deemed Medically Unsuitable	195
Lack of Team Available	33
Timed-out	5
Coroner Restrictions	5
Other	69
Total	**307***
FY 2013/14 projected on nine months April through December 2013.	

Table 9 indicates a further breakdown of consented cases not recovered, projected for 2013/14 from Tier 1 hospitals. As a percent of the donations recovered, the consented cases not recovered for eyes are 15%, high, but not excessively so. However, bone tissue cases not recovered from Tier 1 hospitals exceed the actual rate of donations recovered by almost two to one (197 vs. 92) and, similarly, heart valves not recovered outpace heart valves recovered by three to one (96 vs. 29). Skin tissue has the worst conversion rate at twelve to one (101 vs. 8). Clearly, important differences exist between the relatively strong conversion of eye referrals into donors and the weaker conversion for all other tissues.

Table 9: Consented Cases Not Recovered by Tissue and Region– Tier 1 Hospitals (FY 2013/14 Projected)

TYPE OF TISSUE	Central & GTA	Eastern Ontario	Northern Ontario	Southwestern Ontario	TOTAL
Bone	64	23	23	72	181
Eye	95	24	28	45	192
Skin	57	7	5	32	101
Heart for Valves	44	7	11	34	96
**FY 2013/14 projected based on for the nine months April 2 to Dec 31 2013*					

No single deficiency has been identified to account for the above lack of conversion of donor referrals into recovered donors. However, a number of practices and factors have been identified that are contributing to the unsatisfactory results:

1. A consented donor involving multiple tissues often requires the coordination of as many as four tissue banks.
2. The PRC's Tissue Recovery Coordinator is the TGLN staff person designated to recover eyes within the GTA. The same TRC takes hospital referral calls, screens referrals for medical

eligibility, speaks with next-of-kin for consent, and coordinates recovery logistics with tissue banks and hospitals. It is not unusual for a TRC to have to choose between tissue recovery and coordinating the next case, often to the detriment of one or the other, especially in their timing.

3. For enucleated eyes, recovery must occur within twelve hours from the time of death whereas the excision technique, if implemented, could extend this time to 18 hours.
4. Recovery teams are not always available 24/7.
5. Some cases are deemed medically unsuitable by the recovery team.
6. Coroner refusals and delays (i.e. Coroner's restrictions) sometimes occur (an estimated 5% of the 307 projected missed cases for FY 2013/14).
7. Most consented not recovered donor cases occurred in the Central/GTA region, where all of Ontario's tissue banks are either located or have recovery teams. Southwestern Ontario was second.
8. No skin recovery occurs outside of the GTA. Additionally, local practice requiring skin donors to be refrigerated for four hours prior to recovery is sometimes a limiting factor.

RECOMMENDATION ***TGLN should improve conversion of potential donor hospital referrals already "in the system" into consented and recovered donations by minimizing the number of consented donations not recovered.***

4.1.4 Missed Medically Eligible Referrals

Another area of focus to maximize potential tissue donors already "in the system" is the number of missed medically eligible referrals and consents. These are primarily cases in which TGLN's Provincial Resource Center is not able to reach next-of-kin or reach them in time. The number of missed medically eligible referrals by Tier 1 hospitals is projected to be 2,512 cases in FY 2013/14 (see Table 7). This area alone holds great potential to increase consented and recovered tissue donors. One of TGLN's priorities is bringing designated hospitals into compliance with the "Routine Notification Requirement". Given referral compliance is at 93%, TGLN should make missed medically eligible donors an organizational priority with the same focus applied to referral compliance. Better collaboration with Hospitals to coordinate approaches with next-of kin should be emphasized. In addition, the practice (not a policy) of the PRC not to call the next-of-kin between 11 p.m. and 8 a.m. contributes to the higher number of missed eligible donors. Given the narrow window of opportunity to recover tissues, TGLN should re-evaluate this practice.

The other challenge being addressed by TGLN is outreach to potential donors not currently being captured by the existing system. There are approximately 94,000 deaths per year in Ontario with 65% of them occurring in Ontario hospitals. With approximately 50% of deaths in Ontario occurring at the ages of 79 and younger, it is reasonable to estimate that 31,000 donors eligible by age occur in Ontario hospitals. With TGLN already receiving a projected 25,000 donor referrals, they are already capturing approximately 80% of the age eligible donors from Ontario hospitals.

That leaves 20% (approximately 6,000) of age eligible tissue donor referrals not being captured. As previously mentioned, TGLN already emphasizes hospital referral compliance from existing referring

hospitals. Additionally, routine referral is in the process of being expanded to include additional Class C hospitals.

If 65% of the deaths in Ontario occur in hospitals, then about 33,000 occur elsewhere. One source of potential, non-hospital tissue donors in Ontario is Coroners' offices. The Ontario coroner offices located throughout the province represent a significant source of potential additional tissue donation, but to date, there is no organized program in place to routinely identify and pursue these potential donations. As a result, tissue donation from coroner cases occurs infrequently. Coroner's cases typically represent sudden, unexpected deaths usually unrelated to disease or infection. In 2013, there were 16,586 coroner cases in Ontario, with only 3 percent of the associated deaths occurring in hospitals (see Table 10).

An organized coroner case screening program for potential donors could result in hundreds of additional eye and tissue donations per year. Additionally, tissue recovery in Ontario can be augmented by utilizing the dedicated tissue recovery suite in the newly opened facility housing the Provincial Forensic Pathology Unit in Northwest Toronto.

Table 10: Ontario Coroner Investigations and Autopsies

Region	Investigations	Autopsies	Hospital Deaths
Central East Office - Central Region	1531	212	70
Central West Office - Central Region	1863	318	70
Hamilton Office - West Region	2320	947	75
Provincial Forensic Pathology Unit	N/A	1773	N/A
Kingston Office - East Region	1464	218	52
London Office - West Region	2381	901	77
Ottawa Office - East Region	1853	625	48
Sudbury Office - North Region	1002	428	39
Thunder Bay Office - North Region	559	238	19
Toronto East Office - Central Region	2006	48	9
Toronto West Office - Central Region	1607	0	58
Total	**16586**	**5708**	**517**

RECOMMENDATION ***TGLN should improve conversion of potential donor hospital referrals already "in the system" into consented and recovered donations by reducing the number of missed medically eligible referrals due to not approaching the next of kin. TGLN should re-evaluate the practice of not calling next of kin between 11pm and 8am.***

RECOMMENDATION ***TGLN should establish a province-wide Coroners screening, consent, and recovery program.***

4.1.5 Tissue Recovery

Under an arrangement with the Eye Bank of Canada, TGLN is responsible for eye recovery in the province of Ontario. For consented donations that involve only eyes, the PRC's Tissue Coordinator (TC) will contact the local eye recovery person based in that region, (Eastern Ontario, Northern Ontario and South Western Ontario) to arrange for the recovery and shipment of donor eyes to the Eye Bank of Canada. For the majority of eye recoveries in the Central and Greater Toronto region, a PRC Tissue Recovery Coordinator (TRC) is responsible for responding in the recovery of whole eyes. In many eye donor cases, the TRC who obtained consent and completed the medical social history drives to the hospital and performs the eye recovery procedure. In addition, some potential donors are screened and recovered by direct referral to the EBC by funeral homes, coroners, nursing homes, and palliative care institutions. These eye donations are recovered by on-call, per-diem staff that is trained in eye tissue recovery.

For tissue donations other than eyes, each Ontario tissue bank is currently responsible for the recovery of its respective tissue. Either their own staff performs the tissue recovery or they arrange for another tissue bank to perform the recovery on their behalf. Table 11 indicates the organizations involved in tissue recovery.

Table 11: Tissue Recovery by Organization

Tissue Type	TGLN	EBC	OPFSB	MSAT	RegenMed	HSCTL
EYE	X	X		X		
BONE / MS				X	X	
SKIN			X			
HV				X		

Coordination of teams from several different tissue banks can be logistically challenging, and often results in delays and missed opportunities. TGLN has been in discussion with several tissue banks (RegenMed and MSAT) to develop a multi-tissue recovery team system to address this problem. Multi-tissue recovery teams comprised of staff from the participating Ontario tissue banks will be trained to recover all tissue (bone and associated soft tissue, skin, hearts for valves and eyes). This will eliminate the need for multiple tissue recovery teams on a single case which can delay the release of the body to the funeral home. Moreover, this initiative will broaden the geographical inclusion of donor skin outside of the GTA.

One complicating matter is the requirement by two tissue banks to have physician participation in the tissue recovery team (mostly interns and residents) because they believe it enhances the quality of the recovery. This requirement makes tissue recovery more difficult to staff, given the availability of physicians during the course of a normal work day. It should also be noted that the recovery of skin donors for burn patients is not performed outside of the Central/GTA because of the above physician requirement limits the geographical reach for skin recoveries. To our knowledge, no United States tissue bank or tissue recovery program requires a physician to be part of a recovery team. The following note provides more information on tissue recovery staffing requirements:

Staffing for Tissue Recovery *– Two tissue bank programs within Ontario strongly promote the recovery of tissue only by licensed physicians. While this level of medical training and experience may offer certain advantages, it is not a practice known to be required by any tissue bank in the United States. The American Association of Tissue Banks requires that all members of the recovery team be adequately trained and that the training be documented. These requirements are outlined in Section J2.000 Technical and Quality Assurance Staff - Training/Continuing Education of the Standards for Tissue Banking American Association of Tissue Banks, 13th Edition.*

The AATB requires that technical staff performing recovery must possess the educational background, experience, and training sufficient to assure that assigned tasks are performed in accordance with the tissue bank's established procedures, which must be written and approved by the Medical Director (B2.310). The training at U.S. tissue banks has evolved over time from the use of physician teams to trained technical staff teams that operate under the oversight of physician medical directors who create the written procedures and policies. Quality assurance department staff are responsible for ensuring that standard operating procedures (SOP's) based on practices established by the banks/physicians are followed, and competency of technicians is maintained and documented.

This transition from physician/surgeon recovery teams was a natural evolution due to the number of recoveries performed as the tissue banks grew in size and scope. Additionally, the recoveries became very lengthy and certain recoveries were outside the area of expertise for most surgeons. For example, an orthopedic surgeon is not used to routinely recovering skin, heart valves, veins and arteries. Medical Directors of the U.S. banks made sure that the best practices were established and required by the AATB and written into their own tissue banks SOP's.

Although differences occur at tissue banks in the U.S., a typical recovery team will consist of three or four members when any combination of musculoskeletal, skin, eye, and heart valve tissues is recovered. There is typically a technician on each side of the donor performing the recovery on that side plus at least one circulator. See the AATB Guidance Document – Prevention of Contamination and Cross-Contamination at Recovery: Practices & Culture Results [no. 2, version 2, May 29, 2007]. A fourth person may be present for a variety of purposes including training, responsibility for obtaining copies of or transcribing pertinent donor records, or as part of an internal audit assuring SOP's are being followed. For a heart valve only recovery, a two person team is sufficient, and one well trained technician is all that is required for eye recovery except when there are training or audit requirements.

The circumstances around a "fresh" osteochondral recovery may be viewed differently. The recovery is often a "custom" recovery which may not fit well into a highly prescribed/routinized procedure that can be easily described in a SOP. Additionally, fresh osteochondral recoveries are infrequent, as only one or two such recoveries per month may be needed by the MSAT program. This negates the issue of excessive time demands on the surgeons. In most cases, two surgeons may be needed, either because one is experienced and training another, or they are using the zoning recovery practices described in the above AATB Guidance Document. In any case the surgeon(s) will be part of a larger team containing technicians responsible for other duties.

RECOMMENDATION ***Consolidate and coordinate all tissue recovery under a new TGLN multi-tissue Recovery Department staffed by Certified Tissue Bank Specialists (CTBS).***

4.1.6 Summary of TGLN Strengths and Shortcomings

Strengths:
1. Strong recognition and acceptance of TGLN's role in the donation process by the Ontario hospital and tissue bank communities. 2. BeADonor registry with 25% of the population enrolled and growing. Almost 60% of tissue donations obtained in FY 2013/14 were listed as donors on registry database. 3. Routine Referral of Hospital Deaths currently contains 80% of age eligible hospital deaths within the 25,000 annual referrals projected for FY 2013/14. Referral compliance reported at 93%. 4. The TGLN Provincial Resource Center is well established and is augmented by a good data system, iTransplant, to capture relevant referral, screening and consent information. 5. Strong foundation to perform a centralized role to coordinate tissue screening, consent, and recovery. 6. Volume of eye donors is good with additional potential for growth. 7. TRC staff recovery of donor eyes in GTA (enucleation). 8. Initiation of recovery teams to streamline the recovery of multiple tissues: eyes, skin, bone and hearts for valves.
Shortcomings:
1. Compared to cornea donation, the conversion of bone, skin and heart-for-valve donations are low. 2. High number of consented tissue cases not recovered. 3. High number of medically eligible donors not approached and consented. 4. TRC staff recovery of eyes in addition to screening, consent and tissue coordination duties. 5. No formal program to screen, obtain consent and recover tissue from Ontario Coroner cases. 6. No consolidated multi-tissue recovery program

4.2 Tissue Bank Assessment

4.2.1 Overview

Eight tissue bank establishments involved with the recovery and processing of cadaveric tissue in Ontario are registered with Health Canada, with six of them representing the majority of the in-province tissue recovery, processing and distribution: two musculoskeletal tissue banks, one skin bank, one heart valve bank, one eye bank and TGLN. Two (of the eight) hospital based tissue banks recently discontinued their operations and were excluded from the review. In addition, there are five hospital based femoral head banks.

Users of the allografts processed by the tissue banks in Ontario consider them to be of good quality. There were no reports of quality issues by the surgeons or hospital professionals interviewed during this assessment of the Ontario tissue system. Our review discovered no adverse outcomes or disease transmissions related to allograft tissue provided by the tissue banks. The Ontario tissue bank processors do not provide an adequate local supply of certain high demand allografts, such as demineralized bone, precut corneal tissue and acellular dermal matrix. Because these more highly processed tissue allografts are not available locally, hospitals must source them from tissue providers outside of Ontario. The representations presented below are the results of data and information obtained during visits and interviews with each of the five major tissue banks and TGLN.

4.2.2 Eye Bank of Canada – Ontario Division (EBC)

Established in 1955, the EBC is the sole eye bank in Ontario providing corneal and other ocular tissue for sight-restoring surgery to surgeons and hospitals serving transplant recipients throughout the province. Recently relocated to the Kensington Eye Institute Building in Toronto, the EBC still operates under the auspices of the Department of Ophthalmology at the University of Toronto. The EBC is a registered tissue bank within Health Canada's regulation of organs, tissues and cells as well as an accredited member of the Eye Bank Association of America.

Of all the tissue banks in Ontario, the EBC is by far the most productive as measured by the number of donations obtained and the percent of allograft demand met by tissue sourced within Ontario. Yet, despite the advantage in the number of eye donors, a corneal transplant patient in Ontario may wait as long as 12 months, in part, because of a lack of available corneal tissue at certain times of the year.

a) Eye Donor Screening, Consent and Tissue Recovery:

The full-time eye bank staff do not perform tissue recovery but rely on TGLN's Provincial Resource Center staff in the Greater Toronto Area as well as a network of per diem, on-call physicians, nurses, residents and other trained staff for coverage elsewhere in Ontario. Except for a limited number of in-situ corneal excisions performed in the Ottawa region, all eye donations are obtained via eye enucleation that must be performed within twelve hours from the time of the donor's death.

The vast majority of eye donor referrals from hospitals are received by TGLN, whose staff coordinates the screening and consent of nearly 90% of the eye donor tissue ultimately provided to the EBC for processing and distribution. In addition, some potential donors are screened and recovered by direct referral to the EBC by funeral homes, coroners, nursing homes, and palliative care institutions. These eye donations are recovered by on-call, per diem staff that are trained in eye tissue recovery.

Utilizing the whole eye enucleation technique for virtually all eye donor recovery is rare among eye banks in North America today. Most eye banks outside of Ontario have incorporated the corneal excision technique for the recovery of eye tissue, whereby the cornea is excised, in-situ, and the remaining ocular tissue and posterior poles remain with the deceased.

If the donor tissue is potentially suitable for corneal transplant, whole eye recovery is followed by the excision and preservation of the cornea at the eye bank. Whole eye donor recovery allows for an abundance of scleral tissue for tectonic, glaucoma and oculoplastic surgery, and whole eyes are the most useful form of ocular tissue presentation for medical researchers and for medical education of eye bank staff, ophthalmic physicians, and surgeons. The corneal excision technique, on the other hand, allows the cornea to be placed in corneal preservation media much earlier than the process of eye enucleation. Preservation in a specially designed solution to maintain tissue viability is a critical step in the utilization of the cornea for transplant beyond several days. The time between a donor's expiration to the point at which the cornea is preserved in media, referred to as the "death to preservation" interval, is a key factor in considering donor cornea suitability for surgical use. A shorter death to preservation interval generally relates to improved tissue quality, and corresponding surgical outcome.

A review of 521 eye donor charts was performed for all donor eyes obtained from September to November, 2013. Over a 3 month period, 47 donors exceeded the 12 hour/24 hour preservation limitation for tissue to be considered suitable for corneal transplant. Improvement in this area, on an annual basis, could potentially increase the number of corneal tissues available for transplantation by 10% or 150 corneas from the current donor pool volume.

RECOMMENDATION ***TGLN should implement the corneal excision technique as the preferred tissue recovery procedure for eye donations identified with high potential to result in transplantable corneas. The whole eye enucleation technique should be for all other donations likely to be used for sclera, research and teaching. This should be rolled-out in the GTA in year 1 followed by other high donor volume regions (e.g. London and Hamilton) in years 2 and 3.***

RECOMMENDATION ***Narrow donor criteria to reduce non-transplantable tissue.***

- ***In years 1 and 2 – no change in criteria as a large number of whole eyes will be required for excision and precut training***
- ***In year 3 – conduct statistical analysis to target optimum donor criteria; potentially reduce upper age limit to 75 dependent on demand***
- ***In year 4 – conduct a second statistical analysis to target optimum donor criteria same as year 3; potentially reduce upper age limit to70 dependent on demand***

b) Eye Tissue Processing:

Cornea Evaluation and Preservation - The primary tasks for processing eye tissue are excision of the cornea from the whole eye, storing of the cornea in preservation media, slit lamp microscopy of the cornea and specular image microscopy of the corneal endothelial layer. A concurrent evaluation of the donor's medical and social history and serologic testing (principally done by Clinical Laboratories at Mt. Sinai Hospital) is also required for the detection of infectious disease such as hepatitis. Corneal tissue must meet all physiologic criteria, be free of any medical and high risk contraindications and have non-reactive serology results to be eligible for transplantation. Currently, over half the eye tissue recovered provides tissue for ocular surgery with over 40% used for full thickness or endothelial corneal transplants.

The EBC requires that all corneas be recovered within twelve hours of death and preserved in corneal storage media within twenty-four hours of death. Corneas recovered or preserved beyond either of these timeframes will disqualify the corneal tissue for transplantation. Considering the times, distances and logistics involved in recovering and transporting donor tissue, it is not unusual for some eye donor tissue to fall outside the aforementioned time limitations.

Precut Cornea Lamellar Grafts - Posterior lamellar keratoplasties are corneal transplant procedures that replace only the patient's compromised corneal endothelial layer. Since 2006, these lamellar procedures (referred to by the acronyms DSAEK and DMEK) have been replacing the traditional, full thickness corneal transplant (which replaces all layers of the patient's cornea) as the preferred surgical indication for most patients. EBC tissue distribution data for full thickness or endothelial corneal transplants indicate that between April and December 2013, approximately 65% of the corneal tissues were used in posterior lamellar corneal transplants in Ontario resulting in shorter patient recovery time, potential for less rejection by the recipient and often results in better visual acuity. These innovative surgical procedures have become the new standard of care for many corneal transplant patients thanks, in part, to the availability of equipment that can predictably cut the cornea to the desired, optimal thickness for the procedure being performed.

Currently in Ontario, surgeons cut the corneal tissue just prior to transplanting it into the patient. There are some drawbacks to this approach with the most important being a lack of an opportunity to assess post-cut tissue quality. With the EBC preparing cornea tissue for the surgeons, very rigid quality control processes will be in place that ensures the tissue meets the required standards. Currently there is no way for the surgeons to examine the tissue post-cut to see if the corneal thickness meets the necessary specifications or if any damage occurred during the cutting process. With multiple surgeons preparing tissue using various types of equipment and supplies, there is opportunity for significant variability in the end result. In addition, the surgeons utilize 30 minutes or more of OR time to cut the tissue. A number of corneas have been cut improperly by surgeons resulting in the surgery being cancelled after the patient has already been prepared in the OR and the tissue having to be discarded. This wastes valuable OR time and costs the system approximately $1,000 in wasted supplies and staff salaries.

Ontario lags behind other jurisdictions, both in Canada and the U.S., in the provision of pre-cut tissue as a core service of the eye bank. Specifically, all of the eye banks in Canada (with the exception of Manitoba and Ontario) pre-cut tissue and provide this service to the transplanting surgeon. In the U.S.,

approximately 80% of the eye banks pre-cut their tissue or contract with other eye banks for this service. As such, pre-cutting tissue is an important step in bringing the EBC up to the standard expected of most eye banks.

The EBC incorporated the space and redundancy necessary in their new laboratory and tissue processing suites for the eye bank to offer pre-cutting of corneal tissue. The EBC has started pre-cutting a limited amount of tissue as a small-scale pilot using one microkeratome system provided under a loan agreement from the Toronto East General Hospital. A business proposal for provisioning pre-cut tissue to all surgeons in the province was submitted to the Ministry for approval at the time of this report.

RECOMMENDATION ***The EBC should provision pre-cut tissue to surgeons in Ontario as a standard of practice beginning in year 1.***

Other Tissue Processing – While the cornea is the tissue in greatest demand for eye banks and is a primary focus of the EBC, the eye bank also processes other tissues used in ophthalmic surgery. Scleral tissue is the second most prevalent tissue processed and distributed by the EBC. Approximately 400 scleral grafts are distributed annually for sclera tectonic, glaucoma and oculoplastic procedures. The EBC also obtains donor amniotic membrane for processing into allografts that are typically used to resolve acute eye inflammation or to enhance post-surgical healing. The EBC distributes approximately 120 amniotic membrane grafts per year.

Tissue for Research & Medical Education - The EBC, with the extensive recovery of whole eyes, is the largest single source of whole globes for research and medical training and education in Canada. All donor eyes not processed into transplantable corneal and scleral grafts and free of infectious agents are eligible for research and education. This is an invaluable service for research institutions like the Department of Ophthalmology at the University of Toronto, as well as for the training of future ophthalmologists of all specialties throughout Ontario and the eye bank's own recovery and processing personnel.

c) **Facility & Equipment:**

The EBC's new 4,000 square foot quarters at the Kensington Eye Institute Building provide more than adequate space to handle the current 2,000 annual eye donors and resulting tissues for processing and distribution. Staffing for a second shift and additional equipment like new refrigeration systems would double the eye bank's capacity to process and distribute tissues. The EBC's processing equipment is considered present-day, if not state of the art; it is comprised of slit-lamp microscopes, specular microscopes, air flow hoods, and monitored tissue refrigeration. There was no equipment (specifically microkeratomes and artificial anterior chambers) at the time of our site visits for processing pre-cut lamellar grafts. As such, microkeratome systems for cutting and an Optical Coherence Tomography (OCT) unit to measure post cut cornea thickness and uniformity of the cut grafts would need to be acquired for provisioning pre-cut tissue to surgeons. EBC uses Optisol GS, the leading corneal storage media used throughout the world. On the other hand, some of the medical supplies, particularly the tissue transportation containers, are functional but dated, and EBC would benefit by updating to more modern systems.

RECOMMENDATION ***The EBC should replace the outdated tissue transportation containers with more modern containers.***

The EBC's medical records system is essentially comprised of paper donor charts and written logs. It is augmented partially by standalone Excel spreadsheets and an Access database. The manual and fragmented processes are inefficient and add workload as information is often inputted manually on paper and then transcribed again in another location. Additionally, there is no mechanism to readily query data or generate reports making tissue traceability and performance measurement challenging. Lastly, there is currently no link from TGLN's donor information system to the EBC resulting in delays and inefficiencies in obtaining information. The EBC would benefit from a computer based management information system to aid in daily donor and tissue processing and record keeping. Implementing an information system that is linked with TGLN's donor management system will provide integration between the two organizations in terms of data sharing, reduce workload, reduce human errors, allow for measurement and auditing, and enable quicker decision making and greater information security. Access to timely, summary and comparative data and information can only be of help to the EBC in its management and planning of the eye bank operations. In addition, the EBC's website does not provide good information to the public and is extremely dated in appearance, content and function and would benefit from an upgrade.

RECOMMENDATION ***The EBC should secure and implement new computerized information and data system for tissue distribution capability, order management and performance management***

RECOMMENDATION ***The EBC should upgrade the appearance, content and function of their website***

d) **Corneal Tissue Distribution:**

The EBC distributes approximately 1,500 corneas per year for in-province corneal transplant procedures to 29 surgeons at ten hospitals and the Kensington Eye Institute. Surgeon offices request corneas by phone, fax, or email with no patient identifiers (no request form). Instead they are requested for a specific day based on scheduled OR day(s). The EBC tracks requests manually by date and type of surgery. Surgeons may make special requests for corneas if there are unique considerations based on patient need (e.g. re-graft, monocular, young, procedure type). Some surgeons "reserve" tissue in advance based on a pre-determined OR schedule. The distribution system is a somewhat modified surgeon / hospital based system in that each surgeon is eligible for up two corneas per day for their scheduled block of operating room time. When additional corneas are available, surgeons and hospital are polled to see if they and operating room time are available to permit additional surgeries.

In 2013/14, in an effort to decrease the corneal transplant waitlist time, funding was provided for 400 cornea transplant procedures at the Kensington Eye Institute. Additional funding was provided to the EBC to import corneas from the United States in times of short supply.

e) EBC Staffing & Budget:

In the fiscal period 2013/14, the EBC's budget was reported at $1,707,349. Compared to eye banks in other jurisdictions, the EBC is currently operating at a staffing level lower than the standard. The recommended staffing level is 10 FTEs for an eye bank of similar size. The EBC staff consists of six full time positions performing tissue processing and distribution, two part-time Medical Directors providing medical oversight and numerous, on call, per diem staff performing corneal enucleations. Although the EBC is functioning at the current staffing level, when they move to pre-cutting tissue as a standard of practice, additional staffing will be required. Specifically, pre-cutting tissue requires particular expertise and additional time for set-up, processing, clean-up, training and documentation.

RECOMMENDATION ***To effectively meet the standard of practice of pre-cutting tissue, funding for additional staffing should be provided to the EBC.***

The eye bank's governance structure is not optimal as the EBC is a comparatively small unit within the larger University of Toronto's Department of Ophthalmology and Visual Sciences. The recent relocation of the EBC to the Kensington Eye Institute building makes oversight of the program even more removed. At the time of our review, there was no strategic or long range plan for the EBC thereby providing no context for the EBC to secure approval and funding for necessary operational improvements. The need for the EBC to pre-cut corneal tissue is a good example. There is no active governing board or unit nor medical advisory board or committee. This puts an inordinate amount of expectations and responsibility on the EBC's Manager who is already a very hands-on part of a suboptimal staffing level. The EBC needs an umbrella organizational structure to assist with budgeting, planning and new initiative proposals. Additionally, the EBC would benefit from formalized advisory outreach to its surgeon constituency.

RECOMMENDATION ***Determine the optimal governance and umbrella organization for the EBC. Considering the physical move to the Kensington Eye Institute building, Kensington Health is the logical choice. Additionally, with assistance from Kensington Health, complete a strategic plan and proactive implementation and management of the plan. Lastly, continue to leverage input from the EBC's corneal surgeon and transplant hospital constituencies (e.g. Provincial Corneal Transplantation Working Group).***

f) Eye Bank of Canada Strengths and Shortcomings

Strengths	Shortcomings
1. High donor volumes, relative to those of the other Ontario based tissue banks 2. New facility and modern processing equipment 3. Abundant supply of tissue for research and education 4. Tissue quality and safety – no reported disease transmissions or tissue related patient	1. Training and ongoing competency review of enucleators needs to be formalized. There are inconsistencies and gaps in enucleator continuing education and assessments. 2. Logistics related to corneal enucleation results in lost transplantable corneas 3. No pre-cut lamellar tissue by EBC. 4. Long patient wait times, in part due to inadequate

Strengths	Shortcomings
infections; reported adverse reactions within the norm	supply of corneal tissue 5. Essentially no computerized information and data system 6. Outdated tissue transportation containers 7. Outdated appearance, content, and function of website 8. Low number of staff compared to eye banks of similar size 9. Limited governance and strategic planning 10. Slow to identify and implement change – e.g. corneal excision, wait list and pre-cut tissue

4.2.3 The Hospital for Sick Children Tissue Laboratory (HSCTL)

The hospital based HSCTL program is the largest of Canada's four cadaveric heart valve programs. The other programs, listed in descending order by size, are located in Quebec, Edmonton, and Halifax. The HSCTL HV program is accredited by the American Association of Tissue Banks (AATB) and is registered as a CTO establishment with Health Canada.

a) **Demand for Heart Valves**:

According to HSCTL, they and the other three programs in Canada, cannot meet the national demand for human heart valves, particularly for pediatric patients. The Cardiovascular (CV) program at Sick Kids Hospital purchased 30 heart valves from tissue banks in the United States in 2013 because they could not provide the sizes required. Sick Kids Hospital uses Contegra from Medtronic – a bovine derived conduit used in the U.S. as a Humanitarian Use Device, when the proper heart valve size is not available. HSCTL estimates that about twenty Contegra pulmonary conduits are purchased annually, and that an additional 50-100 heart valves would enable it to provide for their two main users without having to acquire externally.

Because of the shortage of valves, especially pediatric sized valves, 80% of the allograft valves processed by HSCTL are used internally (at Sick Kids Hospital), 10% are used at the University Health Network - Toronto General Hospital, and the remaining 10% at various other facilities throughout Canada. The UHN-TGH Cardiovascular Department also purchases directly from U.S. tissue banks as well as from Sick Kids. Unfortunately, the smaller sized valves are also in short supply and in high demand in the U.S., as U.S. banks preferentially provide tissue to patients in the U.S.

There were 71 donors in 2012 and 53 in 2013. HSCTL estimated that about 50% of the heart valve donors were also organ donors. The program has been showing a slow decline since its peak in the 1990's when heart valve donors reached 167.

RECOMMENDATION ***One well organized heart valve processing centre could serve the entire needs of the country. Beginning in year 1, the HSCTL should strongly consider close collaboration with other HV programs in Canada and this collaboration with other Canadian programs should continue when the consolidated multi-tissue processing bank is fully operational.***

b) **Processing of Heart Valves:**

Pulmonary heart valves are the most commonly used valves for surgery. Some aortic valves and ascending arches are used in adults. The creation of HV allografts requires dissection of the conduits and valves from the heart, inspection of the allografts to determine their suitability for their intended use, sizing the allograft, and controlled rate freezing using liquid nitrogen. The packaged HV allograft is then stored in liquid nitrogen storage units until needed. A substantial number of heart valves are dissected and discarded due to a variety of conditions including positive microbiology and plaque formation.

In addition to HV tissue, the tissue laboratory at Sick Kids provides some cord blood, and pericardium. The tissue lab does not recover or process either arteries or veins which are common at U.S. based cardiovascular tissue banks.

c) **Facilities and Equipment:**

The HSCTL facility is modest but functional for the current level of activity and use. Laminar air flow hoods are used during the dissection of the hearts, control rate freezers use liquid nitrogen to cryopreserve the HV allografts, and liquid nitrogen storage containers are used to store the preserved HV tissue.

As in most hospitals, the space would be difficult to expand. However, since 150 hearts per year were processed in the past, it is reasonable to assume that this tissue lab could process that number again without additional space and equipment.

d) **Distribution:**

A reported 132 HV allografts were produced from the last 81 hearts recovered. From these 132 allografts, only about six pulmonary valves and ten aortic valves were transplanted in children in the Toronto area. This illustrates the primary problem facing HV tissue banks: the most prevalent HV donors (resulting in larger sized grafts) do not match the greatest need. Pediatric patients require smaller valves. This results in large inventories of adult tissue which become expensive to maintain. The upper age limit for the HSCTL program is currently sixty years of age. However, what are needed are smaller heart valves from younger donors. Currently, approximately 95% of hearts processed at the HSCTL are from adults, and of these, most of the heart valve donors are over the age of forty. Donors 50 years and older usually do not provide acceptable/effective aortic or pulmonary valves.

RECOMMENDATION ***The need for additional, younger donors requires special focus and collaboration with TGLN in order to address the need for more pediatric HVs. TGLN and HSCTL should strategize on identifying younger tissue and organ donor referrals and steps that can be taken to maximize consent and recovery of heart for valve donations from younger donors. Specifically:***

1. ***Using the TGLN Data Management System, quantify referrals of potential pediatric donors.***
2. ***From the above, identify potential pediatric donors by hospital confirming the potential will be largely concentrated at pediatric and Level I Trauma Centres. Supplement data gathering with death record reviews as needed.***
3. ***Collaborate with Ontario coroner's to pre-establish a procedure to address this urgent need for pediatric heart-for-valve donations.***
4. ***Address TGLN procedure for potential heart for valve donation to ensure these cases are prioritized by staff for screening, consent and recovery.***

e) **Staffing and Budget:**

The tissue lab's staff size is 3 FTEs plus two co-medical directors. One is a cardiovascular surgeon and the other is an AATB Certified Tissue Bank Specialist, as is the lab supervisor. Currently, the HSCTL staff is underutilized by tissue bank activities largely because of a recent decline in the number of HV donors. Their time is redirected to other activities at the hospital's laboratory departments.

The HSCHTL indicated that their tissue processing program is cost effective in that acquiring tissue would cost double that of processing the tissue in-house. If donor volumes were higher and there were more distributable HVs, that would be a valid contention, but given the current activity level, that premise is questionable. In the fiscal period 2012/2013 reported expenses were $185,079.

f) **HSCTL Strengths and Shortcomings:**

Strengths	Shortcomings
1. Strong medical director support 2. Very experienced supervisor 3. American Association of Tissue Banks Accreditation	1. Insufficient younger donors to meet demand for pediatric HVs 2. Upper donor age limit is too high 3. Unable to achieve economies of scale due to size and volumes

4.2.4 Lake Superior Centre for Regenerative Medicine Inc. (RegenMed)

RegenMed is an independent, free standing, not for profit tissue bank located in Thunder Bay. The processing facility occupies approximately 2,000 square feet of leased space. In addition to the main facility in Thunder Bay, RegenMed maintains a second satellite office in the Greater Toronto Area (GTA) near the Pearson International Airport which is used as the base for their Southern Ontario Recovery Team. The CEO of RegenMed also resides in the Toronto area. RegenMed is a registered CTO establishment with Health Canada but is not accredited by the AATB.

RegenMed is the only tissue bank in Ontario that is not part of a hospital. Its vision is to maximize the recovery of tissue, process tissue at a world class level, and distribute it back to Ontario as inexpensively as possible. They see themselves as responsive and proactive, with a plan for growth and the ability to

change and adapt. Their model is that of the larger free standing tissue banks in the United States such as Community Tissue Services. The processing facility was constructed in 2007.

a) **Tissue Recovery:**

The number of RegenMed's donors increased in 2013 from a re-allocation of tissue donations. Based on the number of musculoskeletal donations through December 31, 2013 (9 months), it is projected that 144 musculoskeletal donors will be recovered in Ontario for 2013/14 for both MS tissue processors. RegenMed's number of MS donations for the fiscal year is estimated to be 60. Beginning in December 2013 and continuing forward, RegenMed can expect to receive half of the provincial MS donations for processing at their Thunder Bay facility. RegenMed, modeling many of their activities on U.S. programs, uses a "technician based" tissue recovery team rather than a "physician based" team.

RegenMed's staff perceives that their organization's donor criteria is not always uniformly applied by TGLN's PRC staff when screening donations. Additionally, RegenMed reports difficulty in obtaining copies of certain information from a donor's hospital chart in a timely manner to complete a thorough medical history review. The TGLN staff of the PRC cited instances where consented cases were not able to be recovered by RegenMed recovery staff and inconsistent application by RegenMed's of its donation acceptance criteria. Monthly teleconference meetings have failed to adequately resolve such perceptions.

RECOMMENDATION ***RegenMed should ensure more frequent MS case review with TGLN, particularly feedback on every MS donation recovered and consented cases not recovered.***

b) **Tissue Processing:**

Twenty-six musculoskeletal (MS) donors were processed from Feb. 2012 to May 2013. The average yield (MS only) was 45 allografts from donors up to 70 years of age with an average donor age of 55. Males averaged 51 allografts per donor while females averaged 25. This is a small sample of processed donors and includes a higher percentage of ground cancellous bone for use in the dental market. These allografts tend to be small, 1 cc and 5 cc, which elevates the per donor yield. The 2007 AATB survey of accredited tissue banks indicates that allografts produced per donor range between 30 and 35. Using the 2013/14 projected recovery level of 60 donors leads to a projection that RegenMed can produce nearly 2,000 allografts per year.

Although RegenMed's intention is to offer a comprehensive catalogue of allografts, the allografts processed are commonly described as traditional, which refers to allografts that are processed using technology and techniques developed in the United States over twenty-five years ago. The tissue donated is essentially cleaned, cut and packaged so that the anatomical source of the tissue is still readily recognizable. The two most common tissue preservation techniques are freezing and lyophilization (freeze-drying) and RegenMed employs both methods. RegenMed is the only tissue bank with the equipment in place to freeze-dry MS allograft tissue in Ontario.

RegenMed also distributes tissue for the dental marketplace in Canada, offering 57 different types and sizes/volumes of dental specific allografts. Most of the dental allografts used in Ontario are currently

imported from the United States. RegenMed does not yet have the capability of either grinding or demineralizing cortical bone.

RegenMed has a tissue supply agreement in place with Community Tissue Services (CTS) in the United States. Located in Dayton, Ohio, CTS is an AATB accredited establishment and is one of the ten largest tissue banks in the United States. The agreement enables RegenMed to import tissue for distribution to Ontario hospitals, helping them maintain adequate inventory levels to complement their portfolio of available allografts, inasmuch as their processing capability is currently limited to a select group of traditional allografts. One such tissue is skin for burn and wound care patients shown in RegenMed's catalog as an available allograft. CTS is one of the largest providers of skin for burns in the United States and skin is not one of RegenMed's reported recoverable tissues.

Another set of tissues distributed by RegenMed are the pre-shaped Achilles tendons and pre-shaped patellar ligaments with a bone block(s) attached. The pre-shaping of the bone block attached to the reconstructive allografts reduces the surgeon's work in the operating room. Tissue banks performing this shaping in the processing facility leads to a routinely higher quality allograft and saves valuable OR time as the allograft can be inserted without significant shaping performed by the surgeon.

A review of RegenMed's processing SOPs, job descriptions and training documents indicate an understanding of modern tissue quality assurance/control procedures consistent with those promulgated by the American Association of Tissue Banks (AATB). At the time of our on-site review, RegenMed had not yet applied for an AATB membership or accreditation inspection, but staff stated that it was an important goal to gain accreditation in the near future.

RECOMMENDATION ***Beginning in year 1, until the consolidated multi-tissue processing centre is operational, RegenMed should formalize a partnership with MSAT to maximize the processing and distribution of musculoskeletal allograft tissue within Ontario to reduce the provincial reliance on imported tissue.***

- ***RegenMed, as the only processor of musculoskeletal tissue currently operating in Ontario, is able to process musculoskeletal tissue into traditional allografts for MSAT to more fully utilize RegenMed processing capacity.***
- ***Inventory sharing of traditionally processed MS tissue by RegenMed and MSAT would allow each organization with a backup supply to enhance and ultimately broaden their abilities to adequately service their Ontario hospital customers, particularly those hospitals relying upon imported tissue.***

RECOMMENDATION ***In year 1, RegenMed should begin processing enhanced allografts beginning with demineralized bone until the consolidated multi-tissue processor is operational.***

c) **Facilities and Equipment:**

RegenMed's facility has a Class 10 clean room for aseptic processing, and a Class 10,000 room for second stage processing and packaging. The facility is relatively new (6 years) and well organized. Key capital equipment in place includes ultra-low temperature freezers and a freeze drying unit (lyophilizer). In 2014, they plan to purchase of a bone grinder for the production of ground cortical bone, an early stage processing step needed for the production of demineralized bone matrix (DBM).

RegenMed claims they can process 120 to 200 MS donors per year in their facility as currently configured. This is likely accurate if the types of allografts being produced are of the traditional type and the same allografts that they already have experience fabricating. The maximum capacity of the current facility footprint may be as high as 200 donors per year for traditional MS tissue processing with the addition of a second shift and a corresponding addition of staff and equipment.

Processing in excess of 200 MS donors annually and/or production of advanced allografts will require two to three additional clean rooms and an expanded processing support space of approximately 5,000 square feet. More modern processing, such as demineralized bone in a carrier, will require multiple processing steps over longer periods of time.

d) **Distribution:**

RegenMed uses a network of medical representatives to market allografts. These distribution reps are independent contractors acting on behalf of RegenMed as well as other medical device firms; companies such as Smith & Nephew. RegenMed reports using distribution representatives across Canada, of which 16 are located in Ontario. RegenMed is also considering building upon a modest direct distribution base.

The five top allografts distributed by RegenMed in terms of revenue in descending order, are femoral heads, Achilles tendon with bone block, posterior tibialis, dental cancellous, and course ground cancellous. These are all traditionally processed, non-proprietary allografts that continue to be in strong demand as they have been for decades. The inventory ready for distribution on the date of the site visit was approximately 500 allografts comprised from frozen non-irradiated, frozen irradiated and freeze-dried irradiated preservation and sterilization processes.

e) **Staffing and Budget:**

In addition to the Director/General Manager and the Quality Assurance Manager, the staff at the Thunder Bay operation consists of 3 full-time and one part time staff. There are 4 per diem staff in the GTA to assist with recovery as well as per diem staff to assist in recovery around Thunder Bay. These recovery teams are comprised of non-physician medical technicians.

RegenMed's tissue revenue was $444,500 in calendar year 2012. At the time of our on-site visit, the monthly revenue in 2013 was about $35,000, and was expected to increase in 2014. Critical factors for successful operations, at this time, are said to be increasing donor numbers and the corresponding revenue levels needed to sustain both the current operating expenses and growth expectations.

f) **RegenMed Strengths and Shortcomings:**

Strengths	Shortcomings
1. Free standing tissue bank 2. New modern processing facility 3. Comprehensive business plan 4. Local support and funding 5. Board of directors/advisors 6. Freeze-drying capability	1. Donor numbers insufficient to achieve break even financials 2. Location is remote 3. Small market share 4. No economies of scale due to small size and insufficient volumes 5. No enhanced tissue processing 6. RegenMed is not AATB accredited

4.2.5 Mount Sinai Allograft Technologies (MSAT)

Mount Sinai Allograft Technologies (MSAT), established in 1972, is a hospital based tissue banking program located in Toronto. At the time, MSAT was one of the few organized tissue banks in North America whose scope of tissue recovery and processing extended beyond the recovery of surgically discarded bone.

Like many of the early tissue banks, MSAT focused on providing musculoskeletal (MS) tissue to meet the new demand for cadaveric MS tissue. MSAT is currently located within Mount Sinai's Department of Pathology/Blood Bank. MSAT is a registered CTO establishment with Health Canada, an accredited member of the American Association of Tissue Banks and a registered tissue bank with the U.S. Food and Drug Administration.

a) **MSAT Fresh Tissue Program:**

MSAT is widely known for its pioneering work in the provision of fresh musculoskeletal tissue. This is a very unique program which is used for certain types of orthopedic surgery (i.e. bone cancer, large trauma cases, etc.). MSAT is the only program that provides this service in Canada. The few such programs in the U.S. provide freshly preserved allografts throughout the U.S., rather than within more limited states or regions. MSAT's fresh tissue program continues because of the higher demand in Ontario associated with Mount Sinai Hospital's reputation as a centre for these surgeries.

For this program, MSAT recovers and processes allografts at the time of tissue recovery. The allografts are then stored "fresh" (not frozen, hence the name) until they are used in surgery within a very short time. Relatively fewer donors are needed for a viable fresh allograft (osteochondral) program. MSAT reports about one donor per month is needed to support the demand for fresh tissue allografts at Mount Sinai Hospital. However, with roughly twenty patients reportedly waiting up to two years, MSAT could benefit from increasing the number of fresh tissue donors. Their current space would allow for storage of three times their current volume should the provincial and national demand increase.

b) **Tissue Recovery:**

MSAT performed 92 MS donor recoveries in 2011 and 108 in 2012. Based on the number of musculoskeletal donations through December 31, 2013 (9 months), it is projected that 144 musculoskeletal donors will be recovered in Ontario for 2013/14 for both MS tissue processors. MSAT's number of MS donations for the fiscal year is estimated to total 84. Beginning in December 2013 and continuing forward, MSAT can expect to receive half of the provincial MS donations for processing.

Recovery staff is typically a 4 person team (for MS), all of whom are physicians. Also, the staff is continually changing. There is currently 12 to 15 staff that can be called on for recoveries. The recovery staff receives reimbursement from the governmental OHIP program when physicians perform the tissue recoveries. MSAT strongly believes that their requirement for physician only recovery teams is a strength of the program. As mentioned in the TGLN assessment, the standard of practice is to use Certified Tissue Bank Specialists and recover tissue using 3 person teams which are more efficient and cost-saving.

In addition to recovery of MS tissue for its own program, MSAT performs eye enucleation for EBC and heart valve recovery for the Hospital for Sick Children's Heart Valve program. At the time of this report, MSAT staff is anticipated to participate in a TGLN led initiative to enable multi-tissue recovery (MS, skin, eye and heart valve) on a routine basis throughout Ontario. This program is expected to begin in FY 2014/15.

RECOMMENDATION ***In year 1, MSAT should move toward utilizing 3 person recovery teams led by Certified Tissue Bank Specialists (CTBS). This should continue until TGLN's multi-tissue recovery program is operational. MSAT should maintain physician led recovery teams for fresh tissue allografts.***

c) **Tissue Processing:**

Modern tissue banking has evolved to the point where 30 to 300 human allografts can be processed from one MS donor depending on the allografts produced. In order to perform to state of the art level processing, a facility of sufficient size and sophistication is required. The processing time can range from hours in the case of aseptically, minimally processed allografts, to months for allografts requiring lyophilization and sterilization. In addition, specialized equipment is required to employ different processing and preservation techniques to craft allografts to the different sizes and shapes required by modern surgery today. On-site visits to MSAT confirmed that the program currently does not have the dedicated space or the comprehensive array of equipment required for in-house, modern tissue processing.

With 70 MS donors per year to process for traditional MS allografts (total of 80 projected less ten for the fresh tissue program), MSAT should be able to obtain approximately 2,000 processed allografts of the types and sizes listed in the MSAT tissue catalog. These MS tissues will include cortical shafts, struts and plates as well as cubed or morselized cancellous and cortico-cancellous bone. Sports medicine allografts include meniscus as well as achilles, patellar, gracilus, semi-tendenosus, tibialis and peroneus longus tendons.

MSAT's solution to the problem of limited donors, space, and facilities, has been to contract with third party organizations to process all of its recovered MS tissue into traditional MS allografts including the production of freeze-dried traditional allografts. At the time of the first site-visit and for the last three years, MSAT's contracted processor was Therapure Biopharma, Inc. located in Mississauga, Ontario. By the time of the second site visit, MSAT had put a new processing agreement in place for traditional allografts with a U.S. tissue bank, Bone Bank Allografts, in San Antonio, Texas. MSAT does not provide or have made for them proprietary tissue allografts such as machined spine allografts, demineralized bone matrix (DBM), and DBM in the form of paste or putty. These allografts must be imported from other sources in the United States. The average yield in units per donor for (MS) applications in 2012 was 34. This may be a result of some allografts being redirected to the MSAT fresh osteochondral program that offers larger allografts.

RECOMMENDATION ***In year 1, MSAT should obtain access to specialty processed allografts from a contract processor(s). This includes demineralized bone, demineralized bone in paste, putty of gel carrier, freeze dried tissue and pre-cut spinal grafts. This should continue until implementation of a consolidated multi-tissue processing bank is completed.***

RECOMMENDATION ***Beginning in year 1, until the consolidated multi-tissue processing centre is operational, MSAT should formalize a partnership with RegenMed to maximize the processing and distribution of musculoskeletal allograft tissue within Ontario to reduce the provincial reliance on imported tissue.***

- ***MSAT can reduce or eliminate the number of Ontario MS tissue donations exported to the U.S. for processing of Traditional MS allografts to more fully utilize Ontario based processing capacity.***
- ***Inventory sharing of traditionally processed MS tissue by MSAT and RegenMed would allow each organization with a backup supply to enhance and ultimately broaden their abilities to adequately service their Ontario hospital customers, particularly those hospitals relying upon imported tissue.***

d) **Facilities and Equipment:**

The current facility at MSAT is about 1,400 square feet, including office space and space for storage of tissue recovery supplies and the storage of unprocessed and processed tissue allografts. MSAT's major equipment includes approximately six -80°C freezers, of various ages, located in an adjacent hallway. Although not observed during either site visit, MSAT reports that they already have the necessary equipment to process traditional MS allografts.

e) **Distribution:**

MSAT's processed tissue available for distribution in Ontario is very basic, the kind traditionally offered by tissue banks for 25 years. A list of tissue available from MSAT can be found on their website. MSAT utilizes approximately 15 independent customer service representatives who also distribute Zimmer and Stryker products. Distribution to hospitals other than Mount Sinai are provided on a per tissue, fee for

service basis. MSAT acts as a distributer for Bone Bank Allografts (BBA) distributed tissues, in addition to BBA returning to MSAT allografts from donors initially recovered by MSAT in Ontario and subsequently processed by BBA.
The tissue inventory contained 57 different allograft types of which 10 are of the fresh osteochondral type produced directly by MSAT. All other types of allografts in inventory were produced by Bone Bank Allografts or Therapure Biopharma. If one includes different sizes of the types of allografts, the total offering was 78. As a comparison, a mid-sized U.S. bank would have about 400 offerings in a portfolio.

f) **Staffing and Budget:**

MSAT currently has 4 full-time staff and one part-time employee. One additional FTE manages MSAT's marketing and distribution. Financial and cost information was not readily available, but a reasonable estimate of their annual operating budget is $1,000,000 to $1,250,000.

g) **Plans for the Future:**

MSAT reported their intent to restart in-house processing when sufficient improvement in MS donor volumes makes it feasible to do so. They expressed interest in participating in the national processing centres of excellence initiative that is under discussion, and are considering establishing a viable business plan for a new facility as a separate business entity, outside the hospital for that purpose. As for frozen and freeze dried traditional allografts, there is no practical limit other than those imposed by the volume of recovered donors and the capacity of their current contracted processor in the United States. Even if BBA does not want to or cannot process the additional donors from MSAT, it would be easy to add a second U.S. processor or change to a larger processor with greater capacity. Contracting with U.S. banks also gives MSAT the ability to have state of the art allografts and technologies processed from their recovered donors and available for their customers.

h) **MSAT Strengths and Shortcomings**

Strengths	Shortcomings
1. Fresh osteochondral program 2. AATB accreditation 3. Long experience in tissue banking 4. Surgical research / publications. 5. Training opportunity for surgeons	1. Insufficient donor volumes therefore, insufficient allograft supply 2. No in-house tissue processing of traditional MS allografts, and no current resources (lab space / staff) to commence such processing. 3. No specialty tissue allografts (e.g. demineralized or precision cut spinal allografts). 4. 4 person physician-based recovery teams used instead of 3 person recovery team lead by Certified Tissue Bank Specialists 5. No economies of scale due to small size and insufficient volumes

4.2.6 Ontario Professional Firefighters Skin Bank (OPFSB)

The Professional Firefighters Skin Bank is located in the blood bank department at Sunnybrook Health Sciences Centre in Toronto, Canada. The stated purpose of the OPFSB is to provide split thickness skin for the hospital, provincial and emergency needs. The blood bank/skin bank also operates a surgical bone bank. The program is registered with Health Canada as a CTO establishment.

a) **Tissue Recovery:**

The number of skin donations recovered in FY 2012/13 was 40 and is projected to be the same or slightly lower in FY 2013/14. Only 7% of organ donors were also skin donors over that time. OPFSB indicated that they require 80 skin donors per year just to meet the demand for the treatment of severely burned patients at Sunnybrook Hospital. In order to offset the local shortfall of processed skin, the processed allograft equivalent of an additional 40 donors per year is imported by the OPFSB for the Sunnybrook hospital burn centre from Hema-Quebec. The OPFSB has recently had to import one skin order from the U.S.

The reported post-processing yield of skin from each skin donor is 0.10 square meter. This is very low compared to the post-processing yield obtained by U.S. based skin programs. Skin recovery should average about 0.30 square meters per donor. The stated reason for the low yield was that recovery was only performed on the posterior of the donor. Most skin donor programs recover skin from both the anterior and posterior areas of the donor. Apparently, this posterior only procedure was developed some time ago because of an agreement with tissue banks that recover musculoskeletal (MS) tissue including fascia, bone, tendons and ligaments, based on the belief that MS tissue could not be removed aseptically from the anterior limbs of the donor after a skin recovery.

This belief needs to be addressed so donation gifts can be maximized and the yield of skin per donor increased. One method that might alleviate this concern is leaving a track of unrecovered/intact skin along the incision line that the MS team follows in their tissue recovery. Alternatively, there is no contraindication in performing the MS recovery just after the split skin recovery, as this is the most common practice. We suspect this practice was also a result of employing multiple recovery teams that were performing tissue specific recoveries. The new recovery practice being implemented in Ontario is to train all teams for all competencies involved in recovering every type of tissue offered by a single donor. Another recovery practice currently in place, refrigerating skin donors for at least four hours to obtain better quality skin, should also be reassessed. This practice is not used in any program known to the authors of this report, and it invariably causes timing problems and missed donation opportunities. Lastly, it had been the OPFSB's policy for skin recoveries to be performed by a physician led recovery team. However, there have been significant instances when the OPFSB could not provide physician led teams, which resulted in missed skin donors. To address this problem, OPFSB is collaborating with TGLN to establish technician staffed multi-tissue recovery teams.

RECOMMENDATION ***Maximize donor yield from skin donors by addressing the following:***

1. ***Removing the requirement to refrigerate the donor's body for 4 hours prior to skin recovery***
2. ***Increase recovery yield to 0.3 square metres per donor***

b) **Tissue Processing:**

Last year, the OPFSB processed about 40 donors from split thickness skin recoveries for burn and wound applications. The preservation method employed is cryopreservation. According to the OPFSB, complete processing of a skin donor can take as much as ninety-six hours, but most skin donor processing can be performed within one day. The OPFSB does not have a fresh skin (refrigerated - not cryopreserved) that a few surgeons prefer. Neither does the OPFSB recover or process skin/dermis for acellular dermal matrix (ADM), which is used in reconstructive surgery for burn patients and other surgical applications utilizing soft tissue allografts. Demand for ADM in Ontario is substantial and growing. ADM is currently is imported from the United States by providers such as LifeCell.

The OPFSB currently does not provide meshed skin. Meshing is a way of processing split thickness skin to enhance healing and to expand the allograft so it can be used to cover a larger area of a wound. The meshing process is currently performed in Ontario by the burn surgeon in the operating room. This adds time to the surgery and requires the hospital to purchase and maintain meshing devices. Today, most skin banks offer both meshed and non-meshed skin for burn surgeons.

RECOMMENDATION ***A consolidated tissue processing bank should pursue the capability to process acellular dermal matrix (ADM)***

c) **Facilities and Equipment:**

The major piece of equipment used in the recovery of split thickness skin is a dermatome The OPFSB's processing and storage equipment includes a laminar air flow hood under which the processing is performed; two control rate freezers, four ultra-low mechanical freezers and three cryopreservation tanks, essentially the same equipment used in heart valve processing laboratories. The OPFSB estimated their annual capacity is large enough to process skin from 150 skin donors.

d) **Distribution:**

The OPFSB distributes more skin than they can process as evidenced by the importation of processed skin accounting for half of the need of the burn center based at Sunnybrook. The OPFSB would also like to maintain an adequate supply of tissue for emergencies, a volume of 1.0 to 1.2 square meters. The reality of skin bank programs is that inventory can be carried for quite some time without much distribution. Major burn events are fairly infrequent, but whenever more than one person is involved in a burn event or a single burn victim is burned over 40% or more of his body, a large amount of skin is required and is used up quickly. Burn allografts applied to patients are not permanent. They are replaced frequently on wounds during treatment. One square meter of inventory can be used in a very short time.

Another hospital in Ontario treating burn patients is the Burn Unit at Hamilton Health Science Centre (HBU). The shortage of supply combined with the high cost of obtaining skin from the U.S. led HBU to rely on porcine xenografts and autografts (skin removed from the patient from non-burned regions and used in burned areas) for patients. HBU has nine beds and treats 130-150 burn victims per year. About 1 burn patient per month is a severe case where human allograft skin may be used. HBU considered

operating their own skin recovery program but found the cost prohibitive so their current need for tissue remains.

When we interviewed the OPFSB, they had 5 femoral heads in inventory and amniotic membrane (5 larger pieces for burns and 2 smaller pieces for ocular applications). The bank also had a few assorted bone and tendon allografts in stock for use in the hospital, which was obtained from other programs.
The OPFSB would like to build a reserve inventory as a contingency measure should there be a large, scale catastrophic event. We estimate that 100 skin donations per year would allow OPFSB to meet the needs of Sunnybrook, Sick Kids and Hamilton hospitals as well as contribute toward an emergency stock of frozen skin

e) **Staffing and Budget:**

The 2013/14 OPFSB budget is approximately $250,000, mostly for staff and supplies. The hospital operating room and blood bank budgets cover the rest of the costs of importing skin and maintaining the program. Their budget was essentially the same as it was five years ago. The staff consists of 2.5 full time equivalents.

f) **OPFSB Strengths and Shortcomings**

Strengths	Shortcomings
1. As part of the hospital blood bank, additional resources can be brought to bear as required. 2. Six blood bank staff are AATB Certified Tissue Bank Specialists. 3. Processed skin considered "high quality"	1. Provincial demand for skin to treat burn patients exceeds the supply. 2. Difficulty keeping intact physician led recovery teams in place. 3. Recovery of donated skin is limited to the GTA. 4. There is no processing of ADM and there is insufficient space to accommodate ADM processing. 5. Donor yield is not maximized due to current recovery practices 6. Missed skin donors due to lack of multi-tissue recovery teams trained in skin recovery

4.2.7 General Tissue Banking Recommendations

Beyond the shortcomings noted in our report including fragmentation, redundancy and the other limits of largely hospital-based tissue banking, the Ontario tissue banks as structured do not have the capacity to process all the tissue at the required donation levels. As such, Ontario should establish a new consolidated tissue processing entity and facility for province-wide processing of musculoskeletal, skin and cardiac tissue. The processing of eye tissue and fresh musculoskeletal tissue are not included in the discussion of consolidated tissue processing. Fresh osteochondral allografts are processed at the time of tissue recovery and the recently built eye bank facility has no capacity limiting factors.

RECOMMENDATION ***Ontario should centralize all tissue processing (MS, skin, cardiac tissue) by implementing a consolidated multi-tissue processing bank that will spread fixed costs over greater volume and achieve greater economies of scale. This will include the following:***

- ***a. Select and communicate a consolidated tissue model to tissue stakeholders***
- ***b. Establish or contract a single processing entity.***
- ***c. Construct a new Toronto based facility.***
- ***d. Provide for contract processing of specialty tissues.***

RECOMMENDATION ***Tissue banks should be AATB or EBAA accredited to process tissue in Ontario***

4.3 Tissue Transplant Listing and Allocation Practices

4.3.1 Overview

One true test of the efficiency of a tissue donation and transplant system is the sufficiency of allograft tissue. The adequacy of tissue supply can be measured by reviewing back orders and tissue allocation or rationing practices. The use of less desirable tissue alternatives such as xenograft tissue, synthetic materials or mechanical devices can be an indicator of an inadequate supply of human allograft tissue.
At the start of our field work reviews, we were aware of the wait list for corneal tissue and the low volumes of musculoskeletal, skin and heart valve donation in Ontario. We anticipated encountering management practices at the tissue banks and surgical hospitals, such as patient wait lists and allocation policies that addressed shortages of certain tissue. Instead, with very few exceptions, hospitals and surgeons reported no problems obtaining their desired tissue allografts in the form and quantity they desired.

As a result of Ontario based tissue banks having limited supplies of tissue, hospitals and dentists secure tissue allografts from a combination of Health Canada registered CTO establishments from other provinces in Canada or the U.S., either directly or through registered distributors in Canada. Hospitals typically utilize two or more allograft tissue suppliers to maintain a timely, sufficient supply. In short, the tissue "markets" made the necessary adjustments to satisfy the unmet demand for tissues. In the absence of shortages of tissue and supplies, there is no need for patient wait lists or tissue rationing.

There are some exceptions to the above such as wait lists for corneal tissue and fresh osteochondral allografts. Although not waiting lists per se, there are some other examples where improved availability of human tissue from the Ontario tissue banks would improve patient access to care.

4.3.2 Corneal Tissue

The EBC has the best performance level of all Ontario based tissue banks, providing over 1,500 transplantable corneas per year. 97% of the tissue for corneal transplants comes from local eye donations and the remaining 3% is imported from other Canadian and U.S. eye banks. However, the total is still insufficient to meet the annual demand and eliminate the corneal transplant wait list, as surgeons and ophthalmology departments rely on the EBC for all of their ophthalmic tissue needs while balancing limits of hospital operating room time and the number of transplants surgeries budgeted per year. Specifically, waiting occurs for patients in need of an endothelial corneal allograft, a procedure that requires the replacement of the patient's endothelial cell layer of their cornea. Corneas for other tectonic or structural corneal surgeries as well as sclera, amniotic membrane and other infrequently requested ophthalmic tissue is readily available.

Since 2010, Cancer Care Ontario's Access to Care Program has been measuring wait times for corneal transplant procedures as part of the Provincial Wait Times Strategy. During the last few years, the news media reported many news stories about patient wait times in Ontario and throughout Canada, some as long as two years, due to an inadequate supply of corneal tissue from the eye banks in Canada, including the EBC.

A review of recent EBC data in conjunction with reports from Access to Care indicate that the current annual supply of corneas in Ontario is slightly above the annual demand. The reported wait times for the percent of transplant cases completed within each Access to Care target for four corneal transplant priority levels have improved from 57% in April 2010 to 82% in December 2013. This corresponding decrease in waiting times is consistent with recent surgeon reports at the TGLN sponsored Cornea Transplant Working Group meeting in January, 2014 where corneal transplant programs reported decreases in their wait list in both number of patients and days. While this represents progress, the ultimate goal, from the eye bank's perspective, is that no patient will wait because of a lack of available corneas.

Solving the corneal patient wait list dilemma in Ontario is not as straightforward as obtaining and providing more corneas, inasmuch as demand in terms of scheduling patients for surgery also depends on available operating room time for corneal surgery and the annual number of procedures budgeted by the hospitals. Until surgeons and hospitals have greater certainty that corneal tissue will be consistently available, surgeon scheduled operating room times and hospital budgets for corneal transplants will likely remain unchanged. The lack of greater demand from surgeons and hospitals, coupled with an allocation system that caps corneal usage, limits the impetus for the eye bank to provide additional tissue.

Two improvement strategies have shown some success. In 2013, the MOHLTC authorized funding for 400 corneal transplants to be performed on an outpatient basis at the Kensington Eye Institute, and the EBC was given additional funding to import corneas from other Canadian and U.S. eye banks to augment local supply. Wait times are expressed in terms of how often the stated 182 day performance goal for corneal transplants to be performed is met. Within each Access to Care target for four corneal transplant priority levels, this measure improved from meeting this goal 57% of the time in April 2010 to 82% in December 2013. This is consistent with recent surgeon reports at the TGLN sponsored Cornea Transplant Working Group meeting in January, 2014 that corneal transplant program wait lists decreased in both number of patients and days. While this represents progress, there are still patients waiting for a corneal transplant and more improvement is needed.

Ideally, improvement of the EBC's allocation and wait list practices should occur in conjunction with the EBC's implementation of a computerized eye bank management system (see Section on IT Infrastructure Assessment). Available eye bank management systems have corneal distribution modules that support tissue ordering and distribution activities. Since the EBC manages corneal distribution and allocation with hand written logs and schedules, it is not realistic to implement a complex system in the interim time period. However, several steps can be implemented in advance of a computerized system:

RECOMMENDATION ***Improve cornea transplant allocation and wait list practices by implementing the following steps:***

1. ***Require each institution to provide a monthly report of the total number of patients on its waiting list, and for the upcoming two months, for every scheduled surgery to include: a unique patient identifier, the urgency category using Access to Care definitions, the type of surgery to be performed, the expected location, scheduled time, and date, and any other information or special request.***

2. ***Formalize the tissue request. At least one month in advance, a tissue request form should be provided to the EBC by each institution for each upcoming surgery. The EBC should cross reference each request form against that institution's monthly patient list.***
3. ***Eliminate the two corneas per surgeon per day allocation limitation.***
4. ***Implement the following capacity building strategies:***
    1. ***EBC to provision pre-cut tissue as a standard of practice***
    2. ***Address holiday and summer OR closures by establishing an alert system for when surplus tissue is available***

Implementation of the above steps will provide the EBC with the information it needs to improve corneal distribution. First, the EBC will be able to measure its customers' long term tissue needs and infer whether demand is increasing, decreasing or stable. It will have more complete recipient information to support tissue selection and maximization of tissue supply, and a more precise, two month window of future tissue needs will aid in its preparation of pre-cut corneas and determine when the EBC needs to import corneas. Perhaps most importantly, during times when the EBC has a surplus of transplantable corneas relative to the scheduled demand, the EBC will be able to better assess which surgeon or hospital can perform additional surgeries.

The long-term solution to the wait list problem is to increase the number of corneal tissues available from the EBC. This report contains recommendations to increase donation volumes, implement corneal excision recovery techniques, and have the EBC pre-cut corneal tissue. All of these interventions will contribute to increasing the supply of corneal tissue, but the EBC should also take steps to establish a patient based distribution system from their current surgeon/hospital based system.

4.3.3 Other Tissues in Short Supply

The Trillium Gift of Life Act charges TGLN "...*to establish and manage waiting lists for the transplant of tissue and to establish and manage a system to fairly allocate tissue that is available."* TGLN is already actively involved in reducing the shortage of corneal tissue, but some other tissues in short supply are not addressed by waiting lists and allocations, as are organs and corneas. These are worthy of TGLN's attention.

a) Fresh Musculoskeletal Tissue (Osteochondral Allografts)

MSAT reports that they have a waiting list of twenty or so patients at any one time for osteochondral or osteo-articular tissue allografts. The number of annual donations for these larger tissue grafts is reported to be between ten and twelve. While it is theoretically possible to obtain more than one graft per donor, the timing of the surgery and the matching of the graft's size with the patient often permits only one graft per donor. Additional donor candidates for fresh tissue recovery can be identified to reduce the waiting list. Optimally, fresh tissue recovery can be performed on additional recoveries and recovery teams can recover the residual tissues for standard musculoskeletal tissue processing.

RECOMMENDATION ***TGLN and MSAT to review every quarter the Mount Sinai hospital patient wait list for osteochondral tissue to determine the optimal number of fresh tissue donations needed.***

b) Skin for Burns

Virtually all skin processed by the OPFSB and about an equal amount imported from Hema-Quebec is provided to the Ross Tilley Burn Centre at Sunnybrook Hospital. The OPFSB does not have an adequate supply of skin for burns to provide other Ontario hospitals. No waiting list is maintained and these other hospitals, notably Sick Kids Hospital and the Hamilton Health Sciences Centre Burn Unit, must obtain any needed tissue directly from other suppliers.

Sick Kids Hospital, whose annual need is modest, also obtains allograft skin from Hema-Quebec. Until recently, the Burn Unit at Hamilton Health Sciences Centre preferred to use porcine skin. However, their distributor recently discontinued supplying this xenograft, and they now report a need for skin grafting material. Although not as large as the Ross Tilley Burn Centre, the Hamilton Health Sciences Centre Burn Unit reports about one severely burned patient per month who could benefit from allograft skin.

Of all the tissue recovered in Ontario, the prospect for donation volume increases is greatest for skin, as is detailed elsewhere in this report. The ultimate solution is to both increase the number of skin donations and increase the yield of skin recovered per donation. The most recent annual number of skin donations stands at 40 per year. An additional 60 skin donations should allow the OPFSB to meet the need of the Ross Tilley Burn Centre as well as have an adequate supply for every hospital in Ontario.

RECOMMENDATION ***TGLN and OPFSB to review the need for skin by the burn units at Sick Kids Hospital and the Hamilton Health Science Centre and work to address this need.***

c) Pediatric Heart Valves

There are no waiting lists for human heart valves maintained in Ontario. Any shortfall is addressed through the increased use of xenograft heart valves and human heart valves imported from the U.S. masking the true need for additional, locally provided HVs. Children with congenital heart defects are one of the patient populations served by the HSCTL, and the need for pediatric heart valves is particularly acute. Pediatric patients require smaller heart valves, typically from similar aged donors. Sick Kids Hospital uses every small valve allograft processed by HSCTL and supplements that supply with human heart valves imported from the U.S. if they are available. Alternatively, xenograft porcine heart valves are used when necessary. The biologic material preferred by most surgeons is an appropriately sized human heart valve. If more were available, fewer alternative materials would be used. The HSCTL estimates 150 hearts for valve donations per year are needed to adequately meet the demand.

RECOMMENDATION ***TGLN and HSCTL should strategize on identifying younger tissue and organ donor referrals and steps that can be taken to maximize consent and recovery of heart for valve donations from younger donors.***

4.4 IT Infrastructure Assessment

4.4.1 Introduction

Tissue donation and transplantation involves organizations collaborating regularly, and sharing and exchanging critical healthcare data. For activities that comprise tissue donation and transplantation in Ontario, information systems and the related technological infrastructure are fragmented, and with few exceptions, modest in scope and practice.

The current methods and processes used to send and receive data will prove to be a limiting factor and unnecessarily increase risks, when tissue donation levels and allograft volume, sourced from Ontario, significantly increase. To extract, transmit and store medical data about donors, tissues and allografts, a variety of methods are currently employed including: paper files, hand written logs, computer spreadsheets, transmission by individual/independent emails and faxes, and other nonaligned processes. Comprehensive reporting of activity across the complete continuum of donation and transplantation (donors → tissues → allografts → recipients) is never contemporaneous and usually must be assembled in a piecemeal fashion.

As with organ donors, TGLN serves as the focal point for information about tissue donors and is the entity initially collecting, reviewing and processing vital medical information. These attributes of TGLN, the basic foundation of IT services in place, coupled with its unique position and role in Ontario, are very important. TGLN embraces and is ready to leverage its position as the focal point for information in the province. Even more importantly, TGLN has already identified the limitations of the current IT practices used in tissue donation and transplantation in Ontario, and recognizes its unique position enabling it to address the shortcomings. Addressing the interdependence of the donation and transplantation field and the need for improved infrastructure in terms of information exchange requires more resources to "maintain and support TGLN's new vendor supported Donor Management System (launched in April 2013) and build web interfaces between TGLN's information systems and other external partners to facilitate data exchange."[1]

4.4.2 Ontario Donor Registry

"BeADonor" is the portal to Ontario's online organ and tissue donor registry. Ontarians, 16 years of age or older, can register their consent to donate specified organs and tissues after their death for the purposes of transplantation or transplantation and research. This information is recorded in a government database. Ontarians may register online, in person at a ServiceOntario center, or by mail. The online registration process is quick and efficient. An Ontario citizen provides basic information including his/her date of birth and unique OHIP health card number, and the registrations are recorded in the Ministry of Health and Long-Term Care database. ServiceOntario is the custodian and operator of the donation registry, which runs on a system called 'Entrust'. The beadonor website and the promotion of the registry and registration process is the responsibility of Trillium Gift of Life Network (TGLN).

Access to the Registry is currently limited to ServiceOntario. TGLN staff must work in collaboration with ServiceOntario to receive consent to donate information. TGLN staff receives consent to donate information for referrals by submitting the OHIP identification number of the donor, along with the donor's name, gender, and data of birth to ServiceOntario which searches the Registry to determine if the donor is listed. If a hit is found, ServiceOntario returns the details about the individual's wish to donate or exclude specific organs and tissues. Registry listings are for affirmation of donation only.

If there is no listing on the Registry, this is communicated back to TGLN. Previously, information was sent from ServiceOntario to TGLN by encrypted email; more recently, a password protected WORD document has been emailed and uploaded to the Donor Management System. As a backup to the Registry information, ServiceOntario provides a 'ticket number reference' which may be used to retrieve the document. There may be instances when the process of obtaining Registry information between TGLN and ServiceOntario threatens the narrow window of time for the approach of the next of kin to offer the opportunity for donation. There also may be instances when the system is down. There is no alternative source for the Registry information.

4.4.3 TGLN Information Systems

TGLN is ideally positioned, in terms of activities and its mandate, to lead efforts for a significant advancement in tissue program information systems and infrastructure in the province. TGLN also has the foundation that can be leveraged to further the progress to develop a world class tissue donation and transplantation system.

a) Professional Staff and the Information Systems (IS) Department

TGLN's literature and business plan emphasize that "Sufficient information system staff resources has become the 'critical success factor' for TGLN to meet its program objectives related to improved patient access and outcomes, efficient and effective system performance, as well as smooth operation of mission critical services."[2] TGLN is focusing additional resources to further strengthen the IS Department. Information systems and technology spending comprises roughly 13% of TGLN's total base operating budget in 2013/14, a further indication of how important information management and reporting are to its success.

b) Risk Management

TGLN's overall risk management plan identifies risks associated with its information systems and supportive technologies. Mitigation strategies, including resource requirements and completion timelines, are communicated to senior management and fully documented. Recently the following risks were noted:

1. The need for the TOTAL software system (see subsequent section for more details about TOTAL) to be upgraded and migrated to an information platform better suited to ensure continuous system functionality;
2. The need to extend the hours of the on-site IS Department to support 24/7 operation of the Provincial Resource Centre (TGLN's contact/call centre);

3. Identifying how to monitor customization and increase the scope of the newly installed Donor Management Systems software and evaluating the impact of this on the data warehouse and other systems.

c) Internal and Public Reporting

Trust and transparency are paramount if TGLN is to continue to build the confidence with other stakeholders in the field of donation and transplantation, and the public. To sustain this, TGLN needs to ensure that the data it holds is robust and accurate and have an adequately funded IS Department. The TGLN Business Plan states that for "…fiscal year 2014/15, TGLN will continue to refine the public reporting initiative. Moving forward on public reporting will require significant support from TGLN's IS department for data validation, analysis and development of electronic tools to aid online reporting and publishing of findings. The need for public reporting was identified by the external reviews conducted by the Expert Panel and OAGO [Office of the Auditor General of Ontario]. Additionally, it is consistent to the spirit of the Public Hospitals Act which requires hospitals to publicly report on patient safety indicators. Public reporting will increase transparency and accountability and support TGLN's quality improvement efforts in the provincial donation-transplantation system."[3]

Effective, consistent internal reporting and communications are also critical to TGLN's success. Information is the primary resource managed by TGLN; consistent real time and historical information are essential for delivering basic services, performance monitoring, quality improvement and program growth.

d) TOTAL Software System

TOTAL, or Trillium Organ and Tissue Allocation System and database, was launched in fiscal year 2005-06 and is used to support donor management and fair allocation of organs from donors to patients on the waiting list for transplantation. TOTAL is a software system that is essential to TGLN's responsibility to manage the fair allocation of organs. Its focus is on the TGLN organ program.

The Provincial Resource Centre (PRC) is the nerve centre for organ and tissue donation. It is the focal point for incoming referral, screening and management of potential and actual donor cases. Incoming and outgoing information, other than voice, is managed in part by software and computer systems. The heart of the PRC call/contact centre is its voice system software: Interactive Intelligence's Customer Interaction Centre (CIC) 3.0. Size and stability are important factors in choosing a software vendor for the long term. TGLN's Information Systems Department plans to upgrade from CIC 3.0 to 4.0 (the newest version). TGLN currently has a one year contract with i3Vision Technologies for maintenance and support.

Telephone calls received and placed by staff in the PRC are recorded digitally, for the purposes of quality assurance and risk management. From a business continuity perspective, the software system has the capability for remote communication from multiple alternative workplaces and locations. An emergency protocol is in place for when calls into the PRC are blocked. Should power to the office be lost, an Uninterrupted Power Source (UPS) unit on site permits the PRC to continue operations for up to four hours. There needs to be a formal, written plan in place for continuity of services at an alternate location

in the event of an emergency. The Eye Bank of Canada – Ontario Division is identified as a likely space for coordination in a disaster recovery event.

e) TGLN Donor Management System (DMS) - iTransplant

TGLN relies on iTransplant, its newly installed Donor Management System (DMS), to record and track donor referrals and related data, and to manage organ and tissue donors. This system is important for organs and perhaps even more so for tissues, for handling the large volume of referrals and cases that must be managed from start to finish.

Feedback from TGLN staff using iTransplant is consistently positive, although not surprisingly, the deployment of new software resulted in some problems in reporting tissue activities. The TGLN DMS iTransplant system went live April 2, 2013. However, although data is currently being entered into the system, the ability to extract and report data has not yet been fully implemented. Referrals and donor information were previously collected and managed by the TOTAL software system, and preprogramed reports could be run by operations staff using the IBM report writer COGNOS. Due to the high level of customization, staff indicated that much of the limited iTransplant standard reporting features are not being utilized. Because iTransplant has the ability to collect data at significant granularity, the system has extensive reporting capability. To tap this potential, TGLN is instead leveraging its existing expertise and resources. Specific features/modules that are available from the iTransplant system include:

- "24/7 Call Center, Donor Referral and Screening
- Organ Donor Recovery and Organ Offers / UNOS uploads (DonorNet, DNR, DDR)
- Tissue Recovery and Offers/Processor Allocation
- Comprehensive Eye Banking, from Recovery through Inventory, Processing and Distribution
- Hospital Development, Family Services, Case Note Logs, Quality Assurance, Staff Scheduling
- Reporting and Management Dashboards
- Automated Notifications and Communication Features
- Audit Log, Case Lock and Other Quality Assurance Features"[4]

iTransplant has the scalability to handle higher volumes of donors and even more importantly its modular features for tissue recovery and eye bank processing may be an ideal prescription for the current limitation of information systems employed for recovery activities. The Tissue Recovery module of iTransplant gives TGLN the capability to capture detailed information on each type of tissue recovered – eyes, musculoskeletal, skin and heart tissue. Ideally the recovery team or individual could enter this data contemporaneously at the recovery site on a laptop computer, either in real time or for later transmission. Alternatively the numerous information screens can be printed and the hardcopy data later transcribed when a computer is available.

iTransplant's Eye Bank Module captures and manages information for the complete continuum of eye bank activities: referral, screening, consent, recovery, processing, tissue quarantine and release, inventory management, distribution and customer service features are all available. The eye bank standard module allows surgeons or their representatives to email tissue requests that can be managed by the iTransplant software. Built into the software is a 'surgery calendar' that enables the eye bank to see and manage requests, confirmed orders, shipped tissue, even returns, for all surgeon customers. Surgeons can provide

recipient information directly into the system with private, secure access into the software. Standard reports are available for the eye bank module. One notable user is the Eye Bank of British Columbia. If the Eye Bank of Canada – Ontario Division employs the software, some already customized features, unique to Canada, will already be in place, ready to be replicated and customized as needed.

RECOMMENDATION ***TGLN should continue to leverage the capabilities and features of the TGLN Donor Management System (iTransplant) beginning with the implementation of the iTransplant Eye Banking module.***

An unexpected snag was identified in discussions with TGLN and Transplant Connect. An important, practical feature of the iTransplant system allows detailed information (e.g. medical history) about a donor to be transmitted digitally from the system to the tissue bank(s) that will process the donor's tissues with a single keystroke. iTransplant information is converted to a PDF which is sent by facsimile. An easier work around is being explored in which information would be converted to an e-document that could be emailed to the tissue bank processors, using the Canadian Government's eHealth Agency's secure ONEMAIL system. However, currently information is not transmitted to the EBC electronically because the mail is not encrypted (i.e. ONEMAIL). This will not be an issue for the EBC once the iTransplant Eye Banking Module is implemented which will result in a streamlined process for sharing information.

4.4.4 Tissue Banks' Information Systems

a) Eye Bank of Canada – Ontario Division

The EBC's information and record keeping system is essentially comprised of paper donor charts and written logs. It is augmented partially by standalone Excel spreadsheets and an Access database. With donor volumes currently 2,000 per year, the EBC needs a computer based information system to facilitate daily donor and tissue data management and record keeping. The ability to quickly access, query and report on individual and aggregate donor and tissue data will better enable the EBC to manage and plan eye bank operations, the EBC's dated website needs refurbishing.

b) The Lake Superior Centre for Regenerative Medicine (RegenMed)

RegenMed's information systems include tracking logs in the form of excel spreadsheets, a program called Freezerworks, which tracks tissue after it is released for distribution, and a product called Q-Pulse that manages and controls Standard Operating Procedures. The spreadsheets include an electronic Referral Call Log, a Deceased Donor Log, and a Processed Tissue Log. Freezerworks records location in freezer/on shelf, and once tissue has been ordered, the distribution location, recipient information, and surgery performed. The Freezerworks company website describes the software as "…a powerful and flexible database program for tracking…frozen samples. It accommodates all freezers and tanks and offers…features for assigning freezer positions, moving samples, and importing and exporting data."[5] Q-Pulse is made by Gael Ltd, a Scottish based company, whose website states: "Q-Pulse is the proven quality, safety and risk management solution for thousands of organisations across the world…used in 86 countries, by over 2,500 organisations and by over 1.25 million users."[6]

c) Ontario Professional Firefighter Skin Bank (OPFSB)

OPFSB uses a number of methods to manage, track, and trace donors, tissues, and allografts. External Allograft Skin is currently tracked on paper. Next fiscal year, that tracking will be done by Hemocare Life Line (HCLL) when it is moved to the Blood and Tissue Bank computer system. Processed Allograft Skin is tracked in a File Maker Pro data base. Allograft Bone and any human or animal manufactured products are tracked in HCLL. FileMaker, Inc., an Apple subsidiary, delivers innovative software to easily create custom business solutions for iPad, iPhone, Windows, Mac and the web. Millions of people, from individuals to some of the world's largest organizations, use the FileMaker Platform to streamline their business processes, manage essential information, and boost overall productivity."[7]

d) The Hospital for Sick Children Tissue Laboratory (HSCTL)

HSCTL currently uses Filemaker Pro (see the previous section) to manage, track, and trace donors. The Filemaker Pro software is maintained by the hospital. Along with electronic databases, they maintain hardcopies of all donor information which is archived indefinitely.

e) Mount Sinai Allograft Technologies (MSAT)

MSAT uses a combination of excel spreadsheets, hard copy paper work, a Lab Information System and an Access database.

4.4.5 Tracking and Tracing Tissues – ISBT 128

Identification numbers for donors, tissues and finished allografts in the province, although apparently unique, do not follow a coordinated and systematic pattern. Of more concern is that specific individual donors, tissues, or allografts may have two or more different identifying numbers. The organization managing the referral, the organization performing recovery, and the organization processing the tissue may all use their own identification numbers, exclusively or in combination with another entity's identification number. This may impede the ability to track tissues and allografts completely, universally, and quickly, when time is of the essence. In the case of a recall, due to a donor issue, a large number of allografts coming from a single donor (recovered, processed and distributed by a number of different tissue organizations) must still be tracked and traced. The current use of multiple identifications coupled with a lack of coordination is a risk that needs to be address.

Uniquely coding allografts naturally aids tracking in the event of a recall or the rare need to link them allografts if implicated in an adverse reaction report.[8] There are a number of initiatives in place or in development to address universal coding of cells and tissues to enhance traceability and recipient safety. The North American Tissue Technical Advisory Group a combination of AATB [American Association of Tissue Banks] and ICCBBA (the International Council for Commonality in Blood Banking Automation, Inc.) have work together to evaluate ISBT 128 use. The membership is composed of representatives from tissue banks across the US and Canada, and liaisons from FDA…[and] Health

Canada…."[9] ISBT 128, along with two other coding standard, "…will likely be approved by the Food and Drug Administration [and]…are globally accepted for medical devices"[10]. Such a coding system as ISBT 128 will not only allow for unique identification of an allograft but promote the use of a labeling system that will include universally understandable defined traits and medically use about the allograft. Such practices in coding coupled with efficient and effective computer systems can make best practices in allograft tracking and tracing possible, even with large amounts of tissue and allografts dispersed in more than one jurisdiction.

RECOMMENDATION ***Adopt and transition to using a UDI (unique device/allograft identification) system for identifying donors/tissues/allografts for best practices and most efficient and effective tracking and tracing capabilities. Recommend the use of ISBT 128. Steps toward implementation include:***

1. ***Ensure TGLN iTransplant software and subsequent systems software implemented by the EBC and the Consolidated Multi-tissue Processing Centre can adopt ISBT 128.***
2. ***Stage 1 – Begin with the adoption of the terminology for tissue developed by ICCBBA in Year 2.***
3. ***Stage 2- update software to enable ISBT 128 data structures in Year 3.***
4. ***Stage 3 – implementation at TGLN and EBC concurrent with new Consolidated Multi-tissue Processing Centre system coming online in Year 4.***

4.4.6 Wait List Registries and Reports

In addition to its recognized activities related to Ontario's fight against cancer, CCO operates the Ontario government's Access to Care (ATC) program in support of the Ontario Wait Time Strategy where data is collected to enable the measurement and reduction of wait times for certain surgical procedures in Ontario. One of the original key health services identified for the Wait Time Strategy was cataract surgery. The scope of ophthalmic surgeries was expanded in 2010 to include cornea transplant surgeries. Information from the ATC contributed to strategies to reduce the wait time for corneal transplant surgery. To date no other surgical procedures that exclusively incorporate allograft tissue are tracked by ATC.

4.4.7 Hospital Information Systems

Hospital information systems in the province vary widely, from paper systems to sophisticated electronic health and medical record management. As an example, one large hospital still uses a DOS (the acronym for the legacy 'Disk Operating System' software) based system that does not allow them to add fields for information about death referrals. Instead, paper documents that provide information about referral, including a TGLN checklist, had to be added to the "death packages". In addition, the hospital wards and units still use a manual 'Admissions/Discharges' log for patients. These logs now include the TGLN donor referral number, which serves as a reminder to staff to complete the referral call to TGLN. This particular hospital's patient charts and health information records are currently still in paper format.

From a tissue and allograft perspective, transplantation surgeries are identified, but more clarity would allow for better precision in the interpretation of data – specifically in what kind of, as well as, how many

allografts are being used. The Canadian Classification of Health Interventions (CCI) codes include hundreds of procedures involving transplantation, but specifics as to whether the implant used was a homograft (another term for allograft), autograft, xenograft or synthetic are not fully discernible. Outcomes for these surgical procedures are not tracked or otherwise reported.

However, data about health care in specific areas and specialties in Canada and Ontario is available. The Canadian Institute of Health Information's (CIHI), "…mandate is to lead the development and maintenance of comprehensive and integrated health information that enables sound policy and effective health system management that improve health and health care across the nation."[11] In Ontario a series of comprehensive databases are used on a continuous and regular basis, and are available for study, analysis and research by heath care managers and workers, epidemiologists, economists and the public. For other sections of this report, data extracted from the Discharge Abstract Database (DAD), the National Ambulatory Care Reporting System (NACRS), the Ontario Case Costing Initiative (OCCI) and the Ontario Health Insurance Plan OHIP by Preyra Solutions Group[12] made possible estimates concerning number of transplantation procedures performed on an annual basis in Ontario as well as related cost estimates.

4.4.8 Collection of Data for Canada

Canadian Blood Services (CBS) currently uses Transplant Connect to assist in capturing nationwide information for tissue recovery and management. TGLN provides them a specific format for the data it sends to CBS each month. The source establishment tissue banks send TGLN pertinent data and TGLN in turn, sends the information onto CBS. The data format used for reporting represents a consensus of the various tissue banks operating across Canada.

4.4.9 Conclusion

From the perspective of tissue donation and transplantation, the information systems and technology used in Ontario are fragmented. Although some silos of progressive systems and technology exist, other areas are rudimentary and antiquated. Trillium Gift of Life Network (TGLN) has the foundation and position in terms of information systems and technology that can be leverage to move data management and sharing to a much more sophisticated and effective level. The TGLN Donor Management System, iTransplant, can be expanded to allow additional data to be electronically captured, transmitted and store for the activities of tissue donor recovery. iTransplant's Eye Bank Module may be an ideal fit for the Eye Bank of Canada – Ontario Division to fully employ, as the eye bank program is greatly in need of updated information systems and technology. TGLN is also in a unique position to introduce and mandate a provincial wide system for tissue/allograft tracking and tracing for recipient safety.

RECOMMENDATION ***Establish linked data management systems with TGLN, the Eye Bank of Canada, and the Consolidated Tissue Processor.***

4.5 Funding Assessment

4.5.1 Funding Sources and Funding Flows

The major activities of the transplantation field can be divided into two distinct but related stages.

1. The first stage includes medical screening, tissue processing and delivery of tissue implants (allografts) to the surgical site.
2. The second stage encompasses transplantation surgeries and the hospital and physician care necessary for successful outcomes for these procedures.

These two stages require significant resources to bring quality health care services to patients in the province on a consistent basis. "In Ontario, many [but not all] of the health care services [citizens and residents] needs are publicly funded. This means that the government pays all or part of the cost. … Services include: visits to…doctor[s] and specialists [and] most basic and emergency health care services, including surgery and hospital stays."[13] The second stage referred to above, transplantation surgery, involves surgeon specialists and, in almost all cases, the use of hospitals for inpatient service or day surgery and its associated support. Although overall Ontario healthcare is paid for by a mix of public and private money, transplantation surgery and its accompanying care are publicly funded. The provincial healthcare system "…is at its most public when it comes to physician and hospital services; 91 per cent of the former and 99 per cent of the latter are paid for by governments."[14]

The first stage, donation, related tissue recovery, and processing and distribution activities, are also funded (ultimately) with public money in Ontario. But the flow of funds in this first stage and the associated activities from tissue donation to allograft placement at the surgical site are more intricate, in terms of the number of small, but unique roles and transactions that contribute to the process.

Many of the activities in the first stage of donation and related tissue recovery, processing and distribution are funded by hospital budgets. Hospitals pay source establishments directly for allografts provided on a fee for service basis. In several unique instances, hospital funding for allografts is made by directly supporting tissue bank programs based at that specific hospital. Four tissue banks that follow this model were reviewed in this assessment. Other public funds are expended from the MOHLTC to further the donation of tissues and related activities and directed to unique entities. One pivotal organization which receives direct public funding is TGLN which plays a leadership role in promoting, supporting and coordinating donation and transplantation activities in Ontario.

The public financing that supports tissue donation and transplantation flows from the MOHLTC through a number of channels. The MOHLTC channels funding, for a number of major health care services, through the 14 Local Health Integration Networks (LHINs). The MOHLTC also makes payments through the Ontario Health Insurance Plan (OHIP) directly to physicians, including transplant surgeons and other physicians who provide supporting services for transplantation cases. OHIP health care procedures codes are defined by the authority of the MOHLTC and each procedure code is linked to a stated reimbursement rate or fee.

Hundreds of OHIP defined procedure codes relate to some form of transplantation in a wide array of specialties (orthopedics, ophthalmology, ENT, neurological, cardiology, etc.). The funding of hospital and physician costs for transplantation activities flows from the MOHLTC by way of LHINs for the former and by payment of OHIP procedure fees for the latter.

Estimating the costs of allografts is complicated by the fact that they are sourced from two different tissue banking systems. One operates within the province of Ontario and the other with tissue providers located outside Ontario. The majority of allografts used in Ontario are from tissue banks from other provinces or the U.S. To a limited extent, some of these imported allografts are first acquired by Ontario tissue banks and then redistributed to hospitals and surgeons in the province. Payments for most of these imported allografts are on a fee for service basis, with funds flowing from the acquiring hospitals directly to the source establishments. However, funding for the services that comprise in province allograft production (identification and referral of donors, obtaining consent for tissue donation, screening and testing, recovery, processing, storing and distributing) is less direct and more fragmented.

Within Ontario, the key funding stakeholders that comprise the Ontario tissue banking system are listed below.

- Trillium Gift of Life Network (TGLN) – tissue dedicated services (not to include organ procurement activities)
- The Eye Bank of Canada – Ontario Division (EBC)
- Mount Sinai Allograft Technologies (MSAT)
- Lake Superior Centre for Regenerative Medicine (RegenMed)
- The Ontario Professional Firefighters Skin Bank (OPFSB)
- The Hospital for Sick Children Tissue Laboratory (HSCTL)
- Physicians involved in tissue and eye donor recovery activities – supporting the above eye and tissue bank programs

4.5.2 Summary of Funding and Costs

Preceding sections of this report summarized activities and costs related to tissue donation and transplantation in Ontario. Most of the costs, although approximated, are relatively straightforward in terms of understanding the source of funding and the activities associated with them. However, some activities and related costs overlap and are less clear. For example, the section 'Transplantation and related costs (Hospitals and Physicians)' reported an approximation of the costs of allografts used in Ontario in a twelve month period in the "Supply specific" column. Further analysis shows that the amount, just over $8.9 million, is not sufficient to represent the total costs of allografts used. Combining all of the previously described costs for tissue and allografts sources recovered and processed within Ontario with the $5.5 million amount for allografts imported, results in a total approximate cost of $14.6 million. And if the survey amount of $5.5 million for total imports is replaced by the more realistic $13.0 million estimate, calculated from Millennium Research Reports[15], the total value of allografts used in the province is approximately $22.0 million. The details of these calculations are shown in Table 12. $22.0 million will be used as the approximate total aggregate allograft costs in this report.

Table 12: Annual Costs of Allografts (Approximate)

Aggregate Costs of Allografts - Approximate Value Used in Twelve Months			
Trillium Gift of Life Network	$ 3,836,187		
Eye Bank of Canada - Ontario Division	1,707,349		
Mount Sinai Allograft Technologies	1,240,750		
The Lake Superior Centre for Regenerative Medicine	1,233,361		
Ontario Professional Firefighters Skin Bank	249,353		
The Tissue Laboratory at the Hospital for Sick Children	144,227		
OHIP Recovery Costs Not Included in Other Entities' Costs	690,600		
Costs for Tissues Sourced Within Ontario	9,101,827		
Survey Amount for Imported Tissue	5,500,000		
Total Value of Allografts Used in Ontario	$ 14,601,827		
Adjusting to higher estimate for Imported Allografts			
Costs for Tissues Sourced Within Ontario	$ 9,101,827		
Adjusted Estimate for Imported Tissue	13,000,000		
ADJUSTED Total Value of Allografts Used in Ontario	$ 22,101,827	~	**$22,000,000**

In Table 13, the $22.0 million amount for allograft costs is included, and stated separately, along with costs for hospital and physician services from transplantation surgery and related costs (hospitals and physicians). The schedule displays costs for all components of donation and transplantation in Ontario as $104.5 million, segmented by total surgical costs ($61.5 million) and total nonsurgical ($43.0 million). It also displays summarized hospital and physician costs broken out for both surgical and nonsurgical components, with the allograft portion of hospital surgical costs displayed separately.

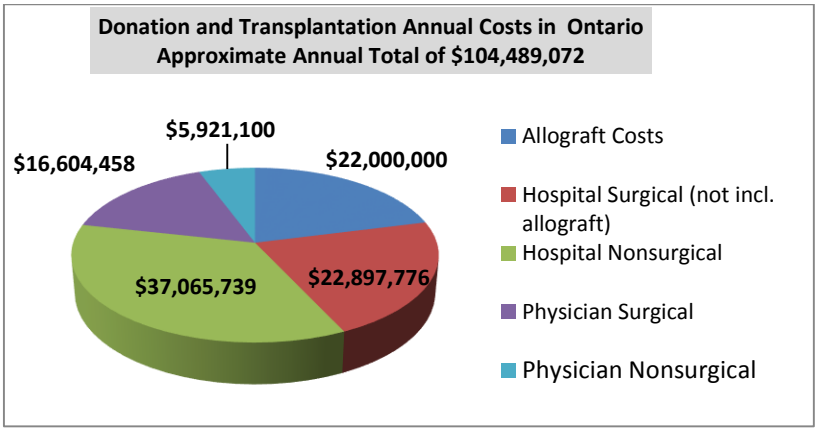
Table 13: Surgical and Non-Surgical Costs

Description	SURGICAL COSTS	NONSURGICAL COSTS	ALL COSTS
Allograft Costs	$22,000,000		$22,000,000
Hospital Surgical (not incl. allograft)	22,897,776		$22,897,776
Hospital Nonsurgical		37,065,739	$37,065,739
Physician Surgical	16,604,458		$16,604,458
Physician Nonsurgical		5,921,100	$5,921,100
TOTALS	$61,502,234	$42,986,839	$104,489,072

Nonsurgical hospital costs include substantial amounts for expenses incurred by clinics, laboratory activities, inpatient nursing, diagnostics, etc. An example of the extent of nonsurgical hospital costs is the amount associated with ‘skin grafts’ used for burn patients. 124 ‘in patient’ and 12 ‘day surgery’ cases

were captured in the Preyra Solutions Group data used. For these 136 cases, the total hospital nonsurgical costs were over $10,500,000 million, which equates to an average hospital nonsurgical cost of $77,000 per skin graft case. The surgical hospital costs, including the cost for allografts, amounted to $1,523,448, or 14.5% of the amount of nonsurgical hospital cost. The substantial amount for nonsurgical hospital costs for skin graft cases appears consistent with the relative lengthy care that must be provided for severely burned patients. Figure 1 displays the proportions of various costs that comprise donation and transplantation expenditures in the province.

Figure 1: Breakdown of Total Costs for Donation and Transplantation in Ontario



The schedule below (Table 14) displays the allograft, hospital, and physician costs broken out as surgical versus nonsurgical. To apportion an estimated total of $22.0 million of allograft costs across the fifteen categories of transplantation, we used the following assumptions:

1. We added an additional amount to corneal transplantation to bring the allograft amount for this procedure group to $4.5 million, equivalent to 1,500 transplantable full thickness corneas distributed at $3,000 per unit. Our initial allograft total in the schedule for the fifteen procedure groups was $8,952,162, while the Corneal Transplant procedure group allograft total amount was only $100,204, due to the fact that the EBC does not assess a fee for service. Adjusting the Corneal Transplant amount to $4,500,000 results in a recalculated total amount of $13,351,958.
2. We proportionally increased the allograft cost for remaining fourteen procedures (Corneal Transplants remain at $4.5 million) in the same proportion as a preliminary schedule that calculated total allografts at the unrealistically low amount of just over $8.9 million.

Table 14: Breakdown of Total Costs for Donation and Transplantation in Ontario

	SUPPLY SPECIFIC (PROXI FOR ALLOGRAFT COSTS)	ADDITIONAL HOSPITAL COSTS	PHYSICIAN COSTS	TOATL COSTS	SUPPLY SPECIFIC (PROXI FOR ALLOGRAFT COSTS)	ADDITIONAL SURGICAL ONLY HOSPITAL COSTS	SURGICAL ONLY PHYSICIAN COSTS	TOTAL SURGICAL ONLY COSTS
Amniotic Membrane Transplant	$ 33,859	$ 183,825	$ 173,781	$ 391,465	$ 33,859	$ 167,997	$ 157,979	$ 359,835
Bone Graft	$ 8,406,445	$ 19,361,220	$ 5,835,598	$ 33,603,263	$ 8,406,445	$ 9,837,941	$ 4,518,688	$ 22,763,074
Cardiac Valve Replacement	$ 386,788	$ 1,420,927	$ 508,545	$ 2,316,259	$ 386,788	$ 378,423	$ 299,661	$ 1,064,872
Cardiovascular Artery/Vein	$ 212,761	$ 1,297,862	$ 1,103,524	$ 2,614,147	$ 212,761	$ 350,073	$ 576,422	$ 1,139,256
Corneal Transplant	$ 4,500,000	$ 2,071,110	$ 1,580,213	$ 8,151,323	$ 4,500,000	$ 1,621,080	$ 1,471,103	$ 7,592,183
Cranium	$ 257,119	$ 872,327	$ 1,482,104	$ 2,611,550	$ 257,119	$ 464,116	$ 959,884	$ 1,681,119
Dura Mater	$ 265,012	$ 2,616,600	$ 1,343,300	$ 4,224,912	$ 265,012	$ 581,525	$ 859,950	$ 1,706,487
Ear, Nose & Throat	$ 16,136	$ 62,689	$ 76,860	$ 155,685	$ 16,136	$ 30,232	$ 69,922	$ 116,291
Eyelid, Sclera	$ 15,715	$ 160,341	$ 199,086	$ 375,142	$ 15,715	$ 159,371	$ 155,470	$ 330,556
Maxillo-facial, Bone	$ 115,602	$ 222,389	$ 301,006	$ 638,996	$ 115,602	$ 193,009	$ 248,390	$ 557,000
Maxillo-facial, NOT Bone	$ 1,161,629	$ 1,052,807	$ 508,702	$ 2,723,138	$ 1,161,629	$ 965,347	$ 415,517	$ 2,542,492
Skin Graft	$ 859,821	$ 11,603,028	$ 2,339,184	$ 14,802,033	$ 859,821	$ 1,088,528	$ 1,364,148	$ 3,312,497
Spinal	$ 3,673,614	$ 16,250,224	$ 5,876,914	$ 25,800,752	$ 3,673,614	$ 4,770,715	$ 4,453,173	$ 12,897,502
Tendon with Bone	$ 2,075,194	$ 2,634,234	$ 977,899	$ 5,687,328	$ 2,075,194	$ 2,157,619	$ 890,845	$ 5,123,658
Tissue - Other	$ 20,304	$ 153,932	$ 218,842	$ 393,078	$ 20,304	$ 131,800	$ 163,306	$ 315,410
TOTAL	$ 22,000,000	$ 59,963,515	$ 22,525,558	$ 104,489,072	$ 22,000,000	$ 22,897,776	$ 16,604,458	$ 61,502,234

In summary, the approximate total annual costs of donation and transplantation is $104.5 million. Limiting the costs to what has been defined in this report as surgical costs results in a total of approximately $61.5 million. Approximate total cost for allografts used in Ontario on an annual basis is $22.0 million.

5.0 Tissue Demand Forecasting

5.1 Overview

Tissue is used in more than 6,000 surgical procedures per year in Ontario, and by some estimates, 80% of the allograft tissue used in Ontario is sourced from tissue providers outside the province. Our review conservatively estimates almost 7,000 surgical procedures in Ontario utilizing approximately 12,000 human tissue allografts in 2012. In addition, about 4,000 procedures requiring 9,000 allografts provided in very small unit quantities were used in dental and periodontal procedures.

Tissue Utilization in Ontario in 2012/13		
	Procedures	**Allografts**
Cardiovascular	140	140
Musculoskeletal	4,500	9,000
Ocular	2,000	2,000
Skin for Burns	140	1,000
Total	**6,780**	**12,140**
** 2012 and 2013 data; excludes dental*		

Information regarding the distribution and demand for ocular, skin for burn and cardiac tissues in Ontario is readily attainable. Since ophthalmologists obtain virtually 100% of their tissue from the EBC and corneal wait times are tracked, annual demand can be precisely estimated. Skin is needed by relatively fewer patients who are largely concentrated in three hospitals in Ontario, which simplifies the collection of utilization data. Similarly, comparatively few patients concentrated at hospitals that implant human heart valve and other cardiovascular tissues implant makes data easy to gather.

Musculoskeletal tissue (MS) and Acellular Dermal Matrix (ADM) are used by a large number of surgical specialties (for example: neuro, orthopedic, plastic surgery and podiatric surgery). MS and ADM tissue use, therefore, is widespread and available in virtually every Ontario tertiary care hospital. The use of morselized bone and soft tissue allografts used in dentistry is also pervasive, but obtaining utilization data for tissue used by dental practitioners which largely occurs outside of hospitals is more difficult. Lastly, MS allografts are provided by dozens of tissue providers (including medical distributors) located in Ontario, other Canadian provinces and the U.S. Therefore, estimating MS and ADM demand is not only more complex but often less precise than for other tissues and organs.

Our estimates of tissue utilized in Ontario made use of information obtained from a number of sources:

- Data provided by the Ontario based tissue banks.
- Interviews with tissue bank management and personnel.
- Interviews with surgeon specialists.
- Interviews with hospital OR managers and purchasing departments.
- TGLN provincial tissue bank survey data (2012).
- TGLN non-provincial (importers) survey data (2013).

- Preyra Solutions Group review of the Discharge Abstracts Database, National Ambulatory Care Reporting System, the Ontario Case Costing Initiative and the Ontario Health Insurance Plan.
- Canadian Blood Services Reports
- Millennium Research Group Reports
- Statistics Canada
- Medical Literature, Publications and Reports

5.2 Tissue Utilization in Ontario

5.2.1 Traditional Musculoskeletal Allografts

Traditional MS allografts include cortical bone shafts and segments and bone dowels. Cancellous bone blocks, crushed cancellous and femoral/humeral heads are also in this category, and some bone allografts have both cortical and cancellous bone elements such as iliac crest wedges. Ligaments and tendons used largely for knee repair in sports medicine are considered traditional MS grafts, and non-proprietary demineralized bone are counted with other MS allografts when they are not combined with a carrier or delivery material. DBM bone in powder or granule form is widely used in dental and periodontal medicine. Lower volume allografts include cartilage used in plastic surgery and fascia lata for soft tissue repair.

Expanded Ontario donation and processing of musculoskeletal tissue will negate the need to import traditional MS allografts. Provincial hospitals import traditional MS allografts worth more than $2 million; substituting imported tissue with Ontario sourced tissue offers the potential to double distribution from locally recovered and processed donors. For the overall market, we estimate that traditional MS allograft demand will increase nominally over the next five years but with important variations among certain families of traditionally processed MS tissue allografts:

MS Allograft Type	5 Year Demand
Cortical Bone	• Slight but steady decline driven by shifting preference in spine surgery to precision cut allografts; • Synthetic and metal cages will be offset by increasing demand for demineralized bone.
Cancellous/ Cortico-cancellous Bone	• Steady growth in demand driven by increased and aging population; • Declining use of unprocessed femoral heads from in-house surgical bone banks and less dependence on autograft material.
Ligaments and Tendons	• Steady growth driven by increasingly active, health conscious population leading to greater knee and ankle surgeries and less use of autograft material.
Dental Bone	• Slight but steady growth in demand fuelled by an increasing and aging population, but offset by preference for proprietary processed DBM in more user friendly application forms (gels, putties, pastes).

5.2.2 Proprietary Musculoskeletal Allografts

MS tissues are included in this category by virtue of patented, proprietary designs or processes. While there are several propriety allografts available, the highest allografts in demand are precision cut spinal implants to enhance interbody fusion and DBM in enhanced carriers or delivery formats.

MS Allograft Type	5 Year Demand
Precision Cut Spinal Implants	• Steady decline in demand for allografts used in lumbar fusions offset by modestly increasing demand for bone spacers in cervical fusion.
DBM in Carrier	• Strong growth potential as DBM with enhanced delivery and handling formats that are more surgeon friendly, enabling further market penetration.

5.2.3 Skin for Burns

Projected demand is steady or increasing slightly with population growth. Contingency supply is an important consideration to protect against large scale catastrophic events resulting in numerous severely burn patients. Skin for burns has short-term growth potential as improved donation volumes and recovery yields preclude the need to import processed skin from other Canadian provinces.

5.2.4 Skin, Acellular Dermis

ADM is expected to be the fastest growing allograft with double digit growth projections in the next five years. Widely used today in Canada for breast reconstruction, it will likely have broader application in Canada following U.S. surgical applications such as graft reinforcement in orthopedics and in dental applications.

5.2.5 Cardiac Allografts

There is an increasing need for pediatric valves due to a recent U.S. FDA surgeon alert stating that the Sorin xenograft valve should not be used in pediatric cases.[16] There has been a downturn in the use of heart valves in adult patients during the past two years due to a decline in the popularity of the Ross Procedure. This coincides, in part, to the decline of HSCTL's distribution of adult HVs from its peak of processing of 150 HVs during this time. According to their recent U.S. Securities and Exchange Commission filing, CryoLife, one of the largest providers of human heart valves in the world, experienced a 5-8% decline in cardiovascular tissue. Future demand in North America is seen as flat or single digit downturns. However, the field is expected to evolve and cycle. The direction for HV banks in the U.S. is to provide a better allograft than what is currently available, basically the same HV as was offered decades ago. The new technology is described in a publication by Richard Hopkins: *Bioengineered human and allogeneic pulmonary valve conduits chronically implanted orthotopically in baboons: Hemodynamic performance and immunologic consequences. RA Hopkins et al, J Thorac Cardiovasc Surg April 2013: 145(4): 1098-1107).*

HV technology will be driven by U.S. companies having access to a higher level of capital and expertise. If successful, these improved valves will find their way into Canada in increasing numbers.

While human heart valves are low volume allografts, their provision helps serve a uniquely young patient population. Although we expect demand for pediatric heart valves to increase slightly in line with expected population increase, Ontario has a short-term opportunity to provide for the provincial need and eliminate the importation of HVs. Providing sufficient supplies of human HVs will also reduce the use of mechanical and xenograft HVs. The demand for adult heart valves is expected to continue its slow but steady decline from current levels.

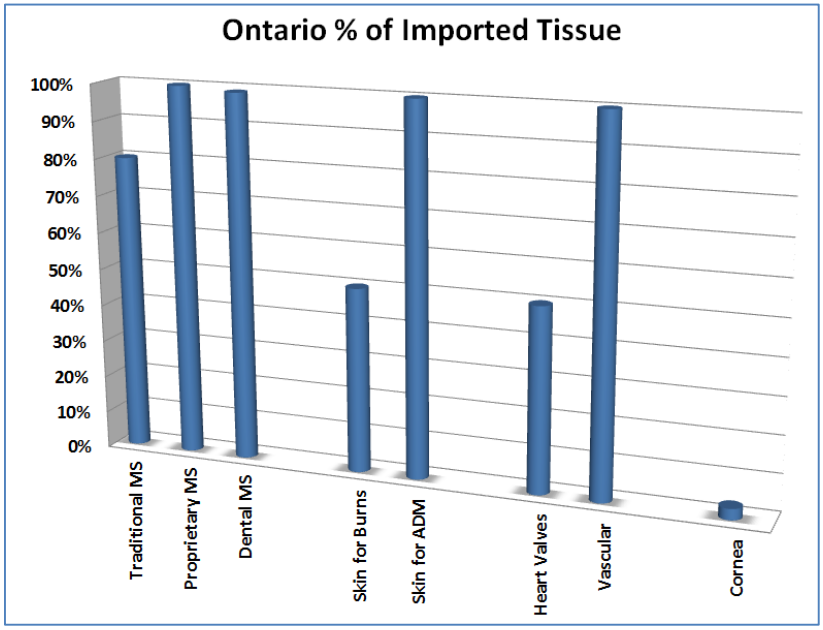
5.2.6 Ocular Tissue

Corneas are the highest volume tissues distributed by the EBC and demand is expected to grow moderately in proportion to the over sixty-five population growth. Additionally, the EBC has a wait list to eliminate, and there is an unfulfilled demand for pre-processed corneal allografts, as 65% of the transplants performed in Ontario are currently prepared by the surgeon in the operating room. Pre-cutting of corneal tissue is expected to spur an increase in demand as operating room time currently used to prepare corneal tissue will be available for additional transplant procedures. A similar increase in demand for scleral tissue is expected as greater numbers of senior citizens with severe glaucoma request treatment.

5.2.7 Imported Tissue

Much of the tissues used in Ontario, particularly proprietary tissue allografts and MS tissues, are imported, some from other Canadian provinces but most from the U.S. Our analysis indicates the following importation levels for human allograft tissue used in Ontario (Figure 2):

Figure 2: Percent of Imported Tissue by Allograft Type



5.3 Future Influences on Tissue Demand

5.3.1 Demographics

One factor that will influence demand for tissue is projected population growth. Ontario's Ministry of Finance estimates that the present population of 13.6 million people will grow at an annual rate of about 1% through 2021, while the annual growth rate for the GTA is estimated at 1.5%. Seniors sixty-five and older are projected to be the fastest growing segment of the Ontario population with annual growth at 3.5% through 2016 and 4% from 2016 to 2021. Demographic influences will generally increase allograft tissue demand by 1% per annum. Procedures typically performed on older patients, such as corneal transplants, can expect greater demographic impact while pediatric heart valve demand, for example, will remain stable.

5.3.2 Allograft versus Autograft

Surgeon preference and training most often determines the tissue used in surgery. Before human allograft tissue was readily available, the grafting of choice and necessity was autograft tissue obtained from the patient. The two most common examples of autograft tissue are the partial recovery of the patient's patellar ligament for the repair of knee injuries and the use of cancellous bone from the iliac crest when tissue is needed to fill bone voids in orthopedic procedures. While there are certainly advantages to using a patient's own tissue, autograft harvesting adds morbidity from a second surgical site. Surgeons trained in recent years increasingly use human allograft tissue since it is now readily available. The trend of less surgeon reliance on autograft in favor of allograft tissue is expected to continue as younger surgeons replace older, retiring physicians.

5.3.3 Decline of Femoral Head Banking

Obtaining donated femoral heads from living patients undergoing hip replacement surgery dates back to the early days of tissue banking when donor programs were immature and cancellous and cortico-cancellous bone from cadaveric donations were less abundant. Surgical bone banking programs have all but disappeared in the U.S., and they are becoming less prevalent in Canada as cadaveric donations increase and cancellous and cortico-cancellous bone is in greater supply from provincial tissue bank processors. The requirements of Health Canada's regulations and the costs associated with these programs, which include the added operating room time required, will likely result in fewer femoral head, surgical bone bank programs in Ontario. This will increase the demand for both cadaveric bone provided by the tissue banks and traditional MS tissue allografts. The latter should be readily met as cadaveric MS tissue donation increases.

5.3.4 Tissue Alternatives

Advances and changes in medical technology such as the introduction of substitute materials for allograft tissue are the least predictable factors impacting allograft tissue supply and demand. Over the years, coral, ceramics, metals, and plastics have been introduced as allograft alternatives, as well as xenograft materials like porcine and bovine derived grafts. Some tissue alternatives have proven successful while

others have disappeared. Despite the expanded options, surgeons continued to show preference for human allograft tissue and its demand continues to increase.

While developmental work in cell culturing, grafts containing stem cells, matrix constructs, regenerative medicine, bio-synthetic materials, and growth factor therapies has shown promise, Canada typically lags behind the U.S. in adopting new, more expensive medical treatment alternatives. Inasmuch as these therapies are in development or early introduction stages in the U.S., we do not see significant penetration into Canadian markets in the next five years.

5.4 Demand Forecasting Methodology

Supply and demand for allograft tissue depend on a number of variables, which are different for each family of tissues. To accurately forecast demand, information will have to be collected from a number of sources and combined or cross-referenced. The general approach should follow these steps:

#	Activity	Description
1	Identify allograft tissue providers	a. Identify all potential providers of human allograft tissue in Ontario. The complete list of approved providers in Canada can be obtained from Health Canada's publication of Organ, Tissue and Cell Establishments. From this universe of possible providers, one needs to identify which are involved in human allograft tissue (e.g. excluding organ banks, cord blood banks, etc.). b. Identify Ontario based allograft tissue providers. This will result in a familiar list that includes the province's primary tissue bank processors, Ontario hospital surgical bone banks, and Ontario based distributors of imported tissue. c. Identify importers of tissue into Ontario, information that should be available from both provincial tissue banks and hospitals. Importers often supply tissues to the tissue banks themselves or their parent hospital and they may also be competitors to the tissue banks.
2	Establish baseline level of allograft tissue distributed in Ontario	a. Ontario based tissue bank processors should be able to provide the number and types of allografts they distribute, and it should be possible to identify which of the tissue bank's customers received them. In the course of our review, the lack of data management systems at the Ontario tissue bank processors made obtaining distribution volumes difficult in our limited time frame. One of the benefits of our recommended build out of the Ontario tissue banking data systems will be the availability of more accurate tissue distribution information at a micro level. b. Establishing a baseline level of imported tissue is difficult given the large number (dozens) of tissue providers. During the course of our review, TGLN surveyed all Health Canada registered OTC Canadian and U.S. based establishments that provide ocular, MS, skin, and cardiovascular tissue to Ontario users. Information collected included the number and types of allografts distributed in 2013 and their customers. In addition to identifying active importers, TGLN was able to identify who does not import tissue into Ontario.

#	Activity	Description
3	Establish a baseline of tissue utilized in Ontario	a. One method is to get Ontario hospitals to report their annual tissue purchases from all providers. Our review only obtained this type of information from the subset of hospitals with whom we conducted interviews. b. Since a large segment of tissue use in Canada is for dentistry, utilization and demand information in this market cannot be captured by hospital surveys, and separate survey outreach to this community will be required. The scope of our review did not include surveying or interviewing users of tissue in this market. c. Another resource was surgical procedure data obtained by the Preyra Solutions Group, which mined data from the Discharge Abstracts Database, National Ambulatory Care Reporting System, the Ontario Case Costing Initiative, and the Ontario Health Insurance Plan. From this we were able to identify surgical cases performed in 2012 that utilized human allograft tissue.
4	Review other Sources of Information	a. Access to Care, in the course of measuring corneal transplant wait times, obtains reports on every corneal transplant performed in Ontario, which provides a cross referencing opportunity. In recent years, Canadian Blood Services has itself reported or commissioned the Millennium Research Group to report on the supply and demand of human allograft tissue in Canada. Some of the reports include subsets of Ontario data.
5	Other considerations	a. Wait list information (e.g. for cornea and osteochondral tissue) is not picked up by the data collection methods listed above. Neither is use of alternative materials like xenograft or synthetic materials in instances when surgeon would prefer to use human allografts (e.g. porcine skin or xenograft heart valves), which is also important to measure. b. It is important to keep track of all factors that can affect future demand for allograft tissue. Timely interaction and feedback from the surgical community is one of the best ways to achieve this. For example, during our surgeon interviews, we discovered that utilization of human heart valves in adult patients is declining and Ontario surgeons do not prefer to use bone in lumbar spinal fusion cases.

5.5 Demand Forecasting Recommendations

Reliable information on supply and demand will help support efforts to improve Ontario's provincial tissue banking systems. Improved information on the market's use of allograft tissue will help Ontario tissue banks make prudent decisions about tissue recovery and allograft processing. Identification of the gaps in Ontario's supply and demand, such as waiting lists and levels of imported tissue, will help determine what interventions, if any, are needed.

A measurement of tissue utilization can be assembled annually. Information about ocular, skin for burns, and cardiovascular tissue, as previously discussed, is readily available and easy to obtain. Measurement of MS and ADM utilization and imported tissue are more complex and will require additional resources.

Therefore, we do not recommend that surgeons, hospitals, dentists and importing tissue banks be surveyed every year. Surgical tissue utilization is not expected to change materially from year to year as no dramatic changes to surgical use are on the horizon. We do recommend that every year, some aspect of demand measurement be performed for Ontario. For example,

a) Years ending in even numbers:
    - Survey Ontario hospitals on tissue purchases and utilization
    - Survey registered OTC establishments on tissue imported into Ontario.
b) Years ending in odd numbers:
    - Survey private dentists on tissue purchases and utilization
    - Obtain information from provincial databases on annual surgical procedures performed and associated costs.

RECOMMENDATION ***Each year, some aspect of demand measurement should be performed in Ontario including data reviews and surveys to surgeons, hospitals, dentists, and importing tissue banks.***

6.0 Cost Recovery Strategy

6.1 Overview

For tissue donation and transplantation systems in Canada and elsewhere, active participation of hospitals and hospital personnel, particularly nursing staff, is essential to acquiring organ and tissue donations from patients expiring in hospitals. The important roles that hospitals and hospital staff play in tissue donation and recovery are varied, and their support is provided in the context of the existing demands placed on hospital and nursing professionals. The potential for tissue donation is typically greatest in the acute care departments of the hospital.

Challenges posed to Hospital Staff (i.e. RN, MD, ancillary staff) includes: death of the potential donor patient, workload from other living patients, time required to refer and/or screen potential donor, and the need for a hospital bed for the incoming patients." In some jurisdictions, full documentation and accounting for these numerous activities require "…written agreements between hospitals and Donation Agencies that indicate the responsibilities of the Donation Agency which include… financial reimbursement for supplies, staff, etc. used during tissue recovery…."[17]

The hospital support for donation and retrieval processes results in the need for alternative protocols and policies, and involves the use of both hospital personnel and facility resources. The education, training, and associated time spent by hospital staff to be aware and responsive in situations where tissue donation takes place is yet another incurred cost. Donation and Transplant Agencies will provide the education and in service programs but hospital staff time must be expended for ongoing training and education. A concise schedule of the supporting roles typically played by hospitals is presented below in Table 15:

Table 15: Supporting Roles Performed by Hospitals in Support of Tissue Donation

#	Activity
1	Timely referral of death and communication of basic patient information.
2	Coordination of contact/communication between next of kin and Donation Agency.
3	Medical information communicated to TGLN for the completion of a secondary, more detailed screening.
4	Interventions to enhance the viability of tissues used in transplantation.
5	Access and direction concerning logistics for the movement/activities of the tissue recovery team.
6	Providing access to medical information and records for the tissue recovery team – and additional information provided to TGLN subsequent to tissue recovery
7	Use of hospital facilities (including operating rooms).
8	Transport of the donor remains post tissue recovery.
9	Regular "in services" and education of nursing and hospital staff about tissue donation and transplantation.

Although not commonly seen in North America, for some hospitals, a monetary reimbursement to cover some part of the costs incurred and the support provided for tissue donation related activities may be viewed as expected or appropriate. Hospitals may be more demonstrative and enthusiastic in their support for tissue donation and recovery when such a reimbursement program is in place.

6.2 TGLN's Current Strategies and Organ Donation Reimbursement Model

A reimbursement model used by TGLN is in place to support hospital efforts (and reimburse corresponding costs) in donation and recovery of organs. TGLN recognizes the importance of such a policy and the "…ministry approved funding methodology is intended to cover incremental direct costs only for the major core expenditures supported by case costing and reported by hospitals to support organ donation."[18] TGLN wishes to review comparable models or strategies that might be applicable for tissue donation and recovery activities. A brief review of the model used by TGLN, and approved by the Ministry, for reimbursements for organ donation is described as follows:

Three phases of activities performed by hospitals are defined below and a corresponding reimbursement amount is determined for each phase.

Phase	Description	Incremental Reimbursement
1	This phase "…corresponds to maintaining on ventilation a patient which meets the inclusion criteria for organ donation…"[19] during the period when the entire donation process is being assessed. The threshold for funding is the organ donation approach made by TGLN staff. Cost reimbursement or "…funding [for the hospital] is not based on the outcome of the request for consent."[20] Thus, even with the next of kin's choice to decline organ donation, subsequent to the entering of this Phase, a reimbursement is made to the hospital.	$800
2	This phase involves medical testing and clinical assessments needed for determination of suitability. When this 2nd Phase is initiated, even in situations where subsequent organ donation is determined to be not suitable, a $2,050 reimbursement will be made to the hospital, in addition to the $800 corresponding to the 1st Phase, for a total reimbursement of $2,850 associated with this potential donor case.	$2,050
3	The 3rd Phase involves the initiation of the actual organ recovery process and includes funding to hospitals for the use of the operating room and supplies, and for providing an OR team. The full recovery process may involve four to five hours of operating room time. The cost reimbursement or funding for the hospital is made regardless of whether "…donors are found medically unsuitable intra-operatively or post-operatively."[21.] Thus, cases that enter this 3rd Phase will result in an additional $3,150 reimbursement to the hospital, regardless of whether the organs are deemed viable. The total reimbursement for this actual (or potential) donor case is $6,000.[22] The actual organ recovery surgeons receive separate and independent remuneration from the Ministry of Health for their services.	$3,150

According to the Trillium Gift of Life Network Annual Report 2011/2012, almost $1.9 million was provided for Deceased Organ Donation Funding to Hospitals. For 222 actual organ donors and 25 donors from whom organs were recovered, but subsequently deemed not suitable, a reimbursement of $6,000 per

case was made. Additionally, 61 potential donor cases went through both the 1st Phase and the 2nd Phase but were subsequently not recovered (as they were considered not suitable for transplant). Hospitals supporting activities for these 61 potential donor cases were reimbursed at a rate of $2,850 for each case. For 301 potential organ donor cases that entered the 1st Phase but did not proceed to the 2nd Phase, the per case reimbursement was $800. A brief summary of the reimbursements made per the Annual Report are as follows:

Recovered Donors (whether or not transplanted)	**247 Cases x $6,000**	**=**	**$ 1,482,000**
Potential Donors processed through the 1st and 2nd Phases	**61 Cases x $2,850**	**=**	**$ 173,850**
Potential Donors processed through the 1st Phase	**301 Cases x $800**	**=**	**$ 240,800**
TOTAL			**$ 1,896,650**

6.3 Comparison of Ontario to Donation and Transplantation Agencies in the US

For United States Organ Procurement Organizations (OPO), higher levels of reimbursement are made to hospitals for the support provided and costs incurred in cases of organ donation. For example, costs that would be incurred directly or ultimately by the U.S. based OPO (rather than the hospital) would include:

- any testing or medical consult that would not have been done if the patient wasn't being triaged for donation or becomes a donor;
- cost incurred by use of an operating room and related anaesthesiology;
- any related medical supplies or pharmaceuticals expended in triaging the donor or used in donor recovery.

Organ cases in the United States can be very costly. In the case of eye and tissue donation and retrieval in the United States there are instances where Donation and Transplantation Agencies provide cost reimbursements to hospitals, coroners and even funeral establishments (the later generally in the case of eye only recovery) that provide support toward tissue donation. However, the number of hospitals requesting such reimbursement is in a distinct minority. In instances where reimbursements are made, the amount may range from $100 to $500 per donor case. There are examples of coroner departments that assess tissue recovery agencies thousands of dollars per month to provide access and support activities for tissue recovery and the use of tissue recovery suites at the coroner's facility. Typically, hospitals or coroners receiving these cost reimbursement payments will have entered into a detailed agreement with the Donation and Transplantation Agency specifying how much is paid based on a per case basis; in some cases (for coroners) the payments are flat monthly amounts.

6.4 TGLN's Options for Developing a Tissue Donation Reimbursement Model

Referring to the prior schedule of nine (9) activities, there is a distinction that may be made between "eye only" donation and recovery and multi-tissue donation and recovery, that is the donation and recovery from a single individual of one or more of the various tissue types, specifically musculoskeletal (bone and tendons), skin and heart valves with such recoveries taking place with or without a corresponding recovery of eye tissue from the same donor.

In the case of an "eye only" donor, a unique hospital space or room may be preferable but not necessary. "Eye only" recovery is typically not performed in an operating room or sterile site and may take as little as one hour to complete, whereas multiple tissue recoveries may take anywhere from 3 to 4 hours and are required to take place in an operating room, or comparable space. Additionally, because of the relatively short time line between eye tissue recovery and transplantation, medical information follow up with hospital personnel, that may be indicated for other tissue types, will generally not take place. For these reasons, the effort and costs incurred by hospitals in support of "eye only" donation may be markedly less. The use of an operating room or sterile environment space in the case of musculoskeletal, skin or heart valve recovery is generally the most costly resource that a hospital provides.

For the initial two Activities listed in the Schedule, the timely referral subsequent to death combined with the coordination of contact/communication between next of kin and TGLN, could be viewed as basic, not significantly costly activities that for the most part are mandated by regulation in Ontario for "designated" hospitals. Referral activity volume for potential tissue donors in Ontario is at 25,000 or more annually and the number is expected to increase, as more hospitals are incorporated into a consistent practice of required routine notification when death occurs. It may be reasonable to consider these activities coupled with Step 9 (ongoing education and training) as already introduced into the process of donation performed by hospitals, and not excessive in costs. Therefore no reimbursement would be made for this 1st Phase (which includes Steps 1 and 2 and 9) of the Tissue Donation and Recovery Process.

The 2nd Phase of the process includes only Step 3, where the hospital staff interacts and communicates with the Donation Agency in providing responses that are needed for the completion of a secondary screening of health information. As this Phase involves more direct involvement and cooperation it may be more appropriately considered as a reimbursable hospital cost. However, there will be many instances in which Step 3 is performed but either the patient is deemed contraindicated for donation or the next of kin declines the option of donation, resulting in no tissue recovery. Whether or not some cost reimbursement should be associated with this Phase will be a matter of discretion, certainly in comparison to the costs that will be incurred during the 3rd Phase. If the 2nd Phase is considered appropriate for reimbursement, an amount of $50 per case may be a reasonable reimbursement rate.

The 3rd Phase of the process for tissue donation and recovery includes steps 4 through 8. As explained previously, the resources used by the Donation Agency's recovery team depend on whether the potential donor is an "eye only" donor, or multi-tissue donor. A multi-tissue donor is an individual donor who donates one or more tissues described as musculoskeletal (bone and tendon), skin or heart valve, with or without a corresponding recovery of eye tissue.

Various rates are assigned by hospitals for operating room time. As indicated above for organ donation activity, 3rd Phase related costs are essentially for the use of the operating room during organ recovery, with a TGLN assigned reimbursement of $3,150. Although multi-tissue recovery may take up to four hours, similar to the time expended for organ recovery, a $3,150 reimbursement multi-tissue donation cases may be seen as prohibitive. A smaller reimbursement level may be more feasible, at least initially, in part because multi-tissue recovery in an operating room will not be a priority case and is unlikely to supersede another scheduled hospital case. Tissue recovery in hospitals often occurs during evening and overnight shifts when surgery and use of an OR are not scheduled. In these instances, there is typically

no opportunity cost to the hospital for permitting tissue recovery in an operating room. But there will still be a cost for cleaning and sterilization by hospital personnel after tissue recovery activities, and in some instances a hospital representative (perhaps an OR nurse) may be required to be in attendance during part or all of the tissue recovery process. Additionally, smaller hospitals may have to call in OR staff from home to complete a recovery which may result in a cost impact.

To keep this proposed model simple and straightforward the threshold for determination of a cost reimbursement payment for the 3rd Phase is the point at which a recovery team of technicians (or a single technician in the case of an eye only donor) is dispatched to the hospital. In the vast majority of cases, once a team or individual is dispatched to the hospital, actual tissue recovery takes place. For "eye only" donors we suggest reimbursement of $100 to $200 for any instance where the recovery technician is dispatched to the hospital. For multi-tissue recoveries we suggest reimbursement of $400 to $500. This higher amount corresponds to the use of an operating room and time length of the recovery activities.

A measurement of what this reimbursement model or strategy might entail can be calculated as follows:

Activity for secondary screening and donor recovery for 2013/14 (projected) is detailed below.

		Case Counts
Total Referrals		25,232
Move to Secondary Level of Screening	44%	10,992
Total Potential Multi Tissue Donors	15%	1,649
Total Potential Eye Only Donors	85%	9,343
	100%	10,992
Multi Tissue Donors Recovered		215
Eye Only Donors Recovered		1,937

Applying the rates suggested above for each type of case (using the lower end of each range):

- For a case that enters 2nd Phase – Step 3 but does not proceed to the next step a rate of $50.
- For a technician performing "eye only" donor recovery - $150 (reimbursement for 2nd Phase [$50] and 3rd Phase [$100]
- For a technician team performing multi-tissue donor recovery - $450 (reimbursement for 2nd Phase [$50] and 3rd Phase [$400]

The following table shows the final calculated costs:

CURRENT ACTIVITY LEVEL	Donor Volume	Reimbursed Costs to Hospitals
Cases screened but NOT recovered (at $50/case)	8,840	$442,000
Eye Only Dispatches for Recovery (at $100/case)	1,937	$193,700
Multi – Tissue Dispatches for Recovery (at $500/case)	215	$ 107,500
TOTAL DOLLARS		**$743,200**

Knowing that donation levels, particularly the multi-tissue donor level, will expand dramatically in the not too distance future, it's important to anticipate what these costs might be in the intermediate and long term. To aid in the calculation of projected funding levels we need additional assumptions regarding the future levels of eye donation and multi-tissue donation:

- The ultimate potential level of multi-tissue donation levels will be a function of eye donor levels, specifically, that multi-tissue donor levels should be approximately 50% of the level of eye donation.
- Eye donor volume in the Ontario is reasonably high but anticipated to increase to a slightly higher level, perhaps to 2,200 or more annually; and multi-tissue volumes will increase dramatically, with a potential of perhaps 1,100. However, the level required for the current system needs may be less, perhaps a total of 900 donors, where one or more of musculoskeletal, skin and heart valve tissues are recovered. We will also assume that one half of all multi tissue donors also include the recovery of eye tissues. It should be noted that when doing out of hospital multi-tissue recoveries, there are times when time-outs will occur for ocular recovery so for those cases, so less than one-half of those multi tissue cases will include ocular recovery.

Activity for secondary screening and donor recovery would be:

	Case Counts
Move to Secondary Level of Screening	10,992
Multi Tissue Donors Recovered	900
Eye Only Donors Recovered (2,200 less 1/2 of 900)	1,750

The following table shows the calculated costs:

FUTURE ANTICIPATED ACTIVITY	Donor Volume	Reimbursed Costs to Hospitals
Cases screened but NOT recovered (at $50/case)	8,342	$ 417,100
Eye Only Dispatches for Recovery (at $100/case)	1,750	$ 175,000
Multi – Tissue Dispatches for Recovery (at $500/case)	900	$ 450,000
TOTAL DOLLARS		**$ 1,042,100**

The above total Funding Levels assume a policy of universal reimbursement to hospitals for their supporting role in tissue donation. In the aggregate, the above totals may seem significant but with medical costs in Ontario in the billions of dollar the amount for any single hospital is not meaningful. For these and other reasons of economy, implementation of any reimbursement model or strategy for tissue

donation and recovery may be better activated on a hospital by hospital basis, with a facility's specific request or distinct notification for such reimbursement being a condition prior to commencement of payments.

6.5 Cost Recovery Strategy and Model for Coroner/Medical Examiner

In other jurisdictions (outside Ontario) the reimbursements for support (and presumably incurred costs) related to tissue donation and retrieval is not limited to hospitals. As briefly mentioned above, in the United States a number of coroner/medical examiner programs expect reimbursement for their participation and facility use related to tissue donation and recovery. Some of these arrangements are by formal contract. In some cases the contract calls for the payment of a flat monthly fee or payments correspond to a specific number of tissue donor recoveries made in a given time frame at the facility – with a distinction between eye donors and multi-tissue donors.

Rather than the term "contract" the arrangement between coroner/medical examiner and the Donation Agency may be better described as a "license" granted by government. The contract (or license) is unusual inasmuch as services to be provided to the "public" by way of a government agency result in payments made by the contracting Donation Agency to the coroner or medical examiner (the government agency). TGLN may want to consider comparable reimbursement strategy options and models for the Coroner in Ontario. "Depending on the involvement and responsibilities that a CC/MCE [Chief Coroner/Chief Medical Examiner in Canada] 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 limited to the CC/MCE ability to participate in tissue donation – to any degree of involvement."[23]

In northwest Toronto, the new Forensic Services and Coroner's Complex (FSCC) housing Ontario Forensic Pathology Service, the Office of the Chief Coroner, and the Centre of Forensic Sciences opened in the fall of 2013. Included in the facility is a dedicated, fully equipped tissue recovery suite. To date, this recovery room suite has been virtually unused except for a few eye donor recoveries. An alternative or complementary approach to reimbursing hospitals for the use of their operating rooms is to transport tissue (non-eye only) cases to the FSCC tissue recovery suite. For example, Hema-Quebec reports 80% of their tissue recovery cases within a 250 kilometer radius are brought to their in-house tissue recovery suite. At the current level of 200 non-eye tissue recoveries per year, the FSCC tissue recovery suite has the capacity to allow for virtually every non-eye tissue case within a similar radius to be performed outside of the hospital settings.

It should be noted that in the United States a number of tissue donation and recovery agencies pay reimbursement for costs incurred to mortuaries and funeral directors and establish who may participate in some manner in the donation and retrieval process – providing access, transportation of the donor, etc. One example of this is provided in a U.S based Organ and Tissue Agency, the Nebraska Organ Recovery, Donation Guide for Funeral Directors which indicates that the Agency "…provides reimbursement to funeral directors for the additional preparation work associated with donation…. $200 for tissue donors, $100 for organ donors and $50 for heart valve only donors."[24]

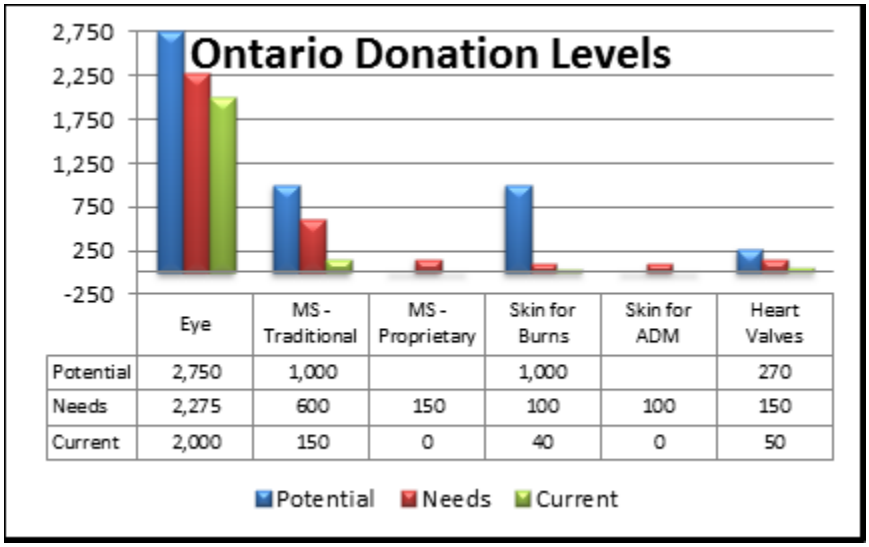
7.0 Tissue System Recommendations for Improvement

Our proposed redesign is intended to promote a more self-sufficient Ontario Tissue Donation and Transplantation system. Central to the redesign are interventions to improve donation volumes, eliminate redundancies and inefficiencies, and attain greater processing economies of scale. The result will be enhanced provision of allografts from tissue donated by Ontarians and processed within the province. The systemic changes concentrate on enabling:

1. Dramatic improvement in tissue donation levels for all tissues (eye, musculoskeletal, skin and cardiac).
2. The consolidation of tissue processing for musculoskeletal, skin and cardiac tissues under the roof of a comprehensive tissue processing centre.

7.1 Increasing Tissue Donation

Ontario's population base of 13.6 million people is certainly sufficient to support the province's tissue needs. The chart below presents a conservative estimate of potential donation levels for each family of tissues.



	Eye	MS - Traditional	MS - Proprietary	Skin for Burns	Skin for ADM	Heart Valves
Potential	2,750	1,000		1,000		270
Needs	2,275	600	150	100	100	150
Current	2,000	150	0	40	0	50

Note: A potential bone donor can be processed into both traditional or MS; a potential skin donor can be for burns or ADM

These estimates actually exceed the donation level required to satisfy demand in the province. Ontario can meet its provincial needs by reaching the following percentages of its full potential: 82% for eye; 75% for musculoskeletal; 20 % for skin and 55% for heart valves. The higher targets for donation are very attainable. The existing level of 2,000 eye donations per year is experience based evidence that higher donation levels can be achieved for other tissues. Within our proposed redesign are specific interventions that will enable Ontario to meet future needs for tissue. The following key strategies are recommended to improve tissue donation levels:

#	Recommendations
1	TGLN should improve conversion of potential donor hospital referrals already "in the system" into consented and recovered donations by: 1. Minimizing the number of consented donations not recovered 2. Reducing the number of missed medically eligible referrals due to the lack of approach with the next of kin including re-evaluating the practice of not calling next of kin between 11pm and 8am.
2	Establish a province-wide Coroner's screening, consent, and recovery program
3	Consolidate and coordinate all tissue recovery under a new TGLN multi-tissue Recovery Department staffed by Certified Tissue Bank Specialists (CTBS)
4	TGLN should implement the corneal excision technique as the preferred tissue recovery procedure for eye donations (corresponds to improved likelihood to result in transplantable corneas). The whole eye enucluation technique should be for all other donations likely to be used for sclera, research and teaching. This should be rolled-out in the GTA in year 1 followed by other high donor volume regions (e.g. London and Hamilton) in years 2 and 3.

The redesign recommends that improvement of donation levels be the first action items to enable sufficient volumes of processed tissue allografts to be produced for provincial distribution.

7.2 Consolidate Tissue Processing

The second area of focused change to the Ontario Tissue System and the most complex aspect of the redesign recommendations must be the establishment of a new consolidated tissue processing entity and facility for province-wide processing of musculoskeletal, skin and cardiac tissue. Beyond the shortcomings noted in our report – fragmentation, redundancy and the other limits of largely hospital-based tissue banking – the Ontario tissue banks as structured do not have the capacity to process all the tissue at the required donation levels noted above. The processing of eye tissue and fresh musculoskeletal tissue are not included in the discussion of consolidated tissue processing. Fresh osteochondral allografts are processed at the time of tissue recovery and the recently built eye bank facility has no capacity limiting factors. The specific interventions presented for the tissue processing system redesign are:

#	Recommendations
5	Ontario should centralize all tissue processing (MS, skin, cardiac tissue) by implementing a consolidated multi-tissue processing bank that will spread fixed costs over greater volume and achieve greater economies of scale. This will include the following: a. Select and communicate a consolidated tissue model to tissue stakeholders b. Establish or contract a single processing entity. c. Construct a new Toronto based facility. d. Provide for contract processing of specialty tissues.
6	The EBC should provision pre-cut tissue to surgeons in Ontario as a standard of practice beginning in year 1.

Implementation of the above recommendations will:

- Enhance capacity;
- Achieve economies of scale
- Allow for processing enhancements
- Ensure tissue quality

The establishment of the consolidated tissue processing centre is a multi-year process that includes meticulous planning, detailed specifications, competitive bidding, construction and process validation. The proposed time frames defers the majority of capital spending to years three and four as the processing centre is envisioned to come online in year four. Pre-cut cornea tissue processing is targeted to commence in year one.

Processing Options:

Our proposed redesign recommends the establishment of a new, consolidated processing centre for production of all musculoskeletal, skin, and cardiovascular allografts in Ontario. The question of who operates such a facility is intentionally left open ended as we believe Ontario has a number of credible options to consider. Among the possible options are:

1. Single entity tissue provider for Ontario. Options include open bid from the following: **o Consolidation of existing Ontario tissue banking providers** **o Existing Tissue Banking Provider** **o New Entity**	
System Benefits	**System Challenges**
1. Improved capacity to handle current and future tissue demand 2. Ability to leverage economies of scale 3. Ability to perform enhanced tissue processing 4. Ability to improve system efficiency by eliminating redundancies and reducing fragmentation 5. Ability to standardize processing practices and reduced reliance on imported tissue 6. Ability to coordinate system planning	1. High degree of change management required 2. Disruption of current tissue banking system 3. Additional infrastructure and capital investment may be required

2. One (or more) of the U.S. or Canadian based tissue processors (out of province).	
System Benefits	**System Challenges**
1. Established tissue processor can more readily commence provision of services 2. Established accreditation and quality assurance practices are established (i.e. SOPs) 3. Ability to provide enhanced tissue processing 4. No capital investment or infrastructure required	1. Limited knowledge of Ontario tissue market 2. A need to establish Ontario based footprint for inventory storage and Ontario distribution. 3. No Ontario based processing operations 4. International or inter-provincial shipment of unprocessed and processed allografts. 5. Possible need to contract with multiple processors. 6. High degree of change management required 7. Disruption of current tissue banking system 8. Services provided under service level agreement

We recommend that the MOHLTC immediately commit to the open bid for a single tissue provider option (consolidated processing model):

- **YEAR 1** - As soon as possible, inform stakeholders of the MOHLTC's commitment to the consolidated processing model, the intended process and timeframe, and a framework for soliciting proposals for a consolidated processing centre operator.
- **YEAR 2** – Solicit proposals from interested parties. Select processing organization.

7.3 Other Key Re-design Recommendations

Three additional interventions are recommended to help establish a more efficient tissue system in Ontario. The first is to establish data management systems within the EBC and the Consolidated Processing Centre. Linking the systems at the tissue processors to the TGLN data management system is an essential step that will provide performance based information from the referral of potential donations through tissue recovery and allograft processing and ultimately through distribution.

Second, since 80% of tissue obtained and utilized by hospitals is distributed on a per tissue fee for service basis, we recommended that the same procedure be used for the remaining 20% of distributed tissue (largely ocular, skin and heart valves). That will achieve uniformity and create a revenue scheme under which tissue processors can manage their operations to achieve self-sufficiency. It will also provide a mechanism that allows the MOHLTC to evaluate the cost effectiveness of Ontario's tissue providers. Planning for this transition can begin in Year 3, for implementation to coincide with initiation of allograft distribution by the consolidated processing centre.

Lastly, optimal communication of the tissue system redesign will include the Ontario hospital, surgical and dental communities many of whom expressed their preference to obtain tissue from Ontario based tissue banks. As tissue donation increases and the availability of locally processed tissue allografts improves, these key stakeholders will be instrumental to ensure that locally provided tissue is utilized in the treatment of their patients. Encouraging the utilization of allograft tissue will reduce reliance on imported tissue and contribute toward the attainment of a self-sufficient system.

The specific interventions are as follows:

#	Recommendation
7	Establish linked data management systems with TGLN, the Eye Bank of Canada, and the Consolidated Tissue Processor
8	Implement the use of per allograft processing fees for all tissues (including ocular tissue from the EBC) as the standard practice concurrent with bringing the Consolidated Multi-tissue Processing Centre online.
9	Communicate redesign model and plans to increase the provincial tissue and allograft supply to Ontario users of tissue (hospital, surgical and dental communities). Encourage these key stakeholders to support the system by first obtaining tissue from Ontario based tissue banks before considering importation of tissue from non-provincial providers.

Refer to Appendix E for Detailed Work Plans for the System Re-Design Recommendations.

7.4 Summary of Additional Recommendations

#	Recommendations
10	Narrow eye donor criteria to reduce non-transplantable tissue. • In years 1 and 2 – no change in criteria as large number of whole eyes will be required for excision and precut training • In year 3 – conduct statistical analysis to target optimum donor criteria; potentially reduce upper age limit to 75 dependent on demand • In year 4 – conduct a second statistical analysis to target optimum donor criteria same as year 3; potentially reduce upper age limit to70 dependent on demand
11	The EBC should replace the outdated tissue transportation containers with more modern containers.
12	The EBC should secure and implement new computerized information and data system for tissue distribution capability, order management and performance management.
13	The EBC should upgrade the appearance, content and function of their website.
14	To effectively meet the standard of practice of pre-cutting tissue, funding for additional staffing should be provided to the EBC.
15	Determine the optimal governance and umbrella organization for the EBC. Considering the physical move to the Kensington Eye Institute building, Kensington Health is the logical choice. Additionally, with assistance from Kensington Health, complete a strategic plan and proactive implementation and management of the plan. Lastly, continue to leverage input from the EBC's corneal surgeon and transplant hospital constituencies (e.g. Provincial Corneal Transplantation Working Group).
16	One well organized heart valve processing centre could serve the entire needs of the country. Beginning in year 1, the HSCTL should strongly consider close collaboration with other HV programs in Canada and this collaboration with other Canadian programs should continue when the consolidated multi-tissue processing bank is fully operational.
17	The need for additional, younger donors requires special focus and collaboration with TGLN in order to address the need for more pediatric HVs. TGLN and HSCTL should strategize on identifying younger tissue and organ donor referrals and steps that can be taken to maximize consent and recovery of heart for valve donations from younger donors. Specifically: 1. Using the TGLN Data Management System, quantify referrals of potential pediatric donors. 2. From the above, identify potential pediatric donors by hospital confirming the potential will be largely concentrated at pediatric and Level I Trauma Centres. Supplement data gathering with death record reviews as needed. 3. Collaborate with Ontario coroner's to pre-establish a procedure to address this urgent need for pediatric heart-for-valve donations. 4. Address TGLN procedure for potential heart for valve donation to ensure these cases are prioritized by staff for screening, consent and recovery.
18	RegenMed should ensure more frequent MS case review with TGLN, particularly feedback on every MS donation recovered and consented cases not recovered.
19	Beginning in year 1, until the consolidated multi-tissue processing centre is operational, RegenMed should formalize a partnership with MSAT to maximize the processing and distribution of musculoskeletal allograft tissue within Ontario to reduce the provincial reliance on imported tissue. • RegenMed, as the only processor of musculoskeletal tissue currently operating in Ontario, is able to process musculoskeletal tissue into traditional allografts for MSAT to more fully utilize RegenMed processing capacity. • Inventory sharing of traditionally processed MS tissue by RegenMed and MSAT would

#	Recommendations
	allow each organization with a backup supply to enhance and ultimately broaden their abilities to adequately service their Ontario hospital customers, particularly those hospitals relying upon imported tissue.
20	In year 1, RegenMed should begin processing enhanced allografts beginning with demineralized bone until the consolidated multi-tissue processor is operational.
21	In year 1, MSAT should move toward utilizing 3 person recovery teams led by Certified Tissue Bank Specialists (CTBS). This should continue until TGLN's multi-tissue recovery program is operational. MSAT should maintain physician led recovery teams for fresh tissue allografts.
22	In year 1, MSAT should obtain access to specialty processed allografts from a contract processor(s). This includes demineralized bone, demineralized bone in paste, putty of gel carrier, freeze dried tissue and pre-cut spinal grafts. This should continue until implementation of a consolidated multi-tissue processing bank is completed.
23	Beginning in year 1, until the consolidated multi-tissue processing centre is operational, MSAT should formalize a partnership with RegenMed to maximize the processing and distribution of musculoskeletal allograft tissue within Ontario to reduce the provincial reliance on imported tissue. • MSAT can reduce or eliminate the number of Ontario MS tissue donations exported to the U.S. for processing of Traditional MS allografts to more fully utilize Ontario based processing capacity. • Inventory sharing of traditionally processed MS tissue by MSAT and RegenMed would allow each organization with a backup supply to enhance and ultimately broaden their abilities to adequately service their Ontario hospital customers, particularly those hospitals relying upon imported tissue.
24	Maximize donor yield from skin donors by addressing the following: 1. Removing the requirement to refrigerate the donor's body for 4 hours prior to skin recovery 2. Increase recovery yield to 0.3 square metres per donor
25	A consolidated tissue processing bank should pursue the capability to process acellular dermal matrix (ADM) and demineralized bone matrix (DBM) in a carrier.
26	Tissue banks should be AATB accredited to process tissue in Ontario.
27	Improve cornea transplant allocation and wait list practices by implementing the following: 1. Require each institution to provide a monthly report of the total number of patients on its waiting list, and for the upcoming two months, for every scheduled surgery to include: a unique patient identifier, the urgency category using Access to Care definitions, the type of surgery to be performed, the expected location, scheduled time, and date, and any other information or special request. 2. Formalize the tissue request. At least one month in advance, a tissue request form should be provided to the EBC by each institution for each upcoming surgery. The EBC should cross reference each request form against that institution's monthly patient list. 3. Eliminate the two corneas per surgeon per day allocation limitation. 4. Implement the following capacity building strategies: a. EBC to provision pre-cut tissue as a standard of practice b. Address OR closures by establishing an alert system for when surplus tissue is available
28	TGLN and MSAT to review every quarter the Mount Sinai hospital patient wait list for osteochondral tissue to determine the optimal number of fresh tissue donations needed.
29	TGLN and OPFSB to review the need for skin by the burn units at Sick Kids Hospital and the Hamilton Health Science Centre and work to address this need.

#	Recommendations
30	Adopt and transition to using a UDI (unique device/allograft identification) system for identifying donors/tissues/allografts for best practices and most efficient and effective tracking and tracing capabilities. Recommend the use of ISBT 128. Steps toward implementation include: • Ensure TGLN iTransplant software and subsequent systems software implemented by the EBC and the Consolidated Multi-tissue Processing Centre can adopt ISBT 128. • Stage 1 – Begin with the adoption of the terminology for tissue developed by ICCBBA in Year 2. • Stage 2- update software to enable ISBT 128 data structures in Year 3. • Stage 3 – implementation at TGLN and EBC concurrent with new Consolidated Multi-tissue Processing Centre system coming online in Year 4
31	Each year, some aspect of demand measurement should be performed in Ontario including data reviews and surveys to surgeons, hospitals, dentists, and importing tissue banks.

Appendix A: TGLN Routine Notification Hospitals

Tier I Hospitals	Newly Designated Hospitals
Central Ontario and GTA	Central Ontario and GTA
- Lakeridge Health Corporation - Mackenzie Health - Royal Victoria Hospital - St. Michael's Hospital - Sunnybrook Health Sciences Centre - The Hospital for Sick Kids - The Scarborough Hospital - Trillium Health Centre - University Health Network - William Osler Health System	- Hamilton Healthcare Services - Humber River Regional Hospital - Markham Stouffville Hospital - Mt Sinai Hospital - North York General - Peterborough Regional Health Centre - Rouge Valley Health System - Southlake Regional Health Centre - St. Joseph's Health Centre-Toronto - The Credit Valley Hospital - Toronto East General Hospital
Eastern Ontario	Eastern Ontario
- Children's Hospital of Eastern Toronto - Kingston General Hospital - The Ottawa Hospitals	- Cornwall General Hospital - Hospital Montfort - Pembroke Civic Hospital - Pembroke General Hospital - Queensway-Carleton Hospital - University of Ottawa Heart Institute
Northern Ontario	Northern Ontario
- Health Sciences North - Thunder Bay Regional Health Sciences Ctr.	- N/A
South Western Ontario	South Western Ontario
- Grand River Hospital Corporation - Hamilton Health Sciences Centre - Hotel Dieu Grace Hospital - London Health Sciences Centre - Niagara Health System - St. Mary's General Hospital * *As of December 31, 2013*	- Bluewater Health - Brantford General Hospital - Cambridge Memorial Hospital - Chatham-Kent Health Alliance - Grey Bruce Health Services - Guelph General Hospital - Joseph Brant Memorial Hospital - Leamington District Hospital - St. Joseph Healthcare System Hamilton - St. Thomas Elgin Hospital - Stratford General Hospital - Windsor Regional Hospital - Woodstock General Hospital

Appendix B: Additional Funding Assessment Details

The financial details have been removed from this version of the report due to non-disclosure agreements that are currently in place.

Appendix C: Data Sources Review

This section consists of a schedule of the major data sources for performance metrics and financial information used for the Report - Tissue Banking in the Province of Ontario: Review and Analysis. For each source we provided a brief definition, the organization providing the information, how the information is captured, any knowledge as to what systems are used, the frequency of the collection data and how the information is reported.

Name:	**Reports / Applications for information from TGLN**
Definition:	Numerous Reports on organ and tissue donors, referrals, approaches, consent rates, tissues consent for, tissue recovered, hospital compliance on referrals, etc.
Organization Providing:	TGLN
Method of Capture:	TGLN's primary IS systems and MS Office Applications
IT System Used:	Information system used by TGLN include iTransplant, TOTAL, and MSOffice
Collection Frequency:	Continuous, Daily, Monthly
Reporting Practices:	TGLN public reporting is available at www.giftoflife.on.ca

Name:	**Survey issued by TGLN to entities providing tissues/tissue allografts.**
Definition:	A survey requesting detail information on tissues/tissue allografts that are sent into the province of Ontario.
Organization Providing:	TGLN
Method of Capture:	Survey issued December 20, 2013
IT System Used:	Various
Collection Frequency:	One time survey
Reporting Practices:	One time survey

Name:	**Ontario Donor Registry**
Definition:	BeADonor is the brand name for Ontarians access to the organ and tissue donor registry (the "Registry") in province. Registration may be completed digitally via the internet (at https://beadonor.ca) or by visiting a ServiceOntario centre or by mail. The Registry database holds information on several million Ontarians who have affirmed their intent to be an organ and tissue donor. The registry data base (which contains the information) is maintained by the MOHLTC
Organization Providing:	MOHLTC and ServiceOntario
Method of Capture:	Registration by mail or via the internet or visiting a ServiceOntario centre.
IT System Used:	Entrust
Collection Frequency:	Real time for internet sign up For TGLN direct use in determining if a donor is registered – affirming there wish to donate. TGLN provides unique identification to ServiceOntario. ServiceOntario responds by transmitting a password protected document to TGLN
Reporting Practices:	The website address (https://beadonor.ca/scoreboard) is where information is publically reported on the percent of persons in the province registered and how many new registrations have been made. The website indicates that it is updated every three months.

Name:	**Routine Notification Rate for Deceased Organ and Tissue Donation.**
Definition:	Provides a list of specific designated hospitals in Ontario which are required to notify TGLN of deaths occurring at their facility. Compliance rates for a select period of time for each of the hospitals are reported.
Organization Providing:	TGLN
Method of Capture:	TGLN's Donor Management System

IT System Used:	iTransplant
Collection Frequency:	Information for the period April I to December 31, 3023.
Reporting Practices:	TGLN public reporting at http://www.giftoflife.on.ca/en/publicreporting.htm#donors

Name:	**Discharge Abstract Database (DAD)**
Definition:	"…the Discharge Abstract Database (DAD) captures administrative, clinical and demographic information on hospital discharges (including deaths, sign-outs and transfers)."[25]
Organization Providing:	Hospitals and Health care providers supply the information to the Canadian Institute for Health Information (CIHI).
Method of Capture:	Mandatory reporting by hospitals and health care entities in standardize formats
IT System Used:	Various; Compiled and reported by CIHI.
Collection Frequency:	Continuous
Reporting Practices:	Reporting is available by fiscal years. The most recent year available is: 2012–2013, next data release is September 2014.

Name:	**National Ambulatory Care Reporting System (NACRS)**
Definition:	"The National Ambulatory Care Reporting System (NACRS) contains data for all hospital-based and community-based ambulatory care: Day surgery; Outpatient clinics; and Emergency departments. Client visit data is collected at time of service in participating facilities."[26]
Organization Providing:	Hospitals and Health care providers supply the information to the Canadian Institute for Health Information (CIHI).
Method of Capture:	Mandatory reporting by hospitals and health care entities in standardize formats
IT System Used:	Various; Compiled and reported by CIHI.
Collection Frequency:	Continuous
Reporting Practices:	Reporting is available by fiscal years. The most recent year available is: 2012–2013, next data release is September 2014.

Name:	**Ontario Case Costing Initiative (OCCI)**
Definition:	"…OCCI are the collection of case costing data in support of improved management decision making and the development of hospital funding methodologies…[involving] Participating hospitals."[27]
Organization Providing:	Participating hospitals health care entities supply the information to the Ontario Ministry of Health and Long-Term Care.
Method of Capture:	Participation by a limited group of hospitals providing cost information to the Ontario Ministry of Health and Long-Term Care.
IT System Used:	Various; Compiled by the Ontario Ministry of Health and Long-Term Care.
Collection Frequency:	Continuous
Reporting Practices:	OCCI Costing Analysis Tool available at http://www.occp.com/main Page.htm may be used to access information.

Name:	**Ontario Health Insurance Plan (OHIP)**
Definition:	Billing data available for physician services sent into the province of Ontario.
Organization Providing:	OHIP and the Ministry of Health and Long-Term Care (MOHLTC)
Method of Capture:	Information is controlled by OHIP and MOHLTC.
IT System Used:	MOHLTC IT systems
Collection Frequency:	Continuous
Reporting Practices:	

Name:	**Reports available on websites for Canadian Blood Services**
Definition:	Various Reports on Donation and Transplantation in Canada and Ontario available on the website and www.organsandtissue.ca

Organization Providing:	Canadian Blood Services – prepared by Canadian Blood Services or other research organizations sponsored by CBS or the Canadian Council for Donation and Transplantation.
Method of Capture:	Published documents
IT System Used:	N/A
Collection Frequency:	Independent Reports
Reporting Practices:	Specific Referenced Reports Included: • Estimating Potential Tissue Donors in Canada from 2005 – 2008: An Update based on Acute Care Hospital Admissions Data January 2014 – Canadian Blood Services • Canadian Imported Surgical Allograft and Acellular Dermal Matrix Study 2013 © 2013 Millennium Research Group, Inc. Published April 2013 by Millennium Research Group, Inc. Toronto, Ontario • Supply of Human Allograft Tissue in Canada Final Report 2010 – Canadian Blood Services • Canadian Imported Surgical & Dental Allografts, Allograft Substitute, & Acellular Dermal Matrix Study 2010 © 2010 Millennium Research Group, Inc. Published March 2010 by Millennium Research Group • Demand for Ocular Tissue in Canada – Final Report January 2010 – Canadian Blood Services • Ryan Kanigan, Peak Research, Inc. Burnaby, British Columbia. Market Evaluation of Demineralized Bone Matrix Products in Canada, Research Highlights. Prepared for the Canadian Council for Donation and Transplantation, June 2006. A strategic plan to improve organ and tissue • Call to Action, Donation and transplantation performance for Canadians, Developed by Canada's organ and tissue donation and transplantation communities in collaboration with Canadian Blood Services • Eye and Tissue Banking in Canada: Where are we headed? November 3, 2012 Mathias Haun, Director, Strategic Planning (Tissues) CBS

Name:	**2012 Annual Report of the Office of the Auditor General of Ontario, Follow-up to VFM Section 3.10, 2010 Annual Report Chapter 4 M**
Definition:	Report on donation and transplantation activities in Ontario
Organization Providing:	Office of the Auditor General of Ontario
Method of Capture:	N/A
IT System Used:	N/A
Collection Frequency:	Independent Reports
Reporting Practices:	OCCI Costing Analysis Tool available at http://www.occp.com/main Page.htm may be used to access information.

Name:	**Environmental Scan of Provincial/Territorial Tissue System, Baseline Data as of July 31, 2013**
Definition:	Collection of data from tissue donation and transplantation agencies (tissue banks) about activities: governance, general information, recovery, processing of tissue donors, procurement of tissue from other entities, distribution of allografts, quality and safety and budgetary.
Organization Providing:	TGLN provided the reports. The survey was issues by the Provincial / Territorial Blood Liaison Committee
Method of Capture:	Survey completed by individual tissue bank representatives
IT System Used:	Assume that tissue banks used their IT and record keeping systems.
Collection Frequency:	Report scan collected in August 2013
Reporting Practices:	Environment Scan Reports were provided for: • Mount Sinai Allograft Technologies

	• Lake Superior Centre for Regenerative Medicine • Tissue Laboratory – Hospital for Sick Children • Eye Bank of Canada – Ontario Division • Ontario Professional Firefighters Skin Bank For all of the above organizations follow up questions were forwarded and additional information was provided.

Name:	**Information provided Eye Bank of Canada – Ontario Division**
Definition:	Statistical information on volume activity for eye donation and use of ocular tissues; Summary financial information.
Organization Providing:	Eye Bank of Canada – Ontario Division (EBC)
Method of Capture:	Spreadsheet information provided by email/pdf file.
IT System Used:	EBC uses MS Access and Excel spreadsheets.
Collection Frequency:	Monthly or more often
Reporting Practices:	Data was provided at request of GJC Consulting Group

Name:	**Information on/about Hospital for Sick Children**
Definition:	Summary financial information
Organization Providing:	Hospital for Sick Children
Method of Capture:	Spreadsheet information provided by email/pdf file.
IT System Used:	Excel file was noted on pdf file provided
Collection Frequency:	Monthly or more often
Reporting Practices:	Data was provided at request of GJC Consulting Group

Name:	**Information on/about the Lake Superior Centre for Regenerative Medicine**
Definition:	Detailed Inventory Report; Business Plan (August 2013); report of tissue donors recovered for 2011-12; Audited Financial Statements for years ended Dec 2011 and Dec 2012; Allograft Catalog;
Organization Providing:	Lake Superior Centre for Regenerative Medicine
Method of Capture:	Computer software
IT System Used:	RegenMed reported that they used the following IT systems: tracking logs in the form of excel spreadsheets, a program called Freezerworks, which tracks tissue after it is released for distribution.
Collection Frequency:	Monthly or more often
Reporting Practices:	Data was provided at request of GJC Consulting Group

Appendix D: Jurisdictional Review

7.5 Tissue Donation and Transplantation in the United States

7.5.1 Overview

As measured on many fronts, such as the high number of tissue donations, lack of patient waiting lists and the enhanced processing of tissue allografts, the United States has one of the most successful tissue transplant systems in the world. The rate of eye donation in Ontario is comparable to one, even greater than the other U.S. program. However, the donation rates of bone, skin and heart valves are significantly less those presented for the U.S. programs.

This is significant in that Ontario not only holds the potential for a high rate of tissue donation, but is demonstrating with the number of eye donors that high volume tissue donation is achievable. The high rate of eye donation is indicative of the potential donation levels for other tissues. Expectations for this potential in Ontario are further confirmed inasmuch as the transplantation environment in the United States reveals more similarities in laws, regulations, culture and approach than differences.

7.5.2 Government Regulation & Authority Concerning Human Tissue

"NOTA [the National Organ Transplant Act of 1984] is the cornerstone of the federal system for organ transplantation[2] [in the United States,] NOTA included language that made it a crime 'for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.' At the time, [the United States] Congress was exceptionally concerned about the rise of an organ market and mindful of the potential inequities that could arise if destitute donors were coerced into selling their organs. The Senate Report accompanying NOTA stated that 'human body parts should not be viewed as commodities.'[3] For the past twenty years, the prohibition against buying and selling organs in the United States has quoted NOTA as mantra."[28]

In addition to NOTA, state legislation applicable to tissue donation and transplantation governs and regulates activities surrounding tissue donation in the various fifty states of the U.S., with the Uniform Anatomical Gift Act (UAGA) used as the guiding framework for legislation enacted. The most recent revision to the UAGA was in 2006. The medical and technical aspects of tissue screening, recovery, processing and distribution as well as tracking and tracing donors and allografts is regulated by the United States Food and Drug Administration.

7.5.3 Government/Other Communication and Promotion of the Benefits of Donation & Transplantation

The federal government demonstrated its support and promotion for tissue donation with a very important ruling, referred to as the "Conditions of Participation", which positively impacted tissue donation by further facilitating the identification and notification of potential organ and tissue donors from hospitals to Donation Agencies. The regulation states that "As a condition of receiving Medicare reimbursements, the

Medicare Conditions of Participation (COP) regulations require hospitals to report all deaths to an (organ Procurement organization (OPO), tissue bank and/or eye bank."[29] Regular notification by a significant percentage of hospitals of potential donors was already in place prior to this ruling in the 1990s, through the concerted efforts of organ and tissue banks, but this federal ruling provided the donation and transplantation community with a powerful tool to use in securing virtually full compliance in terms of routine referral.

7.5.4 Identification and Referral of Donors

In part due to the previously mentioned "conditions of participation ruling" and because of the intensity of eye and tissue banking activities, with robust tissue referral and screening call centers in the United States, referrals and notification of deaths are reported in a consistent, routine manner in significant volumes. The American Association of Tissue Banks, in its 2007 survey, indicated that donor referrals from hospitals totaled 744,212, as reported by the 109 tissue banks in the United States that participated in the survey. In addition, another 15,110 referrals were received from medical examiners/coroners.[30] In its 2012 statistical survey the Eye Bank Association of America's eighty participated member eye banks reported an aggregate 770,479 death referrals.[31]

7.5.5 Approach and Consent for Tissue Donation

In the United States, the approach for consent to tissue donation is typically conducted by a representative of the local tissue or eye bank, or in many cases, by the regional Organ Procurement Organization (OPO) in its corresponding referral/screening/consent call center. Other large entities, such as Statline, a donor screening call center operated by MTF, perform this function for a large group of OPO and tissue/eye bank clients. Individuals employed at these call centers are specially trained for this work. Most tissue and eye banks' policies and practices indicate that these representatives should approach next of kin, as their training and attitude toward donation is considered more likely to result in higher donation rates than approaches by nurses or other hospital personnel. Donation activities for organ, tissue and eye donors in the U.S. is very much a collaborative effort, but some level of competing interests between programs receiving organs versus tissues versus eyes from the same potential pool of donors can at times result in tensions that, if not managed properly, can lead to less than optimum levels for eye and tissue donation. This stratification of priorities, in terms of organs and tissues, is not a uniquely U.S. phenomenon.

Overall consent rates according to the AATB survey of 2007 indicated that approaches by the 109 tissue banks reporting totaled 114,173, with 33,604 consents obtained, 73,484 consents denied. For 11,974 cases, the next-of-kin was unavailable.[32] The Eye Bank Association of America survey for 2012 from its eighty reporting members showed 165,688 death referrals that were deemed eligible, with actual donors recovered numbering 59,221.[33]

7.5.6 Screening of Referrals for Potential Donors

Screening of tissue and eye donors is essentially regulated by the United States Food and Drug Administration (FDA). Here is an excerpt from their website:

"Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P. The [FDA's] Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps under 21 CFR Parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs.
Parts 1270 and 1271 require tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records. FDA has published three final rules to broaden the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission and spread of communicable disease. One final rule requires firms to register and list their HCT/Ps with FDA. The second rule requires tissue establishments to evaluate donors, through screening and testing, to reduce the transmission of infectious diseases through tissue transplantation. The third final rule establishes current good tissue practices for HCT/Ps. FDA's revised regulations are contained in Part 1271 and apply to tissues recovered after May 25, 2005. The new requirements are intended to improve protection of the public health while minimizing regulatory burden."[34]

Consistent with FDA standards for screening are the standards of the two very active and influential professional associations, the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA).

7.5.7 Recovery of Eye and Tissue Donors

There are an estimated eighty eye banks in the United States that recovered 59,221[36] eye donors in the year 2012, which on a per capita basis is about 200 donors per million population. The AATB report of 2007 indicated a total 29,799 deceased donors[35] were recovered – and these donors were often multiple tissue donors, that is, donors comprised of more than one of the following tissue categories: bone, soft tissue, skin, cardiovascular tissues.

7.5.8 Processing of Donors

The AATB 2007 survey indicated the following processing volumes for various types of tissue donations: musculoskeletal (bone, cartilage, osteoarticular) – 23,466; soft tissue (fascia lata, ligaments, tendons, pericardium, dura, nerves) – 20,578; cardiovascular – 8,826; and skin – 17,120[36]. Processing of these tissues covers the full range of technology, from basic implants in traditional forms, to the most sophisticated allografts currently available.

For the Eye Bank Association of American statistics for 2012 the approximate volumes reported included total corneal grafts of 68,681, of which almost 20,000 were exported outside of the U.S. Of the roughly 46,000 corneas used in the U.S., approximately 22,000 were processed, the vast majority of these by microkeratome in preparation for lamellar keratoplasty.[37]

7.5.9 Waitlist Information

Wait lists for tissues effectively do not exist in the United States.

7.5.10 Tissue Distribution and Allocation

As mentioned above, the EBAA's 2012 Statistical Report indicated that there were over 68,000 grafts from corneas. In addition, more 26,000 [38] eye tissues were provided for research or training. The AATB 2007 survey indicated that over 2.1 million allografts were distributed (with twenty-nine tissue banks reporting that they distributed some fraction of their tissues to forty-five countries outside the U.S.).[39]

7.5.11 Traceability and Tracking

In the United States "Manufacturers must track tissues from the donor to the receiving facility, and back; FDA regulations do ***not*** *[emphasis by GJC Consulting]* require tissue establishments to track tissues to individual recipients [but] Tissue products must be labeled with a unique identifier.[40] It is generally assumed that virtually all tissue banks are now in compliance with tracking and tracing standards as promulgated and enforced by the FDA. Focused attention is now being placed on hospitals' and surgeons' requirements for tracking and tracing implants to individual recipients. "In 2005, The Joint Commission set new requirements for hospitals in the U.S. to maintain traceability records for appropriate storage and for investigation and reporting of adverse outcomes associated with tissue allograft use. It previously had standards for recordkeeping and storing tissues in laboratories but not for operating rooms. These standards now affect all departments of the hospitals regardless of where tissues are handled. The tissue supplier is responsible for traceability from donor to the hospital and the hospital is responsible to ensure traceability from receipt of the tissue to the recipient…the hot button in this tissue bank profession revolves around focusing on how hospitals handle tissue and improving this process…[and the] need [for] fool-proof methods of traceability. This is an area of tissue banking that only recently is getting the attention it needs and it is so important to patient safety."[41]

7.5.12 Transplantation Surgery

Donate Life America states on its website that "More than 46,000 corneas were transplanted in 2012 [and] more than 1 million tissue transplants are done each year and the surgical need for tissue has been steadily rising."[42] Surgery and the costs of the allograft used in surgery are typically paid by private insurance companies, similar to the payment of the vast majority of surgical procedures and health care in the U.S. generally.

7.5.13 Financial and Costs References

An estimated 46,000 corneas are distributed in the U.S., and an additional 20,000+ outside of the country. Assuming that typical in country fees for PKP and precut corneas range from $2,500 to $4,000 per allograft, with perhaps a third to a half that fee for tissues exported, it is reasonable to estimate that aggregate eye banking activities total $200 million in service fee revenue, annually. Virtually all of the corneas and other ocular tissues are processed and distributed by eye banks considered to be non-profit

organizations that receive the vast majority of their revenues from fees for service, rather than from financial gifts or government grants. The $200 million in eye bank revenue is but a fraction of the value of musculoskeletal, skin and heart valve allografts distributed by tissue banks each year, and the corresponding fees for service. "Tissue companies — by the industry's own estimates — make more than $1 billion a year"[43]. Many tissue banks (musculoskeletal, skin or heart valve) in the United States are nonprofits, with virtually all revenue made on a fee for service basis, but there are also for profit companies, with several very large and financially viable entities. The cost of related transplantation surgery and hospital costs cannot be easily estimated but may be ten or more times the value of the associated allografts used in the procedures.

7.5.14 Comparing and Contrasting Ontario and the United States

Organ donation rates are higher in the U.S. Eye donation rates in the U.S. are moderately higher than Ontario. Corneas in the U.S. are almost universally recovered by in situ excision, and most eye tissue used for endothelial keratoplasty is pre-cut by an eye bank. In Ontario most recovery is by enucleation of the whole globe, and tissue is currently pre-cut by the corneal transplant surgeon in the operating room. Musculoskeletal, skin and cardiovascular tissues donors recovered, and their associated processing levels are significantly lower in Ontario. In almost all cases, tissue banks in Ontario are parts of hospitals. In Ontario, the primary entity, promoting tissue donation and providing referral, screening and consent services (as well as being the province's organ procurement organization) is TGLN.

Virtually all tissue banks and a significant majority of eye banks in the U.S. are free standing entities, independent from hospitals. Despite the preponderance of the non-profit form of organization, many of the activities and interactions among U.S. eye and tissue banks are highly competitive. Their non-profit status combined with the competitive market for allografts in the U.S. causes many eye and tissue banks to set services fee revenue levels close to the levels of costs incurred, operating in a fashion consistent with the intent of the National Organ Transplantation Act of 1984. Interestingly, and particularly in the case of musculoskeletal tissue banks, this "revenue equal to cost" approach typically based on an entity's aggregate revenues and costs, cannot be applied to specific categories of allografts, particularly those in high demand (examples are tendons and ligament). When demand is not in balance with supply, specific service fees associated with allografts are driven by market forces, perhaps even more so than actual cost of production, whether calculated on a full or incremental cost basis. High market demand for certain kinds of allografts results in much higher contribution margins than allografts; which are less in demand. This pricing structure is not unique to the U.S. and a similar approach to pricing may be found among some Canadian tissue banks.

The TGLN Act and TGLN's mandate of required, routine referral (of deaths) in acute care facilities (and potentially all hospitals) provides a current level of 25,000 death referrals per year, with the opportunity for this level to increase as required referral is expanded beyond the acute care facilities. Tissue and eye banks in the United States benefit from almost universal use of required notification by hospital of deaths that occur. Many jurisdictions within the U.S. have donor registries similar to Ontario's. For example, the two entities from programs in the East and West Coast of the United States reviewed at the beginning this report both have registries that are essentially affirmative only. The California registry specifies the organs and tissues that the individual wishes to donate. In the U.S., the decisions recorded on the registries are usually considered final and a surviving family member (next of kin) may not supersede the wishes recorded on the Registry. In Ontario, in cases in which an individual's donor registration is available and affirmed, TGLN will seek and abide by the final decision of the surviving next of kin.

7.6 Tissue Donation and Transplantation in the British Columbia

7.6.1 Overview

British Columbia, the far western province of Canada, has a government like Ontario and the rest of country, and a similar health care system. British Columbia's population as of December 2012 was 4.62 million (approximately one third the size of Ontario's) and its land area is 95 million hectares[44] (or about 950,000 square kilometres (slightly smaller than Ontario) with most of the population residing in the southern part of the province in or around greater Vancouver. There are ninety-five acute-care hospitals [45] in the province. Total deaths for the twelve months ended 6/30/13 are estimated to be 32,767 in British Columbia versus 93,755 in Ontario.[46]

Table 16: 2013 British Columbia Donation Statistics

Measure	#
Total Organ Referrals*	144
Total Cornea Referrals*	2,860
Organ Donations*	68
Organ Transplants (excluding live donations)*	350
Eye Donations*	626
Corneas Provided for Transplant (2012)xxiv**	662
** source BC Transplant*	
*** source Eye Bank of British Columbia*	
**** No tissue banks in BC recover or process MS, skin or heart valve tissues.*	

Data concerning British Columbia donation and transplantation was made available with the assistance of BC Transplant [47], the Organ Procurement Organization serving the province (see Table 24). Unless noted otherwise the following information is for 2013, for deceased donors.

7.6.2 Government Regulation & Authority Concerning Human Tissue

Regulation of organ and tissue donation is embodied in the Human Tissue Gift Act of British Columbia and, as in Ontario, Health Canada plays an important with its regulation and guidance documents for Cell, Tissue and Organ Establishments - Safety of Human Cells, Tissues and Organs for Transplantation.

7.6.3 Role of Key Government Agencies and Organizations

The two organizations most active in organ and tissue donation in British Columbia are BC Transplant – the Organ Procurement Organization and the Eye Bank of British Columbia (EBBC). Forty persons are employed at BC Transplant and the Eye Bank has a staff of 10.5 FTEs.[50] Promotion of organ and tissue donation is also supported by several national organizations and societies.

7.6.4 Government/Other Communication and Promotion of the Benefits of Donation & Transplantation

Donor Registry Information: *- the following information is taken directly from the website hosted by Provincial Health Services Authority / BC Transplant - the Organ Donor Registry of British Columbia.*

> *"In 1997, a new, remote access, computerized registry was introduced to legally record an individual's decision on organ donation in British Columbia. This registry, the first of its kind in Canada, replaced all previous ways of recording your decision, including placing a decal on your CareCard or driver's license. Although the old system of indicating your decision to be an organ donor was an easy and painless procedure, it had many flaws. It was only available to BC's drivers, clearly missing a large segment of society. It didn't provide individuals with a choice as to which organs, if any, they wanted to donate… BC Transplant's web site communicates the benefits and much information about organ donation. At the time of an individual's death…[BC Transplant or EBBC staff query the registry*[50]*]. If the individual has registered, a copy of their registration form is printed and verified, and then shown to the person's family."*[48]

There are a number of ways to register according to the website: filling out the Online Registration Form, requesting a brochure by mail, or picking up a brochure from Driver Service Centres (Motor Vehicle Branch), all London Drugs locations, ICBC Autoplan Brokers, ICBC Claim Centres, and Doctors' offices.[51]

The form used on the Registry offers several choices – to donate organs and tissues for transplant and research, to donate exclusively for transplant, to indicate exceptions to various organs and tissue one does not wish to donate – six organ groups and three tissues – eyes, skin and bone – are offered as exceptions. There is also a category for indicating items the registrant does not wish to donate. As of December 10, 2013 there were 876,126 [49] persons registered, about 19% of the provincial population.

7.6.5 Identification and Referral of Donors

All in-hospital deaths and impending deaths up to and including seventy-five years of age are referred under the province's Universal Referral Legislation. Calls are made to 1 877 DONORBC, which are triaged by Statline. The remaining referrals are made directly to BC Transplant and the EBBC [Eye Bank of British Columbia…and as indicated above, there were] 144 organ and 2,860 eye referrals in 2013. Statline, a donor screening call center operated by MTF, receives the initial referral and triages accordingly based upon ventilator status: ventilated referrals to BCT; non-ventilated referrals to the EBBC. Thirteen of the total organ donors recovered in 2013 was listed on the Donor Registry. [50]

7.6.6 Approach and Consent for Tissue Donation

The current process for obtaining consent for donation from the donor family involves a review of the Provincial Organ and Tissue Donation registry which "…the EBBC and BC Transplant access for each referral. In the absence of a signed consent the EBBC, either asks the referring healthcare professionals to approach the family or, the EBBC staff will approach, usually by telephone. For organ donation, BC Transplant staff are trained to approach families for consent. When it is logistically impossible for the

staff to be on site to ask for consent, they will coach the most appropriate healthcare professional to approach for consent. When BC Transplant staff approach for consent, they ask for consent for all organs and tissues, including corneas, therefore the EBBC does not have to re-approach the family." [50]

7.6.7 Screening of Referrals for Potential Eye Donors

The only tissue currently recovered is eye tissue and corresponding "qualification and screening [is] performed by EBBC technicians according to Health Canada Regulations and EBAA standards." [50]

7.6.8 Recovery and Processing of Eye Donors

The current processes and logistical practices for recovery of tissue by eye banks are: "For cornea – within the lower mainland, EBBC technicians perform the enucleation and transport the tissue to the eye bank for evaluation and processing. Outside of the lower mainland, on call technicians will enucleate and make travel arrangements (air, ferry, etc.) for the tissue to arrive at the eye bank within an acceptable amount of time." [50]

The website of the Department of Ophthalmology & Visual Sciences, the University of British Columbia states that "The EBBC [Eye Bank of British Columbia] is the only eye bank in Canada to precut tissue for Descemet's stripping automated endothelial keratoplasty."[50]

7.6.9 Wait List Information

Cornea waitlists are physician driven. For each patient requiring corneal transplant, the ophthalmologist completes a wait list form and submits it to the EBBC. The EBBC, in turn, compiles and provides ophthalmologists with their monthly wait lists. The ophthalmologists' surgical booking clerks provide the EBBC with lists of OR times available to the surgeons for corneal transplant and the EBBC arranges for delivery of the tissue. Each surgeon decides which patients on their list will receive transplants. If there is a surplus of corneas, the EBBC notifies the surgical booking clerks to identify additional available OR times. Any remaining tissue is offered to programs throughout the rest of Canada. The cornea transplant waiting list indicates 416 persons waiting for the procedure. [50]

7.6.10 Tissue Distribution and Allocation

For tissue other than corneas: for elective surgery, surgical booking clerks make requests for tissues. If the required tissue is not in the bank inventory, the staff sources the tissue and makes every effort to procure it. For very complex cases or for new procedures, a clinical rationale must be provided and it and the tissue request must be reviewed by the new technology board, prior to ordering. [50]

7.6.11 Traceability and Tracking

Health Canada Regulations are followed for all tissues. [50]

7.6.12 Transplantation Surgery

Tissues other than eye tissues are obtain from tissue banks outside of British Columbia. The various health authorities in the province source the allografts.

7.6.13 Comparing and Contrasting Ontario and British Columbia

On a per capita basis, organ donation rates are slightly higher in Ontario. Eye donation rates are comparable in the two provinces. Musculoskeletal and skin donation levels are low in Ontario and limited processing of tissue takes place at several locations. Currently, no musculoskeletal, heart valve or skin tissue recovery from deceased donors takes place in British Columbia.

As is the case in the rest of Canada - tissue donation and transplantation is organized and governed at the provincial level in both jurisdictions. Both provinces have legislation that mandates required, routine referral (of deaths). TGLN has its own Provincial Resource Centre and BC Transplant uses Statline.

Both jurisdictions have effective donor registries that are actively promoted. About 19% of the population of British Columbia is registered compared with 24% of Ontario's. The Ontario registry limits signing up to those individual who wish to affirm their intent to be a donor. There is no method for a person to record his/her intent to decline or not to donate, at least for declining to donate in a full and complete manner. In the case of the British Columbia Registry, one may either affirm the donation or alternatively may indicate their intent to not donate organs and tissues. Both registries allow for those affirming donation to indicate exceptions as to specific organs and/or tissues to be donated.

Much of the information above was graciously provided by Mr. Ed Ferre, Director Program Development and External Relations - BC Transplant. We wish to express our appreciation for his assistance.

7.7 Tissue Donation and Transplantation in Quebec

7.7.1 Overview

Quebec has a governmental structure similar to Ontario and the rest of Canada, and a comparable health care system. Its population is 8,028,400 which is 23.6% of the Canadian national population. With a recent 4.7% population growth rate Quebec is the second most populated province in Canada. Ontario is the most populated province with 13.6 million people and British Columbia with 4.6 million inhabitants ranks third.[51] Quebec's land area is 1,356,128 square kilometres[52] (greater than Ontario's) and as in the rest of Canada, its population resides primarily in the southern part of the province, particularly in and around the city of Montreal. Québec's health care system public. The Provincial Government defines its scope, finances, service production and implementation. In October 2004, Québec's health and social services network was comprised of 322 institutions, of which 199 were public. The 123 private institutions were nearly all residential and long-term care centers."[53] Total deaths in Quebec for the twelve months ended 6/30/13 are approximately 61,250 compared to 93,755 in Ontario.[54]

7.7.2 Statistics on Referrals, Consents, Donors and Tissues

Table 17: 2013 Hema-Quebec Donation Statistics

Measure	#
Tissue Donation Referrals*	646
Tissue Donations Recovered	175
Hearts for Valves Recovered*	62
Bone Donations Recovered*	160
Tendon Donations Recovered*	94
Skin Donations Recovered*	133
Eye Donation Referrals	1,862
Eye Donations Recovered	714
Organ Donations Recovered	120
Number of Organ Recipients	364
Organ Wait List	1,250
** source Hema-Quebec*	
*** source Transplant Quebec*	

7.7.3 Government Regulation & Authority Concerning Human Tissue

Organ and tissue donation is not specifically referenced in legislation in Québec. Transplant Québec, the OPO in the province is a non-profit corporation (NPO) legally constituted pursuant to Part II of the Companies Act (Québec). It receives its mandate from the province's health and social services department, the Ministère de la Santé et des Service sociaux (MSSS)."[55] "Hema-Quebec [the blood and tissue banking organization serving the province] was constituted on March 26, 1998 by letters patent issued under Part III of the Companies Act (R.S.Q., chapter C-38), and is continued in accordance with the provisions of the Act respecting Hema-Quebec and the Haemovigilance Committee (S.Q. 1998, chapter 41). [Its]…mission is to efficiently provide adequate quantities of safe, optimal blood

components and substitutes, human tissue and cord blood to meet the needs of all Quebecers; to provide and develop expertise, services and specialized and innovative products in the fields of transfusion medicine and human tissue transplantation. Hema-Quebec operates in a regulated environment in compliance with the requirements of the Food and Drug Act and under a license from the Biologics and Genetic Therapies Directorate of Health Canada…Hema-Quebec is not subject to income taxes."[56]

7.7.4 Role of Key Government Agencies and Organizations

The two organizations most active in the field of organ and tissue donation and transplantation in Quebec are Transplant Quebec and Hema-Quebec. A press release issued by Hema-Quebec in 2012 states: "Héma-Québec is celebrating its 10th year of human tissues activities. Better known for its role in managing the collective blood supply of Quebecers, Héma-Québec has been the supplier of human tissues for transplantation since December 18, 2001. In addition to the collection of eyeballs for use in corneal transplantation, the organization makes available to hospitals skin grafts, heart valves and musculoskeletal tissues, such as tendons and bones".[57]

The tissue side of the Hema-Quebec has thirty-five employees with an annual budget of $2.5 million.[58] Total employment by Hema-Quebec is nearly 1,300[59] persons.

7.7.5 Government/Other Communication and Promotion of the Benefits of Donation & Transplantation

Transplant Quebec and Hema-Quebec collaborate to promote organ and tissue donation in the province.

Donor Registry Information There are two donor registries in use. Hema-Quebec's website http://www.hema-quebec.qc.ca/tissus-humains/index.fr.html links to another website that instructs Quebecers about registering their intentions concerning organ and tissue donation: http://www.signezdon.gouv.qc.ca/index.php?signifier_son_consentement_en. This site explains the three ways of marking their wishes:

1) Recording their decisions on the Registry for donation of organ and tissues – Registre des consentements au don d'organes et de tissus of the Regie de l'assurance maladie du Quebec (RAMQ) - by completing and returning a form mailed with their health insurance card renewal;
2) signing the sticker sent with their health insurance card and attaching it to the back of the card renewal time; and,
3) recording their decision on a second Registry, the Registre des consentements au don d'organes et de tissus of the Chambre des notaires du Québec.[60]

Hema-Quebec reviews information on both donor registries primarily to ascertain that there is no decline for donation indicated. In any case, Hema-Quebec approaches the decedent's next-of-kin to gain consent. The registries do not play a significant role in Hema-Quebec's tissue donation.[61]

7.7.6 Identification and Referral of Donors

Héma-Québec is responsible for raising the awareness of the public and the various stakeholders in hospitals about the importance of identifying potential donors and referring them to Héma-Québec, which

takes charge of the procedure for retrieving human tissues, including corneas".[61] There is a directive for routine referral of deaths, but compliance is variable.[61]

7.7.7 Approach and Consent for Tissue Donation

Transplant Quebec's website informs donor families that "Pursuant to the Civil Code of Quebec, they must honor the deceased's decision documented on a registry. Cases in which loved ones who had been notified of the deceased's wishes do not honor them are rare. It is usually when the deceased's wishes are not known that the family refuses having to make a difficult decision on their loved one's behalf. In practice, doctors take families' wishes into account, especially if they are aware of recent changes to their loved one's wishes. They may also be able to provide invaluable information on the medical and social background of the deceased that is used to assess a potential donor's eligibility."[62]

Hema-Quebec staff is available to take potential donor referrals at any time. This is described as someone continuously "on call" 24/7, rather than as a functional "call center". Hema-Quebec performs all of the screening and consent for tissue donors.[61]

7.7.8 Screening of Referrals for Potential Donors

Under "Donor qualification", the Health Professionals section of Hema-Quebec's website says Hema-Quebec "…always complies with the highest standards to provide safe grafts and reduce the risks associated with infectious diseases. Its donor qualification process includes: a medical-social questionnaire to be filled out with the donor's next of kin; review of the medical record; calculation of hemodilution; physical examination; screening tests for infectious diseases; complete technical review by the medical director and quality assurance division; bacterial contamination control; strict measures applied to minimize the risks of bacterial contamination in the form of aseptic collection techniques, bacteriological tests…"[63]

7.7.9 Recovery and Processing of Eye and Tissue Donors

Hema-Quebec's website specifies: "Tissues prepared in 'clean rooms', Terminal decontamination through irradiation of musculoskeletal tissues, Valve and skin grafts soaked in an antibiotic solution, Preservation methods that ensure tissues remain aseptic [and that] Hema-Quebec has an operating room specially equipped for human tissue collection (ISO class 8 clean room, in accordance with ISO 14644-1). Human tissue processing is performed entirely in the Hema-Quebec laboratories. Products are processed in clean rooms (ISO classes 5 and 7), environments where air quality is rigorously controlled, in order to minimize the risks of bacterial contamination"[64]

In its 2012-13 annual report, Hema-Quebec reported processing 3,369 human tissues, and that they will soon begin offering pre-cut cornea to ophthalmologists who specialize in cornea transplants."[65]
Hema-Quebec performs all tissue donor recovery activities including eye tissues in the province, and it processes musculoskeletal, skin and cardiovascular tissues in its facility. Ocular tissue is sent to the eye bank labs in Montreal and Quebec City for processing. The 5,000 square foot Hema-Quebec facility for processing and recovery of other tissues became operational in 2004 at a cost of $1.2 million. It includes

a procurement suite with ante-room. Approximately 80% of recoveries are performed in this dedicated suite to which donors are transported with permission of next-of-kin. Recovered donors must be transported to the procurement suite from Montreal at distances up to 250 kilometres. Grafts processed are the basic, traditional types of allografts. Processing is performed in a class 100 environment for musculoskeletal processing; and class 1000 with flow hoods for skin and heart valve processing. Certain tissues are lyophilized and sterilized (as applicable) with Gamma irradiation. [61]

7.7.10 Waitlist Information

"In 2008, Héma-Québec took over the co-ordination of the province's three eye bank centres in an attempt to cut down wait times and increase donations… Now, five years later, the system in Quebec is close to reaching self-sufficiency…According to figures obtained by CBC, the average wait time for a corneal transplant in Quebec was under one year in 2012. In 2011, the average patient could expect a two or three-year wait"[66]. Currently there is no wait for tissues, in part due to the importation of corneas. The system used for the distribution of tissues may be described as order taking. [61] According to the Transplant Quebec web site there are over 1,200 persons waiting for organs.[67]

7.7.11 Tissue Distribution and Allocation

Hema-Quebec distributes various tissues in the province. Press Releases on its website report that distribution of human tissues was up 41% in the last fiscal year. The total number of human tissues distributed was 3,708 in FY 2010–2011, compared with 2,631 the previous year. There was sustained growth in all types of tissues, especially tendons (+110%) and skin tissue (+76%). Distribution of corneas rose 48% compared with 2009–2010 to 599. Finally, the number of heart valves distributed increased by 14%, going from fifty-eight last year to sixty-six this year [FY 2010-2011]. Given the global shortage of this type of product and the difficulty in obtaining referrals, this performance was excellent."[68] Hema-Quebec's 2012-13 Annual Report notes that it distributed 3,771 human tissues, 13.7% more than the previous year, an increase that occurred while there was a 63% reduction in imported tissues (excluding corneas)".[69]

Table 18: 2013 Hema-Quebec Allografts Distributed

Allograft Type	#
Heart Valves	47
Skin	1,231
Tendons	291
Cancellous Bone	749
Cortical Bone / Femoral Heads	241
Imported Tissues	96
Local Cornea	429
Imported Corneas	306
Sclera	381
Total Allografts	3,771
** source Hema-Quebec Annual Report*	

Organizations other than Hema-Quebec, which are licensed with Health Canada, may also distribute human tissue in the province. Hema-Quebec imports tissues from U.S. including allografts for spinal procedures, DBM and osteochondral. It also exports approximately 15% to 20% of its tissues, mostly skin, outside of Quebec. Service fees for tissues distributed are comparable to those in the U.S. [61]

Hema-Quebec's on-line catalog lists its tissue products (in French): frozen traditional bone allografts - including cancellous bone, freeze-dried cancellous bone, cryopreserved heart tissues, frozen sports medicine allografts (tendons, etc.), cryopreserved skin and corneas and other ocular tissues.[70]

7.7.12 Traceability and Tracking

Health Canada Regulations are followed for all tissues. Hema-Quebec used paper records until 2012. They now use is Edgecell/Edgelab, a software system[61] customized for cell/tissue labs.

7.7.13 Transplantation Surgery

A 2004 study of the distribution of corneal surgeons across Canada states: "In 2004, there were seventy-six corneal transplant surgeons distributed as follows: British Columbia 17.1%, Alberta 11.8%, Saskatchewan 3.9%, Manitoba 7.9%, Ontario 36.8%, Quebec 17.1% and the Atlantic provinces 5.3%."[71] According to other news reports, in the past, when healthy corneal tissues could not be used in-province they were sometimes discarded after being offered to Canadian surgeons outside of Quebec. "[In 2012,] seventy healthy surplus corneas were destroyed after other provinces could not accept them, since Quebec's eye bank credentials aren't recognized by banks in the rest of the country."[69] There is no post-surgical outcome tracking for tissues distributed, though there is a system for adverse reaction reporting.[61]

7.7.14 Comparing and Contrasting Ontario and Quebec

On a per capita basis organ donation rates are generally comparable while actual tissue donors (other than eyes) appear to be greater in Quebec. Eye donor rates are higher in Ontario. As is the case with the rest of Canada, tissue donation and transplantation is managed at the provincial level in both jurisdictions.

Ontario has specific, detailed legislation, the Trillium Gift of Life Act, which makes clear how activities with respect to donation of tissues and organ should be conducted. Quebec has no similar specific legislation. Both jurisdictions have donor registries. The Registry in Ontario appears to be more actively promoted.

In Hema-Quebec, the province has a centralized, focused approach to the recovery and processing of human tissues from musculoskeletal, skin and heart valve donors. Ontario's recovery and processing of tissue donors is more fragmented.

Much of the information above was graciously provided by Dr. Marc Germain, Medical Director of Hema-Quebec. We wish to express our appreciation for his assistance.

7.8 Tissue Donation and Transplantation in Australia

7.8.1 Overview

Australia, like Canada, is a member of the Commonwealth, with a shared language and government structure. Australia consists of eight states or territories: Victoria (VIC), New South Wales (NSW), Queensland (QLD), Northern Territory (NT), Western Australia (WA), South Australia (SA), Tasmania (TAS) and the Australian Capital Territory (ACT). Australia is a large country with a land area of 7.6 million square kilometres, about seven times the size of Ontario.

Despite its vast land area, Australia's resident population is only 23,444,417.[72] 89.3% of the population is of European descent, with only 2.3% of indigenous or Aboriginal descent.[73] 89% of the population is in urban areas, highly concentrated in the southeast of the country. Australia has 1,367 hospitals including 735 acute care facilities.[74] "There were 147,098 deaths registered in Australia in 2012."[75]

Australia has a mix of public and private insurance funding. Many citizens and permanent residents supplement the coverage provided under the Australian Government national program (Medicare) with various levels of private insurance, to protect against uncovered additional medical expenses.[76]

7.8.2 Statistics on Referrals, Consents, Donors, Tissues and Utilization Rates

Government sponsored websites report donation and transplantation data in Australia. Other, related sources report actual numbers of donors. Referral numbers and consent rates must be inferred or gathered from less accurate sources. The Government's Organ and Tissue Authority website[77] records the following for deceased donors for 2013:

Table 19: 2013 Australia Donation Statistics

Measure	#
Tissue Donations Recovered	228
Hearts for Valves Recovered	109
MS Donations Recovered	159
Skin Donations Recovered	123
Eye Donations Recovered	1,144
Eyes / Corneas Recovered	2,280
** source Australia Organ and Tissue Authority*	

Australia has a very active surgical bone retrieval program. 3,785 living persons donated femoral heads in 2013.[78] At this volume, the living donor program (femoral heads) and related allograft tissues, play an important part in meeting the need for related surgeries in the country.

There is no nationwide data for potential donor referrals, but some local information is available. Western Australia, with a population of approximately 2.2 million, "[had] 2,901 referrals in 2006, 35% coming from police and the state mortuary, and 65% from public hospitals. 47% of these referrals (1,376)

were pursued for tissue donation, resulting sixty-three donations (forty corneas, fourteen bone and nine heart valves) from forty-three donors."[79] Queensland's 2008 government report indicated that its automated system had increased donor participation rates to about 100 donors for every 1,000 notifications.[80]

Information on tissue donor consent rates is limited, while there is specific data on organ eye tissue donations from families initially consenting to organ donation. Past sources reported a 53% consent rate for organ donation.[81] For cases in which organ donation was consented, donation rates for various tissues was: musculoskeletal 58%; skin 57%; cardiovascular 86%; and eyes 99%.[82]

7.8.3 Government Regulation & Authority Concerning Human Tissue

The Australian donation system is based on an 'informed consent' or 'opt-in' legislative framework. Since the late 1970s it has been regulated by legislation in each of the States and Territories. Banked human tissue is classified as a therapeutic good by the *Therapeutic Goods Act 1989*, which is enforced by the Australian Government Department of Health and Ageing's Therapeutics Goods Administration (TGA). Manufacturers of therapeutic goods for human use must obtain licenses by demonstrating compliance with the *Code of Good Manufacturing Practice (GMP)* - Human Blood and Tissues,[83] which regulates the processes tissue and eye banks use in their activities. The Australian Code of Good Manufacturing Practice (GMP) for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products applies to manufacturers that undertake the collection, processing, testing, storage, release for supply, and quality assurance of these items.[84]

7.8.4 Role of Key Government Agencies and Organizations

The Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA) was established by statute in 2008 to boost the levels of organ and tissue donation and transplantation. The AOTDTA's supports and provides funding for clinicians, hospitals, professional associations, governments, and NGOs to develop a nationally consistent approach to the collection, reporting and analysis of eye and tissue donation and transplantation.[85] Another important advocate for donation and transplantation is Transplant Australia, which is a member organization for the advocacy of donation and transplantation.
In the past, despite having a dedicated group of tissue and eye banks, numerous efforts to move organ and tissue donation and transplantation forward, were hampered by fragmentation. Australia did not operate a national donor coordination network or single coordinating agency. The system was and in many ways still is state and territory-based, with a large number of stakeholders working at various levels differences in procedures, processes and legislation among jurisdictions.[86] However, in recent times, the new DonateLife program has been beneficial in bringing about a more coordinated approach to donation.[87]

7.8.5 Government/Other Communication and Promotion of the Benefits of Donation & Transplantation

Donor Registry Information: The government sponsored Australian Organ Donor Registry (AODR) is the only national register where people sixteen years and older can record decisions about becoming an organ and/or tissue donor for transplantation after death. Recording a decision on the Australian Organ

Donor Register is voluntary and offers complete choice over which organs or tissue to donate. The government permits authorized medical staff to check the AODR anywhere in Australia, twenty-four hours a day, seven days a week, and pass information on to a deceased's family. Because family consent is always needed before donation can occur, registrants are urged to discuss their decision with family and others they feel close to.[88] Registrants may express both intent and refusal to donate, and those who affirm can select from five organ groups and bone tissue, corneas (eye tissue), heart valves and skin tissue. They can also choose "all" organs and tissues. On 28 February 2014, there were 5,993,786 registrants on the AODR, with the overwhelming number affirming the intent to donate from one or more categories.[89]

The primary national advocate for organ and tissue donation is the AOTDTA, more recently referred to as the Organ and Tissue Authority (OTA). Advocacy for donation and transplantation is the responsibility of the DonateLife Network, which comprises organ and tissue donation agencies and hospital based staff in seventy-two hospitals across Australia that work specifically on organ and tissue donation. The OTA is an independent statutory agency within the Australian Government Health portfolio charged with establishing, in partnership with states, territories, clinicians, consumers and the community, - a nationally coordinated approach to organ and tissue donation for transplantation.[90]

7.8.6 Identification and Referral of Donors

With no comprehensive, countrywide system of routine notification, programs and activity levels vary in different areas. We inferred from the volume of web based information concerning organ donation and transplantation that most systems for identification and referral focus heavily on organ donors.

An assessment of referral systems focused on organ donation, the National Clinical Taskforce on Organ and Tissue Donation Supporting Evidence — Final Report states on page 24:

> *"…donor coordinators from all agencies spend more than 50 per cent of their time in educational and support activities to assist intensive care units to identify and refer potential donors and in providing support to donor families; • close professional relationships between donor coordinators and hospitals impact positively on referral rates; • referrals primarily come from intensive care unit in Queensland, NT and Victoria and intensive care units and emergency departments in NSW, ACT, SA and WA; • the majority of referrals come from tertiary hospital intensive care units in the public sector in all states and territories with NSW and Queensland supporting large numbers of level four and above metropolitan and regional intensive care units…."*[91]

"For eye donation the majority of hospital referrals come about through the activity of the Eye Banks and the referral systems they have set up with the hospitals."[92]

Western Australia's identification and referral system that uniquely focuses on potential tissue and eye donors captures all coronial deaths and deaths occurring in metropolitan public hospitals. It provides real time detailed notification to aid the investigation for tissue donation. It also enables auditing of missed potential organ donors and monitoring of variables relevant to tissue donation such as age exclusions for specific tissues."[94]

The Lions NSW Eye Bank based in Australia's largest city, Sydney, reported in its brochure that in 2008, it received 12,265 referrals (in greater Sydney), primarily from hospitals and coroners…[93]

7.8.7 Approach and Consent for Tissue Donation

For tissue and eye banks, the Australasian Transplant Coordinators Association issued very extensive National Guidelines for Organ and Tissue Donation, defining the coordinator's role as: ensuring that donation is consistent with the wishes of the deceased and managing approach and consent, performing medical/clinical assessments, allocating organs and tissues, procurement activities and bereavement support for donor families.[94] The Guidelines refer to the specific roles of Tissue Coordinators focused on coroner programs and Eye Donation Coordinators as follows:

> *"The role of the Tissue Coordinator within a coronial system is to identify and assess potential tissue donors, and offer the opportunity of donation to the next of kin of recently deceased persons… The Tissue Coordinator reviews each death reported to the Coroner and when a potential donor is identified, assesses each case according to age, time and cause of death, circumstances of the death and past medical and social history... The role of the Eye Donation Coordinator is to…[provide comparable services as indicated above; also some eye donation coordinators are]…trained to perform the surgery of donation, process, assess and distribute ocular tissue to ophthalmic surgeons… [Tissue and eye donation coordinators both also] promote and encourage…donation and act as an informative resource…within the hospital, [or coroner's office,] and general community."*[95]

As noted earlier, regardless of any intent by the deceased recorded on the Australian Organ Donor Registry, the family will be approached and the family member's decision is paramount with respect to consent or decline for donation.

7.8.8 Screening of Referrals for Potential Donors

Referring again to the Guidelines issued by the Australasian Transplant Coordinators Association, "…exclusion criteria for tissue donation are more stringent than for organ donation due to license by the TGA. In some jurisdictions a full autopsy that includes the brain is required if certain tissues are to be donated. If an autopsy is required the family must be fully informed. All potential donors are screened to exclude any pathology, diseases or risk behavior that may present a risk to the recipient. Screening includes medical records review, completion of a medical/social history questionnaire by next of kin, and testing of a donor blood sample for mandatory infectious diseases…"[96]

7.8.9 Recovery and Processing of Eye and Tissue Donors

Recovery of tissue and eyes from deceased donors is facilitated by individuals employed or otherwise directly linked to the respective tissue and eye banks. In Victoria the Donor Tissue Bank of Victoria (DTBV) until recently was "...the only operational skin bank in Australia and … the national source for skin grafts for the treatment of burns… the DTBV is regularly faced with a limited availability of skin grafts for distribution."[97,] Recently the Queensland Skin Bank has begun activities and is providing

sufficient tissue for patients in that state, with the DTBV still providing skin tissue to the rest Australia. Supplies continue to be limited in availability.[90]

The Eye Bank Association of Australia and New Zealand (EBAANZ) lists five eye banks in Australia - Lions NSW Eye Bank (New South Wales), Queensland Eye Bank, Lions Eye Donation Service (Victoria), Lions Eye Bank of Western Australia, Eye Bank of South Australia. It appears that the vast majority of eye retrieval in Australia is enucleation rather than in situ excision. "…For the past fourteen years, Australian eye banks have predominantly used Optisol storage to preserve corneal tissue. There has also been a resurgence in the use of Organ Culture for storage since 2007."[98]

The median time between donor death and penetrating corneal graft surgery for corneas stored in Optisol was 102 hours."[101] But since 2012, the majority of corneas in Australia are preserved by the organ culture method whose longer preservation time has helped expand the donor pool and assisted with pursuing a larger number of donors because the distribution of the corneas would be better facilitated.[95]

Eight deceased donor tissue banks provide bone, skin and heart valves operating in the five largest states: WA – Perth Bone and Tissue Bank and Royal Perth Hospital Heart Valve Bank; SA – South Australian Tissue Bank; Victoria – Donor Tissue Bank of Victoria; NSW – NSW Bone Bank and Sydney Heart Valve Bank; and Queensland – Queensland Bone Bank and Queensland Heart Valve Bank. There are also six surgical-only bone banks operating in NSW, ACT, Victoria and Tasmania.[99] The newsletter entitled *The Gift: Winter 2013* published by the government of New South Wales pronounces that a new eye and tissue bank facility opened in June of 2013 will improve the lives of 1,200 people this year.[100] There are no deceased donor tissue banks in NT, Tasmania or the ACT.[102]

Established in 1987, The Queensland Bone Bank is the largest bone bank in Australia, and is responsible for retrieving and distributing bone tissue throughout the country. Bone tissue retrieved by the Queensland Bone Bank comes from donors whose next of kin has consented to donate after death and from patients who require total hip replacement surgery, where the hip joint is replaced with a prosthesis. This is the Living Donor Program.[101]

With respect to processing techniques use: "Musculoskeletal tissues may undergo debriding of unwanted tissues, portioning, sawing and milling. Products may also be subject to Gamma irradiation at doses between 15 and 25 kGy to reduce bioburden… The final allograft [is] frozen or cryopreserved at less than minus 40°C for a maximum of 5 years from completion of processing."[102]

"Australian Biotechnologies was founded in 2000…and has become the first privately owned tissue processing facility in Australia. The company focuses on four areas of manufacture: Milled Bone, Demineralized Bone Matrix (DBM), Allograft Bone and Tendon Grafts and Machined Cortical Grafts. The milled boned offered by the company is now terminally sterilised utilising the company's novel super critical fluid sterilisation technology."[103]

7.8.10 Waitlist Information

The Australian Government Department of Human Services website reports that "…around 1,700 people are on the Australian organ transplant waiting lists at any one time."[91] For corneal transplant wait lists information review for past years was exacting, but a 2007 report said Patients wait between one and six months on average. Surgeons request tissue when they schedule surgery, and they provide patient details to their local eye bank which is responsible for managing the transplant waiting list. Waiting time for corneal transplants depends on service planning factors such as theatre availability for public patients, surgeon availability and patient factors than corneal supply; Australia's five banks reported 443 of surgeon scheduled surgeries pending on one particular date in July 2007.[104]

But this is changing. While 'patients on list' increased in 2011 the number fell in 2012 and 2013, indicating that transplants were being performed faster than new patients were coming on the list. Australia presently has a surplus of corneas. Western Australia reported that the 443 scheduled patients on their list in 2007 had been reduced to thirty-two by the end of 2013, and they now have surplus tissue. This information was readily available because EBAANZ asks all member eye banks to report the number of patients they have scheduled for surgery every month, which accounts for 100% of their list as the Eye Banks now schedule all of their surgeries except for urgent cases.[95]

"Tissue banks face different issues in relation to waiting lists to organ donation agencies and there are no 'waiting lists' for tissue per se. Agencies will generally have a list of local surgeons awaiting tissue, however, surgeons have a range of other options including autografts, other types of allograft, prosthetics and access to tissue from interstate banks."[105] "Access to paediatric heart valves is a national problem. There are also major shortfalls in skin and some patients may die if skin is not promptly available."[106]
The National Clinical Taskforce on Organ and Tissue Donation's initial assessment was:

> *"There are no waiting lists for eye and tissue transplantation as there are for organs. Cornea allocation for transplantation is based on a scheduled operation system and tissues allocation is based on requests by surgeons as the demand occurs. Corneal transplantation practice has essentially eliminated the concept of waiting lists and instead transited to a booking system with delivery of the cornea on demand to the operating suite. In the case of tissues, if a specific type of tissue is not available from the local tissue bank, then the surgeon 'rings around' to other banks or uses alternative material or treatment options. However, information on patients awaiting tissue transplantation would be invaluable in enabling the better management of current demand and projecting future needs. Consideration should be given to a single access point or clearing house for information on tissues where each tissue bank would provide information on the inventory of tissues available. The inventory could then be used by clinicians to more easily match their patient needs within the available supply. This would require the development of standardised reporting processes as well as adequate resourcing for the tissue banks to maintain up-to-date inventory information."*[107]

A recent news article about a severely burned woman reported there are times when there is a shortage of available skin for burn patients. The report stated the "…facility that harvests and processes the temporary grafts had none in its bank - the result of policies that reduce its capacity to stockpile disinfected and

frozen skin, leaving the nation dangerously dependent on imports. The Donor Tissue Bank of Victoria instead had to beg for the precious resource from its counterpart in California…"[108]

7.8.11 Tissue Distribution and Allocation

Approximately 2,000 corneal transplants are performed in Australia each year. Apparently, eye tissue distribution and allocation is state oriented, that is, ophthalmologists scheduling surgery will typically order and receive tissue from their local eye bank. "There is also an established system for transporting corneas interstate to supply emergency cases with cases generally supplied between 24 and 48 hours. The system is generally seen to be working well."[109]

According to the January 2014 ANZOD preliminary report, in 2013 transplants totaled 5,289 musculoskeletal allografts for 3,436 patients, 166 cardio vascular tissues for as many patients and 793 skin grafts for eighty-nine recipient patients.[110] It's important to remember that a significant number of the musculoskeletal allografts were sourced from living donors.

No corneas are imported into Australia because supply meets demand. Additionally, license approval would be required to import corneas under the TGA, as is the case for routine importation of tissue which the Special Access Scheme (see below) does not cover. Australian Eye Banks are instead likely to begin routinely exporting corneas in the near future.[95]

With no available information on imported tissues other than corneas, the level of importation of allografts to Australia is unclear. Surgeons can import tissue into Australia via the TGA Special Access Scheme.[90] In May of 2011, the U.S. based Musculoskeletal Transplant Foundation announced that they were "…the first tissue bank to receive approvals to market tissue under the Australian Biologics Framework…" with the first two approved biologics being DBX Putty (bone allograft) and Flex HD (allograft from human skin).[111]

7.8.12 Traceability and Tracking

The Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products Version 1.0 April 2013 released by the Therapeutics Goods Administration states that "A written procedure for product recall should be established, implemented and maintained. The procedure should specify the actions to be taken for all reasonable contingencies that may be anticipated. It should be capable of being put into operation at any time, and should include emergency and 'out of hours' contacts and telephone numbers. Distribution records should be maintained, to expedite the recall of any product or material whenever necessary."[112] In the case of eye banks in Australia "corneas and sclera…are only released to a surgeon for a known recipient – thus full traceability from donor to a known recipient"[95] of course, relying on information provided by the surgeon on any subsequent changes to the surgical schedule after release of tissue.

7.8.13 Transplantation Surgery

Approximately 2,000 corneal transplantation procedures are performed each year, with readily available outcome information thanks to the Australian Corneal Graft Registry (ACGR), the longest running clinical registry in the world which commenced operations in 1985. It contains recipient and donor details and reports annually on the outcomes of corneal transplantation. The ACGR is the only national outcomes register in the sector. It receives annual funding from the Commonwealth Department of Health and Ageing, but, annual funding does not allow for adequate future service planning; this should be addressed. Australia has no national tissue register.[113]

Corneal surgery utilization rates are eighty-six pmp[95] (procedures per million persons), which given a population of about 23 million is consistent with the estimated 2,000 surgeries taking place each year. With 2,280 individual eyes, donated the rate of transplanted corneas to donated corneas is quite high.

7.8.14 Financial and Costs References

Australia's health system is a mix of public and private funding. "A small majority of cornea transplants are performed in the private sector, though the majority of glaucoma surgeries and oculoplastics surgeries requiring ocular tissue are undertaken in the public sector.[95] A patient who elects to have a transplants performed privately must discuss all costs with his ophthalmologist, including surgeon and anaesthetist fees, hospital bed, operating theatre, and other charges, and Lions Eye Donation Service fees. While it is illegal to buy or sell human eyes, organs and tissues, Lions Eye Donation Services are allowed to recover their eye donation costs by charging service fees for the provision of corneas. Lions Eye Donation Service expenses include staff salaries, laboratory testing, equipment and maintenance, medical consumables, office supplies, utilities and infrastructure costs. If a patient has private health insurance, it will pay 100% of the service fee levied by the Lions Eye Donation Service – Melbourne. A private patient without medical insurance will be personally liable to pay the Eye Donation Services fee, which is not covered by the Medicare national health system. The State Government Health Department reimburses Lions Eye Donation Service directly for all transplants performed under the public health system in a public hospital.[114] This process of recovering costs in donation is also used by all eye and tissue banks in Australia.[90]

Some references were made to the lack of sufficient funding. In a news account the New South Wales State the "…medical director of the Australian Organ and Tissue Authority, said the sector, run by state governments and charities, was 'tiny…and all funded by cost recovery', severely limiting its capacity to pay for even essential capital items such as new freezers."[111]

7.8.15 Comparing and Contrasting Ontario and Australia

Organ donation rates in the two jurisdictions are comparable. Eye donation rates per capita in Ontario are roughly twice high as in Australia, but Australia's utilization rates (i.e. number of transplants per capita) are closer to Ontario's although still somewhat less. Musculoskeletal and skin donation levels are low for both Ontario and Australia compared to several other industrialized nations.

Tissue donation and transplantation are run at the Provincial/ State level in both countries.

The TGLN Act and Trillium Gift of Life Network's mandate of required, routine referral (of deaths) in acute care facilities provides a current level of 25,000 death referrals per year, with the opportunity for this level to increase, as required referral is expanded beyond the acute care facilities. Australia has limited routine referral systems in place.

Both jurisdictions have active donor registries that are heavily promoted. About 25% of the population of Australia is registered, the same percentage as Ontario. The Ontario registry limits signing up to those individual who wish to affirm their intent to be a donor. There is no way for a person to record his/her intent to decline or not to donate (at least in all manners and form). In the Australian Registry, one may either affirm the donation or indicate their intent to not donate organs and tissues. Both registries allow for those who donate to specify which tissues and/or organs they wish to donate. In both Ontario and Australia it is important for the persons registering to make their wishes known to family members, as the surviving next-of-kin will make the final decision about consent for donation, regardless of the information recorded on the Registry.

Australia has an extensive program, organized at individual medical facilities, of surgical bone banking, that provides a notable portion of donor material in terms of traditional bone processing, banking and distribution of related allografts. Ontario's surgical bone banks are less active.

The Australian Corneal Graft Registry is the longest running clinical registry in the world. There is no similar data collected on surgical outcomes for eye surgery in Ontario, and no surgical outcome data for tissues (other than corneas) in either jurisdiction.

We wish to extend our appreciation to Kellie Hamilton, Senior Research and Development Scientist, Donor Tissue Bank of Victoria and Dr. Graeme Pollock, Director, Lions Eye Donation Service, Centre for Eye Research Australia Department of Ophthalmology, University of Melbourne for providing valuable information used in this report.

7.9 Tissue Donation and Transplantation in the United Kingdom

7.9.1 Overview

The United Kingdom has much in common with English speaking Canadian provinces like Ontario in terms of history and structure of government, and both the UK and Canada are both important members of the Commonwealth. The United Kingdom consists of England, Wales, Scotland and Northern Ireland. Total population is 63,700,000 and the country has an estimated 2,300 hospitals of one variety or another[115]. The number of large, critical care facilities is much lower, perhaps "200 acute hospital Trusts and Health Boards [are in operation]…"[116]

Health care in the UK is essentially public, that is, funded by the government. The total land mass of the UK is 241,930[117] square kilometers (about a quarter the size of Ontario), and the reported "death rate [is]: 9.33 deaths/1,000 population (2013 est.)."[118] Using this rate, the approximate annual number of deaths in the UK would be 588,000. The population of the UK is 92% Caucasian and 8% Black, Asian, and other ethnic/racial groups.[119] Its largest city, London, is very diverse. Britain is a member of the European Union, which has been active in introducing consistent regulation with respect to human tissues for transplantation across the EU's member states.

7.9.2 Statistics on Referrals, Consents, Donors and Tissues

Though statistics and data on tissue related activities in the UK are sparse we were able to reasonably approximate general activities of tissue donation and transplantation. L. Guam, et al, report in a 2012 paper "that annually there are ~450 multi-tissue donors and 2,500 eye donors, resulting in many thousands of transplants, including 3,564 cornea transplants [in a recent 12 month period].[120] The Tissue Services of the NHS Blood and Transplant (NHSBT) website states they "…operate the UK's largest tissue bank and are the largest not-for-profit organization supplying the NHS [National Health Service] with human tissue." They provide around 8,500 transplants per year that help save and improve the lives of 2,600 patients. They supply skin, bone, heart valves, arteries, tendons and amniotic membranes, and provide support services to tissue banks across the UK. Their National Referral Centre gains consent to donate from over 1,800 eye only donors per year, over 50% of all eye donors in the UK.[121] The "NHSBT receives > 6,000 potential deceased tissue donor referrals per year via the Tissue Services National Referral Center (NCR) in Liverpool."[122] An August 15, 2013 article in the Mirror News reported that in the twelve months ending 3/31/2013, 6,390 corneas were donated[123], which equates to about 3,200 eye donors for that period. Annual data for the same twelve month period also lists 1,212[124] total deceased organ donors.

Numbers in the preceding paragraph were for deceased donors, but there is also a very active surgical bone retrieval program a number of institutions in the UK that gain donations from living donors, generally undergoing hip surgery, where femoral heads would otherwise be discarded. The NHS Blood and Transplant report that they manage the living donor programmes in twenty-three hospitals throughout England.[125] A 2004 article by D. Fehily et al, reported that "…5,630 bone donations were collected from living donors…" in Scotland and England ten years ago.[126]

We drew several inferences about donor referrals from the above information and a review of the literature. About 1,800 eye donors were consented through the National Referral Centre, and there were an estimated 3,200 eye donors nationwide. The additional 1,400 eye donors were likely referred and consented through the eye banks or their contacts in hospitals. If the 1,800 eye donors mentioned above result in part from an initial 6,000 referrals, roughly 30% of all referrals become eye donors. Using the same approach for a total eye donor volume of 3,200 and assuming all the corresponding referrals are *"advanced"* referrals (i.e., referrals past the initial/preliminary evaluation stage) we estimate a total advanced referral volume of 10,000 to 11,000 (3,200 eye donors ÷ 30% = 10,667).

Although "only 30% have confirmed this support by registering with the UK ODR, [the United Kingdom's Organ Donor Register] actual family consent/authorization rates hover around 60%."[127] Because the definitions for referrals and consents are not fully explained by the different sources and we had to rely on some assumptions, the data scheduled below, although useful in gaining some understanding of the volume of these activities in the UK, has limited usefulness.

Summarizing the above we estimate a twelve month period of activity in the United Kingdom from deceased donation as follows:

Measure	#
Total Annual Referrals (NHSTB reported + other inferred volume) – comparable to an advanced, secondary, detailed screening level	10,000
Total Organ Donors	1,200
Total Tissue Donors (bone, tendon, skin, cardiovascular)	500
Total Eye Donors	3,200
Consent Rate Estimate	60%

Recovery of eye tissue from solid organ donors in recent times has increased. "[After] a steady reduction in eyes donated from consented organs donors over the past 10 years…a specialist group to promote eyes from potential solid organs (EPSOD)…reversed this trend, with eye donation increasing from 29% of medically suitable organ donors between April and December 2008 to 41% between September 2010 and March 2011."[128] Thus, nearly 500 (41% X 1,200) of the total of 3,200 eye donors come from corresponding organ donors. More recently, the NHSBT Statistical Report on Corneal Activity indicated that 31-32% of organ donations included the recovery of eye tissue from the same donor.[129]

7.9.3 Government Regulation & Authority Concerning Human Tissue

As a member of the European Union, Great Britain is obliged to formulate and implement legislation and regulation consistent with EU Directives. In the UK, the primary legislation consistent with and related to EU Directives is the 2004 Human Tissue Act. (England, Wales, Scotland and Northern Ireland in some instances have unique elements of this legislation). The Act covers all potential activities involving the use or handling of organs, tissues and cells, with donation and transplantation being just one area covered. The national government created an overall governing body, the Human Tissue Authority to control and monitor activities covered by the Act. It developed and issued "Codes of Practice", including guidelines on consent, and a Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient

Treatment[130], which is particularly applicable for tissue donor recovery and processing activities. In 2015, new legislation will become effective which essentially will introduce an "opt out" form of consent for organ and tissue donation in Wales.

7.9.4 Role of Key Government Agencies and Organizations

The National Health Service Blood and Transplant (NHSBT) is the dominant national organization involved in organ and tissue donation and transplantation. It plays numerous critical roles in organ and tissue donation including, but not limited to: active public promotion of the computerized, web based, national registry; employing a professional cadre of nurses who are specialists in organ and tissue donation (designated Specialist Nurse – Organ Donation); operation of a centralized organ and donor referral telephone call centre; operation of the primary tissue processing facility in the UK; and ubiquitous interface with the entire National Health System in furthering organ and tissue donation and transplantation. The NHSBT was established in 2005 as a Special Health Authority when the National Blood Authority and UK Transplant merged. This helped bring tissue banking and organ transplantation under one umbrella organization. ~95% of all deceased donors, whether tissue, organ or both, are now facilitated by one organization.[131] The NHSBT employs around 6,000 persons.[132]

"The NHSBT Tissue Service, the largest tissue establishment in the UK, is a multi-tissue bank that specializes in consent, retrieval, processing, storage, and dispatch of donated tissues coordinated from a purpose built, state-of-the-art tissue bank built in Liverpool."[133]

7.9.5 Government/Other Communication and Promotion of the Benefits of Donation & Transplantation

Donor Registry Information: The UK's countrywide registry, the NHS Organ Donor Registry (website: http://www.organdonation.nhs.uk/) is managed by the National Health Service. Its message and concept are promoting organ and tissue donation. Although the preponderance of information concerns the donation and use of organs, the website has a number of links, pages and sources of information specifically about the donation and use of tissues (bones and tendons, skin, heart valves and eyes). The web based registry is easy to use, allowing someone to sign up in a matter of minutes. It also provides a telephone number.

The registry is for affirming consent to donation only. It is actively used by donation and transplantation professionals during the referral and screening process to determine a patient's intent. A registrant can select one or more of six organ categories two additional categories for tissues and eyes. The website does not appear to require a unique, presumably private identifier such as a personal identification number to sign up. The number of people registered is 20,241,910[134], 32% of the national population.

The NHSBT plays a nationwide role in the promotion of tissue. Its website is comprehensive and detailed, and although the significant preponderance of information is about solid organs, its extensive content also includes useful information and advocacy about tissue donation and transplantation.

The NHSBT is active in hospitals throughout the UK with an apparent focus on acute care facilities. Education in hospitals and the health care community about donation is a major role of the Specialist Nurses – Organ Donation (SN-OD) who perform many field work services. These services include education and training for nurses and hospital staff who work in referral and preliminary screening, as well as the active participation in the planning of approach and consent for organ donation.

7.9.6 Identification and Referral of Donors

The role of the NHSBT SN-ODs is extensive, varied and centrally focused on organ and tissue donation. Published literature suggests that although the concept of tissue donation is apparently familiar to most nursing and hospital staff, there is neither an absolute requirement for notification nor a comprehensive, nationwide system of routine notification. Notification and referral, whether routine, intermittent or infrequent, appears to be a function of whether the particular acute care facility is in regular, consistent contact with the SN-OD assigned to service that particular facility.

Given the abundance of available information about organ donation, we concluded that potential organs at these facilities are regularly identified, referred, and managed. But the relative lack of similar information about tissue donation, coupled with comparatively low tissue donation volumes suggests that this is not the case for tissues. The active cadre of SN-OD professionals appears to have only limited hospital outreach, with their focus primarily on acute care facilities.

In service notifications, educational brochures, presentation write-ups, and the like, the evidence indicates that in many, if not all, potential organ and tissue donor cases which are identified and referred, there is involvement of a SN-OD or other professional working for the NHSBT to whom the referral is made. Apparently, regular nursing staff and hospital personnel are not expected to perform the actual approach of next of kin, offering the option for donation. This, despite the many references to the very important initial role nurses can play in initial assessment, communication to family members that tissue donation is an option, and helping to arrange contact with an SN-OD or other NHSBT representative.

Nevertheless, it appears that some hospitals and nurses (in addition to SN-ODs) are very supportive and engaged in informing the next-of-kin about donation and approaching families of deceased patients, presumably taking the process through to actual consent. The Organ and Tissue Donation Information Folder, a brochure issued by the West Midlands Donor Transplant Coordination Service [of the NHSBT] advises how initial communication with decedent families might best be conducted, and who is the individual best suited to approach for consent, depending on circumstances and other particulars of a given case and situation, like rapport and relationship with the family and tissue donation experience.[135]
Three hospital trusts near Liverpool are involved in and activity initiated by the NHSBT Tissue Services National Referral Centre (NRC) that, while not unusual in a number of other countries, is unique within the UK. Deaths occurring in those hospitals are referred to the NRC, and NRC Specialist Nurses make the initial contact with the deceased next of kin by telephone. More information is available from the British Association of Tissue Bank (BATB) website www.batb.org.uk in a presentation by the NHSTB Tissue Services' Mark Brown at the 2012 BATB Annual Scientific Meeting which is linked to YOUTUBE address https://www.youtube.com/watch?v=9LLL-3RjZTc&feature=share&list=PLQSOy-TZnNlSougnXzvCb-KJSU8smYbd6[136].

7.9.7 Approach and Consent for Tissue Donation

Approach for consent is regularly performed by NHSBT Specialist Nurses – Organ Donation but may be performed by others, particularly regular nursing staff. Another important entity, a part of the NHS Blood and Transplant Service, is the National Referral Centre referred to earlier, which is staffed with nurses specially trained in organ and tissue referral, consent, secondary medical screening and other related duties. This is a telephone call centre located in Liverpool where a "…team of specialist nurses receive donor referrals, approach potential donor families in order to discuss the options of donation, and complete the consent and donor screening process to allow assessment of the donor in compliance with UK legislation and European Directives."[137]

The Organ Donor Registry has the paramount role in the consent for donation process. Even the surviving next of kin may not overrule the wishes of the donor as recorded on the Registry, although family members who are uncooperative in participating in a thorough medical and social history questionnaire can preclude tissue recovery from taking place. Indications are that SN-ODs, the NHSBT, and other health care professionals are required to determine if the individual was registered prior to donation. When the donor's wishes are not recorded on the Registry or otherwise not substantiated, next of kin is approached and a full, informed consent, including consent for research and teaching, is required.

7.9.8 Screening of Referrals for Potential Donors

SN-ODs based around the UK and in the National Referral Centre in Speke (Liverpool) handle the majority of medical screening for potential and actual tissue donors, including the medical and social history conducted with the family. Regulation and guidance for screening of tissue donors is governed by Codes of Practice issued by the Human Tissue Authority, which includes guidelines on consent and a Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment[138]. The Royal College of Ophthalmologists Standards states that "It is the responsibility of the donor centre [eye bank] typically through SNODs, the NHSBT National Referral Centre, or local Tissue Donor Coordinators to obtain most of the information required to determine the suitability of the donor."[139]

7.9.9 Recovery of Eye and Tissue Donors

"Tissue and eye retrievals are usually performed in a hospital's mortuary by trained professionals. Eye retrieval follows the guidelines of the Ocular Tissue Advisory Group of the NHSBT and the Royal College of Ophthalmologists… Other tissues such as bone or skin may be retrieved up to 48 h [hours] post-mortem. The NHSBT has three tissue donation departments based at Leeds, Liverpool and London. There are six tissue donation teams available at any one time to perform tissue retrieval in a hospital mortuary. The team routinely travel 2 h [hours] or 100 miles from their base. The donor is prepared as if undergoing a surgical procedure in an operating theatre before retrieval and is reconstructed afterwards to a normal appearance."[140] Tissue recovery may be performed by cornea retrieval coordinators and is generally performed at the recovery site by enucleation of the whole eye.

The NHS Blood and Transplant Tissue Services play a direct, significant role in the recovery of tissues from deceased donors, including bone, tendons, skin and cardiovascular tissues. "In 2005, a…state-of-

the-art tissue banking facility [operated by the NHSBT] was opened…near Liverpool [which includes] an operating theatre standard tissue retrieval suite where tissue can be obtained to the highest possible standards."[141] "Next of kin are asked if they object to the movement of their relative to a specific site for donor recovery and the donor is returned to the hospital or other location according to the family's wishes…."[142]

7.9.10 Processing of Donors

Processing of eye tissue is the role of eye banks. "Retrieved eyes are sent to the UK eye banks from hospitals across the country for assessment and preparation, with the corneal sclera disc being placed in organ culture for up to 4 weeks before transplantation."[143] "There are currently four eye banks in the UK".[144] The CTS [Corneal Transplant Service's purpose is] to give equal access to corneas throughout the UK. 90% of transplants [across the UK] use corneas [processed] and stored in the [two designated] CTS Eye Banks in Bristol and Manchester.[145] One important distinction for the UK eye banks is the use of organ culture media processing (used by a number of eye banks in Europe), which varies significantly from the what is referred to as the "cold storage media" processing, typically used in Ontario and the U.S.

The primary centre in the UK carrying out the processing bone and other non-eye tissues is the NHSBT facility near Liverpool. "The facility includes 14 cleanroom…27 microbiological safety cabinets…and 50 ultra-low temperature freezers for tissue storage, and a cryopreservation suite…for…banking…in liquid nitrogen."[146] There are a number of other facilities in the UK that process heart valves.

7.9.11 Waitlist Information

Wait lists in the UK are an urgent matter. The NHSBT website indicates that "Currently there are over 7,000 people on the UK national transplant waiting list and, during the last financial year, over 1,300 people either died whilst on the waiting list or became too sick to receive a transplant."[147] Wait list information for tissues is sparse. The shortage of eye tissue is estimated at between 500[148] and 1500[149] per year, though some references suggested that eye donation is now adequate to meet demand. No data was found on wait list for musculoskeletal and cardiovascular tissues. Apparently "It is difficult to assess demand for other tissue as the supply has been relatively uncoordinated in the UK. NHSBT are the only UK suppliers of skin and processed bone although similar tissue products can be imported from the USA and Europe. There are no waiting lists held for tissue in the UK, although whether this represents a surplus of supply or the choice of alternative surgical solutions (e.g. use of a prosthetic heart valve rather than an allograft) is unclear. All the UK heart valve banks now collaborate under a single 'National Fulfillment System' in order to manage all requests for heart valves, record any unmet demand, and allow services to be planned in the future."[150]

7.9.12 Tissue Distribution and Allocation

As the sole distributor of processed skin and bone tissue in the UK, the NHSBT has an online catalog of the tissue allografts that are made available across the country. The tissues identified in the catalog include the more traditional musculoskeletal allografts and skin for burn patients, but demineralized bone matrix with a carrier and acellular dermis are not listed.[151]

Bone allografts used in the UK are thought to number 10,000[152], and could possibly be much more if imports were an important factor. The Tissue Services of the NHSBT website says they "…operate the UK's largest tissue bank and are the largest not-for-profit organization supplying the NHS with human tissue…and provide around 8,500 transplants per year that help save and improve the lives of 2,600 patients. The tissues we supply include skin, bone, heart valves, arteries, tendons and amniotic membranes".[153] Much of the distribution of bone allografts necessarily comes from femoral head surgical bone programs. The NHS indicates that they "…bank and supply tissue grafts from around 400 deceased tissue donors per year and…We also offer a live bone donor programme, where patients who are having hip replacement surgery can donate the bone they are having removed. We currently work with 75 hospitals to run this program, and bank bone from more than 3,000 living donors. We also operate a program that allows new mothers can donate amnion for use in eye surgery."[154] "Grafts are issued to surgeons in the UK on a first come, first served basis."[155]

The MIRROR.CO.UK, the online edition of The Daily Mirror, reported "A record high of 3,697 patients had their sight restored following a cornea transplant in 2012/13, according to a report by NHS Blood and Transplant (NHSBT)…"[156]

7.9.13 Traceability and Tracking

The European Tissues and Cells "…Second Technical Directive (Directive 2006/86/EC) covers standards for traceability, notification of serious adverse reactions and events, and requirements for coding processing, preservation, storage and distribution"[157]…which, as an EU member, the UK follows. The Traceability and Coding Traceability section of the Human Tissue Authority's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment states:

> *163. LHs [tissue establishments] must have systems in place to ensure that all tissues and cells procured, processed, stored or distributed in the UK are traceable from donor to recipient and vice versa. Full traceability must also be in place for all products and materials coming into contact with these tissue and cells and that could have a critical impact on the quality and safety of the tissue or cells. 164. Tissue establishments that receive and distribute tissues and cells must have a donor identification system, which assigns a unique code to each donation and to each of the products associated with it. 165. All tissues and cells must be identified with a label that contains information referred to in paragraphs 159 to 161. 166. Tissue establishments must keep the data necessary to ensure traceability at all times. Data required for full traceability, must be kept for a minimum of 30 years after clinical use, in an appropriate and readable storage medium. Data storage may also be in electronic form."*[158]

Furthermore, "In England, the HTA has developed an electronic reporting system for tissue and cell facilities, in line with the requirements of Directive 2006/86/EC. Each tissue bank receiving information about a [serious adverse] reaction or event must report it to the HTA when it comes to their attention…such reactions can also be reported by organization applying the graft, direct to the HTA."[159]
Also, according to the Guideline for Blood Transfusion Services in the UK, "Some UK tissue bank facilities use Codabar product codes at present. The use of Codabar product codes for UK tissues will be phased out over time and the ISBT 128 product coding will be fully adopted in its place."[160]

7.9.14 Transplantation Surgery

Outcome information for tissue transplantation is generally not available. Waldock and Cook note that there is "…a lack of information on the outcome of UK corneal transplants beyond 18 months…"[161]

References to the importation of tissue into the UK are sparse. An interesting inference may be made from a document published by the NHSBT concerning revenues apparently earned from distribution of tissues to transplant centres. The information, which is from NHSBT Tissue Services indicates that forecasted fee for service revenue for tissue distribution was £8.4 million in 2012/13 and that, much of this revenue corresponded to the 19-25% market share for bone allografts (exclusive of DBM). The same report indicates the target forecast for tissue distribution is £14.3 million (with only a negligible amount attributed to DBM) by 2017/18, and this increase in revenues will correspond (in part) to a 50% share of the market for bone allografts (other than DBM).[162] Since the NHSBT Tissue Services is the sole UK provider of processed bone and skin, and assuming the market shares reported here for are reliable, the result indicates that in addition to the low volume of bone grafts recovered from UK donors and distributed, there is not a significant volume of imported bone grafts.

7.9.15 Financial and Costs References

"[The NHS Blood and Transplant] Tissue Services [department] operates a cost recovery system where charges for the service are made to cover the costs incurred in providing the service. No profit is made…Our objective is to provide high quality, cost effective grafts for our patients…"[163] "The tissue function is small compared to the blood and organ donation functions of the NHSBT. Revenue forecast for 2011/12 [was] £7.6 million…"[164] This would be revenue from the distribution of tissue products such as skin, bone, and tendons. If one assumes that the full costs of tissue services are recovered it follows that tissue related expenditure for the NHSBT are the same £7.6 million. These costs likely have little or no allocation included for the infrastructure and operating department of the NHSBT dedicated to the donation of organs and tissues or the cost incurred by the eye banking programs operating in the UK.

7.9.16 Comparing and Contrasting Ontario and the United Kingdom

Organ donation rates for the two jurisdictions are comparable, while eye donation rates in Ontario are roughly twice those in the United Kingdom. Both countries rely on enucleation of eye tissue for the most part. The UK uses organ culture media and techniques for preservation (allowing for a lengthier distribution time frame) whereas Ontario uses the cold storage method of preservation. Musculoskeletal and skin donation rates are perhaps slightly higher in Ontario, but both are quite low compared with some industrialized countries.

The NHSBT Tissue Services is a government run tissue banking operation carrying out processing, storage and distribution activities. Although currently limited in size, its position and mandate, as the single key entity organizing and carrying out tissue processing may be an approach that Ontario wishes to emulate.

The TGLN Act and TGLN's mandate of required, routine referral of deaths in acute care facilities and potentially all hospitals provides a current level of 25,000 death referrals per year, with the opportunity for this level to increase, as the required notification and death referral is expanded beyond the acute care facilities. The UK has no such "routine" referral system for reporting deaths on a nationwide level, although with its centralized NHSBT National Referral Centre it seems to be in a position to launch such a program if appropriate legislation/regulation were enacted, a related mandate were put in place, and resources committed.

Both jurisdictions have active donor registries that are heavily promoted. 32% of the UK's population is listed compared with 25% of Ontario's. Both registries limit signing up to those individuals who wish to affirm their intent to be donors. There is no way for a person to record his/her intent to decline or not to donate. However, both registries allow for choices to be made as to which tissues and/or organs the participant desires to donate, or may wish to decline to make an affirmative indication to donate. One important distinction in the UK is that the individual's registered wishes are considered paramount, and a family member may not supersede the wishes indicated in the Registry. In Ontario, in cases where an individual's donor registration is available and the wish to donate is affirmed, TGLN will nevertheless seek next of kin consent, and abide by the final decision of the surviving next of kin.

The United Kingdom has an extensive program, organized at a national level, of surgical bone banking that provides a notable portion of donor material for traditional bone processing and distribution of related allografts. Ontario's surgical bone banks are less active.

On a per capita basis, Ontario appears to import a greater amount of musculoskeletal and skin allografts than the UK, perhaps in part due to its proximity to the enormous tissue banking industry in the U.S. It appears that the UK imports at notably lower rate per capita.

Appendix E: System Re-Design Work Plans

The redesign of the Ontario Tissue Donation and Transplantation System put forward in this report is supplemented with project work plans for each of the key recommendations in this report. The work plans to follow in this section are:

1. **Tissue Referral and Consent**:
    i. Improve Conversion of Tissue Referral and Consent
    ii. Establish a Coroner Program
2. **Tissue Recovery – Improve Tissue Recovery**
3. **Tissue Processing**
    i. Consolidate Tissue Processing
    ii. Implement Precutting of Corneas
4. **Data Systems – Improve Information Systems and Data Management**

7.10 System Re-Design Work Plan to Improve Conversion of Tissue Referral and Consent

7.10.1 Executive Summary

The level of tissue donation is lower in Ontario, particularly for musculoskeletal, skin and cardiac tissue, when compared to other organizations serving communities with similar population bases and geography. Yet the number of eye donations in Ontario is strong and similar in volume to these same, more highly performing organizations, demonstrating much of the potential to increase donation is already "in the system". Three areas have been identified to improve the conversion of potential donation referrals from hospital into additional consented and recovered donations. They are consent rate and the cases already tracked by TGLN and referred to as "missed medically eligible" and "consented not recovered" cases.

7.10.2 Background and Important Information

The challenge of bringing designated hospitals into compliance with Routine Notification Referral (RNR) has been managed well. The reported compliance rate is 93% for the current fiscal year, and expected to continue to increase. This success has resulted in the referral of many potential donations into the PRC referral screening and consent system, but conversion of this potential into consented and recovered MS, skin, heart-for-valve and, to a lesser extent, eye tissue donors, is insufficient to enable the Ontario tissue banking system to respond to the province's demand. Added focus on improving certain key donation conversion indicators will ultimately increase the number of tissue donations for processing and transplantation. Specific areas identified for further improvement are "consented cases not recovered" and "missed eligible donor cases".

The aggregate consent rate (TGLN and Hospital staff) for tissue donation in Tier 1 hospitals was 41% for the period of time we reviewed (April 2 to December 31, 2013). Medically suitable referrals already in the system totaled 6,303 on an annualized basis. 2,512 or 40% of the referrals to the Provincial Resource Center (PRC) were not approached and are defined as missed eligible referrals. Additionally, 307 cases in which consent was obtained did not result in a tissue donation. This resulted in a loss of about 19% of consented cases not being recovered. The number of missed medically eligible referrals by Tier 1 hospitals alone holds great potential to increase consented and recovered tissue donors.

With the addition of the new Donor Management System, implemented in April 2013, TGLN has the ability to capture comprehensive data on tissue donation and recovery in Ontario. We recommend developing a cross-functional team that will take an interdisciplinary approach to Root Cause Analysis of referral conversion data. A thorough review of the data will identify and allow monitoring of specific areas of shortcoming. Actions and strategies for improvement in the conversion of referrals into donations can then be formulated and implemented.

7.10.3 Goals and Objectives

Goal:	
Improve the conversion of tissue referrals to achieve increased numbers of consented and recovered donations	
Objectives:	
1	Improve consent rates
2	Reduce the number of "consent not recovered" cases.
3	Reduce the number of "missed eligible donors" cases.

7.10.4 Resources and Constraints

This is an internal effort by TGLN to identify donation conversion gaps and their root causes, develop strategies and actions for improvement, and monitor and manage the initiatives.

The effort will benefit from the following internal and external resources:

1. TGLN management's declaration that this improvement process is an organizational priority.
2. TGLN management's approval for personnel to dedicate time to the initiative.
3. Funding to hire a full-time clinical informatics resource with demonstrated performance improvement experience to support analysis.

7.10.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	Conduct internal TGLN/PRC pre-review of "consent rates", "missed medically eligible" and "consented not recovered" cases to frame the effort, identify potential members of the Root Cause Analysis team and determine experience and capability requirements for outside expertise.
2	Select TGLN personnel to serve on a cross-functional team. We suggest including the PRC Tissue Director and Organ Director, ODTCs from both the GTA and South Western Regions, hospital development coordinators, a representative from IT familiar with the iTransplant System to help in data mining, and one or more Tissue Coordinators.
3	Identify individuals that may be invited to participate in certain aspects of the review. These may include representatives from the EBC and other tissue bank processors, TGLN hospital development staff, and key hospital personnel knowledgeable about the donation referral process.
4	Recruit and hire a clinical informatics resource
5	Define mission statement and expected outcomes, work time frame, and frequency of meetings.
6	Launch the effort. Specific recommended areas to review include: • the current practice and impact of PRC staff not making contact with families between the hours of 11 p.m. and 8 a.m. • the documented reasons for "consent not recovered" (e.g. determined medically unsuitable, recovery team not available, time expiration). • A comparison of ocular tissue consent rates vs. non-ocular tissue consent rates.

	• A comparison of consent rates with and without donor registry affirmation. • An examination of consent rates by tissue, requestor, shift, week day vs. weekend.
7	Gather data on each identified area of interest.
8	Identify interventions to achieve improvement.
9	Measure potential for improvement; establish goals and milestones.
10	Prepare an action plan including any necessary staged implementation.

YEAR 2: ACTION PLAN	
Step	**Activity Description**
11	Communicate Work Plan goals and activities throughout the TGLN.
12	Implement planned changes.
13	Monitor and measure improvements.
14	Incorporate goals and performance improvement into organizational and individual goals and objectives.

7.10.6 Appendix: Financials

Trillium Gift of Life Network

Consented Donor Not Recovered - Missed Eligible Potential Donors

Summary Pro Forma Financial Report for Work Plan

	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries & Compensation (full time clinical informatics analyst)	$90,100	$90,100	$90,100	$90,100	$90,100

7.11 System Re-Design Work Plan to Establish a Coroners Program

7.11.1 Executive Summary

Coroner's offices located throughout Ontario represent a significant source of potential tissue donation, but there is no organized program in place to routinely identify and pursue these potential tissue donors. Coroner's cases are typically sudden, unexpected deaths, usually unrelated to disease or infection and thus are more apt to meet the medical eligibility criteria for tissue donation. An effectively organized coroner case screening program for potential tissue donation will result in hundreds of additional eye and tissue donations per year in Ontario.

7.11.2 Background and Important Information

In 2013, there were 16,586 coroner cases in Ontario, with only three percent of the associated deaths reported as occurring in hospitals. As discussed in the TGLN Assessment section of this report, significant increases in tissue donation can result if TGLN establishes a Coroner Program. This program would allow TGLN staff to screen and identify coroner cases that are medically eligible for tissue donation on a daily basis. These deaths almost always occur outside of TGLN's routine notification program with hospitals.

The Office of Chief Coroner and Ontario Forensic Pathology Service included a tissue recovery suite located in its newly opened, state of the art facility housing the Provincial Forensic Pathology Unit in Northwest Toronto. The inclusion of the tissue recovery suite in the design of their new facility is an indication of the Chief Coroner's Office's commitment to being an active partner in support of tissue donation. To date, this facility has been used only sparingly to recover tissue.

While the Ontario coroner system includes ten regions to cover all of Ontario, the reporting and coordination is centralized in Toronto, thereby enabling ready access to information regarding potential tissue donation. Daily, in-person screening will identify potential donors, and enable quick communication of the Coroner's authorization of cases deemed suitable for procurement of tissues. Medically eligible, authorized cases can then be pursued by TGLN's PRC for potential consent and recovery. Additionally, the establishment of a Coroner Program will add new working relationships that may be helpful in resolving "coroner restrictions" issues.

7.11.3 Goals and Objectives

Goal:	
To increase tissue donation in the Ontario by establishing a formal tissue screening, consent, and recovery program in collaboration with the Office of the Chief Coroner	
Objectives:	
1	To establish a Coroner Program that identifies and pursues potentially eligible tissue donors.
2	To expand use of the tissue recovery suite at the coroner's office in Northwest Toronto.

7.11.4 Resources and Constraints

TGLN will need additional resources, including:

1. TGLN Coroner Program Coordinators with prior technical knowledge, organizational and marketing skills, and the ability to relate to people.
2. Funding for remote computer access, telephones, and coordinator travel to and from TGLN offices.
3. Non-recovery work office space at the Coroner's office

7.11.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	Secure the Chief Medical Examiner's support to establish a tissue screening and donation program for Ontario Coroner cases.
2	Establish a TGLN – Coroner Office task force to outline program goals and address issues of importance to each organization. a. TGLN's need for timely access to coroner case information. b. The Coroner's need for absolute confidentiality. c. TGLN's need for timely tissue recovery (pre-autopsy preferred). d. The Coroner's need for pathological examination of the heart. e. The Coroner's need for vitreous humor to perform toxicology testing. f. TGLN's need for copies of autopsy reports. g. Utilization of the Coroner Tissue Recovery Suite.
3	TGLN and the Office of the Chief Coroner meet with the leadership from Ministry of Community Safety & Correctional Services and the Ministry of Health and Long-Term Care to secure top level endorsement.
4	Communicate Ministries' strong written endorsement throughout TGLN and Coroner's organization.
5	Develop a joint press release announcing the start of collaboration efforts by TGLN and the Coroner's Office (and/or Ministry of Community Safety & Correctional and Ministry of Health and Long-Term Care).
6	Establish a mechanism to resolve any problematic case issues.
7	Outline program; write SOPs; communicate with TGLN and Coroner staffs
8	Complete job description for TGLN Coroner's Program Coordinator
9	Hire the first TGLN Coroner Program Coordinator.
10	Develop an orientation for all PRC and tissue program staff to understand the work and role of the Coroner and the Forensic Pathology Unit.
11	Develop an organ and tissue donor educational program for staff at the Coroner's office.

YEAR 2: ACTION PLAN	
Step	**Activity Description**
12	Prepare and stock the Coroner Tissue Recover Suite for tissue recovery.
13	Initiate a program for daily screening of Coroner cases managed in the GTA.
14	Prepare Program Assessment Reports for Coroner and Ministry. ○ 3 months ○ 6 months

	○ Annually thereafter
15	Expand to other Coroner regions where autopsies are performed; coordinate availability of TGLN recovery teams.
16	Hire additional FTEs for screening of cases in added Coroner regions and ensure seven days per week coverage.

YEAR 3: ACTION PLAN	
Step	**Activity Description**
17	Continue the expansion of the program to remaining Coroner regions where autopsies are performed.
18	Assess the need for an additional ½ FTE; add if necessary.
19	Assess the feasibility of using the coroner tissue recovery suite for recovery of hospital sourced multi-tissue donations.

7.11.6 Appendix: Financials

Trillium Gift of Life Network

Recovery of Tissue Donors at the Coroner's Office

Summary Pro Forma Financial Report for Work Plan

	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries & Compensation	$ 38,981	$ 116,944	$ 155,925	$ 155,925	$ 155,925
Office and Support Expenses	5,000	7,500	10,000	10,000	10,000
Subtotal	43,981	124,444	165,925	165,925	165,925
Depreciation	1,500	3,000	3,000	3,000	3,000
Total	45,481	127,444	168,925	168,925	168,925
Capital	$ 15,000	$ -	$ -	$ -	$ -

7.12 System Re-Design Work Plan to Improve Tissue Recovery

7.12.1 Executive Summary

The recovery of tissue in Ontario will benefit from a consolidation of all tissue recovery activities under the management and direction of a single organizational entity. TGLN is the best suited organization in Ontario to accomplish this. Consolidating all tissue recovery activities within TGLN's purview will increase the donation volume for all tissues.

TGLN shall establish a new Tissue Donor Recovery Department which will provide coordinated and expanded musculoskeletal, skin, heart valve and ocular tissue recovery for Ontario. As the sole tissue recovery agency, the new department shall be responsible for all tissue recovery in the province. Tissue donors recovered by TGLN will be distributed to tissue processors in Ontario, with the option to utilize other tissue processors if doing so better matches the demand for allograft tissue. Recovery volumes for all tissues will increase over a five year period. This Work Plan will be executed in coordination with several others to effect a full realignment and redesign of tissue donation and transplantation in Ontario.

7.12.2 Background and Important Information

Currently, tissue recovery activities in the province are fragmented and employed in a manner that neither maximizes tissues recovered from a single donor nor is cost effective. Certain tissue banks lack dedicated recovery personnel. The quantity and kinds of tissues recovered from single donors are less than optimal, and on occasion, pending tissue donors are simply not pursued. This disconnected and fragmented system fosters an approach to tissue donation and recovery that does not reflect the level of urgency and intensity that befits the work. Effective tissue recovery programs require uniform procedures and a focused, clear direction, all of which are conducive to better quality and reduced risk.

The volume of tissue recoveries (excluding eye tissue) are insufficient to fully supply even the existing, modest capacity of processors of musculoskeletal, skin and heart valve tissue in Ontario. Our proposed redesign work plans will increase the conversion of identified medically eligible cases into consented donors and increase tissue processing productivity. For these goals to be met, a tissue recovery plan capable of achieving higher tissue volumes must be concurrently implemented. In Ontario, the rate of recovery of multi-tissues donors is between one quarter and one half of the rate of recovery for similar jurisdictions in North America.

TGLN is the entity best positioned to bring uniformity, consistency and a sense of urgency to recovery activities and coordinate and manage the additional resources needed for higher tissue donor volumes.

7.12.3 Goals and Objectives

Three separate but closely related and interdependent work plans will be initiated in conjunction with this work plan to increase the volume of tissue donor recoveries. These work plans are intended to:

- increase the conversion of medically eligible potential donors into consented donors
- establish a tissue screening and recovery program of Ontario Coroners' cases

- increase the productivity, capacity and coordination of tissue processing in the province

During the transition period when processing capabilities are being added, other alternatives for processing tissue can also be considered when donor recoveries exceed the existing capacity or capabilities of local tissue banks, especially for allografts where the technology is not yet in place in Ontario, such as skin for ADM. The overall goal for Ontario is to reach and maintain equilibrium between supply (from donation and recovery) and demand (from processing and distribution activities) for all tissue donors within a five year period. Backup processing systems will be put in place to ensure that waste and loss are avoided.

Within five years the targeted numbers of tissue donors recovered and processed in Ontario are:

- Musculoskeletal donors – 500 donors
- Skin donors – 100 skin donors
- Heart Valve donors – 150 donors with a focus on donation to serve pediatric patients
  Note: For Musculoskeletal, Skin and Heart Valve donors actual targets for recovery will be 550, 110 and 165, respectively (10% higher than planned processing levels), anticipating a normal 10% rate for donors determined to be not suitable for transplantation.
- Eye donors – increase donors by 10%; increase surgical quality donors by 20% - achieved in part through in situ corneal excision.

Other related goals and objectives:

- A coordinated, customer focused recovery program that is flexible and responsive to changes in medical standards and the evolving field of cells and tissues used in transplantation.
- AATB and EBAA accreditation for recovery activities

7.12.4 Resources and Constraints

The only organization in Ontario with the mandate, management, and position to achieve these goals and objectives is TGLN. To accomplish them, TGLN will require additional resources:

1. Management personnel for the newly formed TGLN Tissue Recovery Department, including a recovery program manager, a specialist for quality assurance, and a specialist for training.
2. Standard Operating Procedures which will be put in place as will other systems and related documentation for managing donor files, training, reporting, etc.
3. Greater utilization of the already installed iTransplant software, which comprises the nerve centre for the Donor Management System of the PRC.
4. Additional recovery staff to be employed by TGLN in increasing numbers over the five year period as the program grows. These positions will be permanent and allow for higher levels of tissue donor recovery to be sustainable.
5. Recovery teams to be stationed in several densely populated locations in the province in addition to the GTA. Additional facilities (expanded in Toronto and other new locations) to house equipment, recovery supplies and instruments, and the temporary storage of recovered tissue. These facilities will allow for basic office activities and will be equipped for voice and digital communications. They may be situated in hospitals or locations that minimize additional expense.
6. Additional staff for administrative and clerical support of the tissue donor recovery department.

7. Resource options for recovery team transportation (particularly in the case of multiple tissue donor recoveries) still to be identified, such as owned or leased vehicles or mileage reimbursement for use of personal vehicles.
8. Recovery instruments for each recovery facility, and a system for cleaning and sterilizing instruments. Sterilization services may be contracted with a local provider such as a hospital or set up within each location. Each site should have water and sink capacity for cleaning equipment before autoclaving. At each facility, refrigerators with monitoring devices will be needed to store supplies such as cornea storage media, skin donor recovery solutions, etc. The GTA facility will require one or more -80°C freezers for short term storage of donor tissue.
9. Recovery supplies for all types of donors will be needed as the Department assumes responsibility for all recovery activity and as the volume of activity increases.
10. Legal services will be required as new relationships with other entities are formed and agreements are made.
11. Funding for appropriate staff to achieve AATB certification as Certified Tissue Banking Specialists, and EBAA certification as Certified Eye Bank Technicians; and for the TGLN Tissue Recovery Department to receive accreditation from the AATB and EBAA for recovery.
12. Shared Resource: This resource shall be included in the Work Plan for Increased Tissue Processing but is very important for the Tissue Donor Recovery Work Plan. An agreement, managed by TGLN, will be entered into with a tissue bank that will have the capacity to process donors sourced in Ontario, in the event in-province tissue processing capacity proves insufficient to handle the increased volume, or the demand for specific allografts.
13. Staffing Levels for Best Performance: It is important to have the right staff balance for recovery of Multi-tissue Donors (i.e. Musculoskeletal, Skin and Heart Valve donors). If too few persons are on staff, missed donor opportunities will occur; too many, and individual staff members may not participate at an activity level best suited for proficiency and a fully developed skill set in multi-tissue donor recovery. This is particularly important for team leaders. At an annual rate of 300 multi-tissue donors per twelve month period, an appropriate recovery staff level is three full time team leaders and five per diem staff persons (experienced per diems may also serve as team leaders). This works out to an average of eight multi-tissue donor cases per month for each full time team leader, a level conducive to maintaining competency. A suggested target for case activity is five to eight cases per month per full time team leader. Teams should also be employed in more distant areas where TGLN facilities are added (facility locations remote from the GTA). In addition, it is important to employ the best balance of per diem staff. Proficiency may suffer and turnover may be higher than expected if individual per diem staff are not assigned to a sufficient number of cases. The following table is a guide to staffing levels for increasing levels of donor volume. Three to four full time team leaders would most likely be employed in the GTA, and one to two full time tem leaders for each remote location. Team leaders in different locations in the province might need to travel to remote facilities (or the GTA) when donor opportunities occur and back up resources are required, and as mentioned previously, experience per diems in the GTA or remote locations may also serve as team leaders.

TGLN RECOVERY TEAMS (for Multi Tissue Donors)

Donor Number	Full Tme Staff /Team Leaders	Per Diem Recovery Staff *	Average donors/ per month/ per full time team leader
200	3	4 - 6	5.6
300	3	5 - 7	8.3
400	4	6 - 8	8.3
500	5	7 - 9	8.3
600	6	8 - 10	8.3

* Experienced per diems may serve as team leaders

Note: For the initial period the three new management individuals of the department will also serve as the active team leaders performing recoveries.

ANCILLARY ISSUES

- Clear authorization to consolidate tissue recovery under TGLN from the MOHLTC along with an executable plan will be important as this represents a significant change that affects every Ontario tissue bank constituency. Questions, second guessing, and even some resistance should be anticipated.
- A risk that some important elements of the overall realignment and various work plans for Ontario Tissue Donation and Transplantation may not succeed, or may not be completed on a timely basis, which may dampen the positive impact of the Tissue Donor Recovery Work Plan. Generally, turning down the number of donors being recovered due to lack of capacity in processing or distribution is not a good solution as this causes many trust issues with the donating facilities.

7.12.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	TGLN shall complete a five year Strategic Plan for developing a tissue donor recovery program that will be charged with the recovery of all tissue donors in Ontario.
2	TGLN shall complete a detailed Business Plan that addresses tactics and required resources for year one of the five-year Strategic Plan. With the Strategic Plan and Business Plan completed, the case for approval and funding must be presented to the MOHTLC.
3	With MOHLTC approval and funding in place, all TGLN constituents and other provincial stakeholders shall be informed that the organization is ready and committed to the process of this Work Plan as well as for Tissue Donation and Transplantation Realignment in Ontario.
4	Begin to coordinate activities with existing recovery groups/entities for a planned transition, being prepared for concerns, questions and criticism.
5	With finalized job descriptions in place, fill the positions of Manager, Quality Assurance Specialist, and Training Specialist for the new TGLN Tissue Recovery Department. Until the size of the recovery effort dictates otherwise, these positions will be considered acting team leaders performing tissue donor recoveries.

6	Initiate and conduct intensive training for the new leadership team (acting team leaders) in eye and multi-tissue donor recovery.
7	Make plans and review options for additional space and equipment needed for the GTA facility. Expected activity levels will increase so that by year three or four at least 3,000 square feet of space will be required.
8	Move responsibilities for eye donor recovery from the Provincial Resource Centre to the newly created Tissue Recovery Department and increase the number of TGLN performed eye donor recoveries.
9	Engage a contracted physician with expertise in infectious diseases and sepsis to support the new Medical Director. This MD would be available 24/7 for consultation.
10	Identify a Medical Director for the program. The best backgrounds for the Medical Director are infectious disease, internal medicine, or pathology. The Medical Director will also serve as the Chair of a new Medical Advisory Committee.
11	Establish a Medical Advisory Committee for tissue recovery, to include representation from tissue processors, supplemented with key physicians recruited for both their interest level and expertise.
12	Begin the process of establishing TGLN specific recovery SOP's. The starting point is a combination and expansion of the best SOP's that already exist at the tissue banks.
13	Initiate recoveries of multi-tissue donors performed by TGLN Tissue Donor Recovery Department.
14	Continue communicating and coordinating plans and activities with existing recovery groups/entities for efficient transition and maintaining quality. Finalize transition plan for MSAT and RegenMed recovery individuals to be under the direction of TGLN. Update SOPs as needed to complete transition.
15	Secure additional space in GTA.
16	Purchase freezers, refrigerators, autoclave, instruments, furnishings, and office equipment for the GTA offices/lab of Tissue Donor Recovery Department.
17	Recruit and employ Administrative / Clerical Support for Tissue Donor Recovery Department.
18	Arrange for payments for technicians performing eye and multi-tissue recovery (other than OHIP to physicians) to be made from TGLN (rather than tissue processors).
19	TGLN to begin the transition to assume responsibilities and costs for all aspects of eye donor recovery – training, supplies, transport, etc.
20	TGLN to begin the transition to assume responsibilities and costs for all aspects of multi-tissue donor recovery – training, supplies, transport, etc.
21	Continue to expand the number of tissue recoveries performed by TGLN Tissue Donor Recovery teams.
22	Initiate in situ excision of corneas in GTA that will require a training initiative.
23	Support professional training/certification for recovery personnel

RESOURCES NEEDED IN YEAR 1
Resource Description
• Consultation services to guide and assist in facilitating planning and implementation of this and other Work Plans • Recruitment costs for Manager, Quality Assurance, and Training positions • Compensation for Manager, Quality Assurance, and Training positions • Expenses associated with training of staff (e.g. AATB seminars, internship, etc.) • Additional compensation for Tissue Recovery Coordinators due to enhanced skills sets needed to recovery tissue • Contracted fees for specialist in infectious diseases and sepsis.

- Stipend/compensation for new Medical Director
- Legal fees for consultation on new contracts and responsibilities
- Initial sets of recovery instruments and supplies for initial tissue donor recoveries performed by new TGLN Tissue Donor Recovery team leaders.
- Travel and meeting expenses should be budgeted for:
    - Medical Advisory Committee
    - Medical Director
    - Training for recently hired staff
    - Training for in situ excision in GTA
- Payments for eye donor recoveries (other than OHIP) in TGLN Budget (no longer paid by eye bank).
- Payments for multi-tissue donor recoveries (other than OHIP) in TGLN Budget (no longer paid by RegenMed, MSAT, Sick Children's or Firefighters.)
- Facility rental payments for expanded Tissue Recovery Department location in GTA.
- Equipment, instruments and furnishings for Tissue Recovery Department facility in GTA.
- Recruitment expenses and compensation for new Administrative Support.
- Supplies including inventories for eye donor recoveries and multi-tissue donor recoveries activities assumed by TGLN, including recovery of corneas by in situ excision.
- Additional supplies for beginning in-situ excision of corneas
- Training travel and courses for in-situ excision of corneas

YEAR 2: ACTION PLAN	
Step	**Activity Description**
24	During Year Two the Manager and Quality Assurance Specialist, but not the Training Specialist, will be phased out of recovery duties. Newly hired team leaders will take over much of the recovery. It would be best to transition recovery staff from the existing tissue bank programs because of their experience.
25	Hire first full time team leader for the GTA area (to free up Department Manager).
26	Expand in situ excision of corneas for the entire GTA and start program in other high donor regions.
27	Expand the number of tissue donors recovered by TGLN Tissue Recovery Department.
28	Review and determine the best locations for recovery facilities (remote from Toronto) to be situated.
29	Secure facility lease agreement for remote facility #ONE location.
30	Hire one full time team leader recovery individual for remote facility #ONE and begin intensive training.
31	Purchase refrigerator, autoclave, instruments, furnishing and office equipment for remote facility #ONE location.
32	For remote facility #ONE location - recruit and employ per diem/casual staff.
33	Start the process of obtaining AATB and EBAA Accreditation for Recovery Only.
34	Start the process for the recovery staff to obtain Certified Tissue Bank Specialist status with the AATB and Certified Eye Bank Technician with the EBAA. Require CTBS certification for all team leaders.
35	Work with Eye Bank of Ontario to develop and finalize plans for TGLN to assume all responsibilities for eye donor recovery (training, coordination of cases, payments to recovery individuals, all aspects of instrumentation and supply needs, transportation procedures, dealing with "stray" referrals, etc.)
36	Hire second full time team leader for Toronto area (to free up Specialist in Quality Assurance).

RESOURCES NEEDED IN YEAR 2
Resource Description
• Payments for ADDITIONAL eye donor recoveries (other than OHIP) in TGLN Budget. • Payments for ADDITIONAL multi-tissue donor recoveries (other than OHIP) in TGLN Budget • Recruitment expenses and compensation for first full time team lead based in GTA to free up Department Manager. • Additional supplies for expanding in-situ excision of corneas to entire GTA. • Training, travel, and course expenses for in-situ excision of corneas • Facility lease payments for new remote location #ONE. • Recruitment expenses and compensation for new remote location #ONE full time team leader. • Equipment, instruments and furnishings for new remote location #ONE. • Expenses associated with certification and accreditation for staff and recovery program. • Recruitment expense and compensation for second full time team leader based in GTA to free up Specialist for Quality Assurance.

YEAR 3: ACTION PLAN	
Step	**Activity Description**
37	Hire third full time team leader for GTA area (to free up Specialist for Training).
38	Expand in situ excision of corneas wherever feasible in-province.
39	Review and determine best location for recovery facilities #TWO (remote from Toronto) to be situated.
40	Secure facility lease agreement for remote facility #TWO location.
41	Hire full time team leader recovery individual for remote facility #TWO and begin intensive training.
42	Purchase refrigerators, autoclave, instruments, furnishings and office equipment for remote facility #TWO location.
43	For remote facility #TWO location - recruit and employ per diem / casual staff.
44	Secure AATB Accreditation and EBAA Accreditation for Recovery Only.
45	Recovery staff to be designated as Certified Tissue Bank Specialist status with the AATB and CEBT with EBAA. Require AATB certification for all team leaders.

RESOURCES NEEDED IN YEAR 3
Resource Description
• Payments for ADDITIONAL eye donor recoveries (other than OHIP) in TGLN Budget. • Payments for ADDITIONAL multi-tissue donor recoveries (other than OHIP) in TGLN Budget • Recruitment expenses and compensation for third full time team leader based in GTA to free up Specialist for Training. • Additional supplies for expanding in-situ excision of corneas to entire province. • Training, travel, and course expenses for in-situ excision of corneas • Facility lease payments for new remote location #TWO. • Recruitment expenses and compensation for remote location #TWO full time team leader. • Equipment, instruments and furnishings for remote location #TWO. • Expenses associated with certification and accreditation for staff and recovery program. • Expenses associated with certification and accreditation for staff and recovery program.

• Recruitment expense and compensation for second full time team leader based in GTA to free up Specialist for Quality Assurance.

YEAR 4: ACTION PLAN	
Step	**Activity Description**
46	As multi-tissue donor volume continues to increase, recruit and hire sixth full time team leader position.
47	Expand the number of tissue donors recovered by TGLN Tissue Recovery Department.

RESOURCES NEEDED IN YEAR 4
Resource Description
• Recruitment expense and compensation for sixth full time team leader based in GTA or remote location.

YEAR 5: ACTION PLAN	
Step	**Activity Description**
48	Stay the course to reach goals on donor volumes.

RESOURCES NEEDED IN YEAR 5
Resource Description
• Full year of expenses while meeting targets and goals.

7.12.6 Appendix: Financials

Trillium Gift of Life Network: Tissue Donor Recovery Work Plan
Summary Pro Forma Financial Report for Work Plan

	YEAR 1			YEAR 2	YEAR 3	YEAR 4	YEAR 5
Donor Goals	Donors			Donors	Donors	Donors	Donors
Multi - TOTAL	360			450	525	600	660
Multi - Recovered by TGLN	135			450	525	600	660
Ocular - TOTAL	2000			2100	2275	2275	2275
Ocular - Recovered by TGLN	775			1575	2275	2275	2275
	TOTAL ($)	**NEW ($)**	**EXISTING($)**	TOTAL ($)	TOTAL ($)	TOTAL ($)	TOTAL ($)
Salaries and Comp - Full Time	404,875	404,875		665,738	859,463	956,325	995,070
Salaries and Comp - Per diem/casual	301,521		301,521	842,161	1,043,266	1,141,366	1,141,366
Operating Expenses	889,588	142,200	747,388	1,439,925	1,756,075	1,919,400	2,054,025
Administrative and Other Expenses	102,500	102,500	-	147,900	175,400	168,000	168,000
Depreciation Expense	22,150	22,150	-	54,050	73,550	83,300	83,300
TOTAL OPERATING EXPENSES	1,720,634	671,725	1,048,909	3,149,774	3,907,754	4,268,391	4,441,761
Capital Budget	$221,500			$97,500	$97,500		

7.13 System Re-Design Work Plan for the Consolidation of Tissue Processing

7.13.1 Executive Summary

A major component of the redesign of the tissue donation and transplantation system in Ontario is the transition from a fragmented and limited tissue banking system to a consolidated, state of the art centre that processes all musculoskeletal, skin and cardiovascular tissues sourced in the province. The Consolidated Processing Centre will incorporate all the allografts currently provided within Ontario. In addition, the centre design will enhance tissue processing capabilities to include MS tissue lyophilization, MS demineralization, pre-meshing of skin and cryopreservation of vascular tissue. The Consolidated Processing Centre will also have the capacity to add certain specialty tissue such as ADM in the future. The presented plan estimates the Centre can be operational in four years. An environment supportive of existing tissue banking programs in the near term will facilitate a transition that best serves the province.

7.13.2 Background and Important Information

For transplantation surgeries performed in Ontario, evidence indicates that the vast majority of allografts, other than corneas, are imported from the United States. For many types of allografts, the importation rate is near 100%. Yet, interviews with surgeons and hospital staff indicate a preference for obtaining allografts from Ontario tissue banks with reliance on outside sources, particularly outside of Canada, only if necessary. This feedback is an indicator that a state of the art tissue banking system in Ontario would be supported. Current tissue banks may be described as:

- Small, hospital based
- Modestly funded
- Lacking new technology required to provide more modern allografts
- Lacking the capacity to process the number of allografts needed in Ontario
- Unable to achieve economies of scale

These shortcomings can all be alleviated with consolidation. Processing like tissues in fewer locations would:

- Eliminate redundancies – donation screening, quality assurance; charts; serology testing performed by the multiple tissue processors currently in place.
- Reduce the fixed costs per donor of cryopreservation of skin and HVs
- Achieve economies of scale and provide the wherewithal to afford newer technologies for the processing of musculoskeletal tissue.

7.13.3 Goals and Objectives

To meet Ontario's anticipated annual demand, the volume of tissue donation, recovery and processing must achieve the following levels within a five year period:

- Musculoskeletal donors – 500 donors
- Skin donors for burn– 100 skin donors
- Heart Valve donors – 150 donors with a focus on donation to serve pediatric patients

Note that the required recovery levels are approximately 110% of these volumes, since about 10% of donors are generally determined to be medically unsuitable for transplantation.

The consolidated state of the art tissue processing centre, which is the overall objective of the Processing Work Plan, will:

- provide 'in province' capacity for processing all locally recovered donors.
- process all musculoskeletal, cardiovascular, and skin tissues recovered from each donor.
- achieve processing efficiencies to maximize the number of allografts, and process all types of allografts from each individual donor.
- incorporate technology that enables the centre to produce the types of allografts most in demand that are currently imported by the provincial health care system.
- drive down the allograft unit cost and otherwise eliminate inefficiencies inherent in the current system to enable tissue processing and distribution to become economically self-sufficient. Part of that effort is the development and implementation of a fee for service model that is consistent with self-sufficiency and competitiveness.

7.13.4 Required Resources

1. The MOHLTC must mandate necessary changes and foster an environment that encourages current stakeholders to work collaboratively and with a sense of priority and urgency toward the ultimate goal.
2. The inclusion of well-trained tissue bank personnel already working in Ontario in this evolving and dynamic field of medicine.
3. The addition of key staff from Canada and the U.S. who are experienced in new technologies and processes, brought in on temporary or permanent assignments to accelerate the transition.
4. Contingency plans for tissue to be processed on a contract basis should existing Ontario tissue banks be unable to process increased levels of donated tissue prior to the consolidated tissue processing centre coming online. Although processing capacity and expertise currently in place at existing tissue banks will be fully utilized, and tissues from each donor will be directed to the programs best able to maximize the allograft output, donor numbers may increase faster than current tissue banks can process them.
5. A project manager and supporting professional service providers must be engaged to complete the start-up phase for new facility.
6. The new 36,000 square foot, consolidated, state of the art processing centre for musculoskeletal, skin and heart valve tissues will require a staff of thirty-three full time employees.

7.13.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	Clearly establish authority and governance in the form of a high level agreement or mandate for changes in Ontario's tissue processing system. The MOHLTC must fully support the Work Plan and ensure that resources are available for its implementation.
2	Establish a communication framework and management structure for consolidating multi-

	tissue processing. Meetings with staff from all the tissue banks will develop interim tissue processing strategies, and an individual with excellent knowledge in advanced tissue processing and practical experience in multi-tissue processing will be identified and empowered to help guide this process. The first operational step is to determine each organization's current capability and allocate tissue from recovered donations for processing among existing tissue banks to maximize allograft yield in the near term.
3	Begin the allocation of tissues from shared donors to the preselected tissue banks focusing on their determined specialties.

RESOURCES NEEDED IN YEAR 1
Resource Description
• Expenses for stakeholder meetings including possible travel • Selection, appointment and compensation of a Project Manager reporting to TGLN

YEAR 2: ACTION PLAN	
Step	**Activity Description**
4	The planning for a new facility will start in year two. This step will include: facility design, site location review, determining specifications, and the development of a request for proposal and bid process to be used for future selection of principals/entities that will build, manage, and operate the processing centre.

RESOURCES NEEDED IN YEAR 2
Resource Description
• Beginning expenses for professional services (building planner, engineering, etc.)

YEAR 3: ACTION PLAN	
Step	**Activity Description**
5	Identify and engage a contractor/subcontractors, engineer, and architect to complete specifications and determine the cost of construction.
6	Complete the requirements document for the new processing facility. Conduct the request for proposal and bid process. Select the principal/entity that will build, manage, and operate the processing centre.
7	Begin facility construction.

RESOURCES NEEDED IN YEAR 3
Resource Description
• Expenses for professional services (designers, planners, engineering, site inspection, etc.) • Assuming the facility is leased – upfront costs for leasehold improvements of the processing centre will be incurred.

YEAR 4: ACTION PLAN	
Step	**Activity Description**
8	Complete facility construction. All validations of equipment, facilities and processes will have been completed before operations begin. Recruit and hire the initial group of employees (managers and others) who will complete the validation work.
9	Recruit and employ operational staff as actual processing of tissue donors begins.

RESOURCES NEEDED IN YEAR 4
Resource Description
• Payments for any remaining capital costs for leasehold improvements of the processing centre. • Expenses for the recruitment and compensation of a management team and essential staff prior to actual processing operations. • Expenses for recruitment and compensation of additional staff to begin processing of donors recovered in Ontario.

YEAR 5: ACTION PLAN	
Step	**Activity Description**
10	The new centre shall process all donors recovered in Ontario, with the possible exception of a limited number which will be sent to other tissue banks for the production of certain enhanced grafts not yet processed at the new centre.
11	Include additional specialty allografts in the portfolio which were not incorporated in Year Four. During year five, other enhanced allografts such as stem cell grafts may be considered. New allografts will be developed from ideas and needs originating from the distribution channels that are already in place. These entities are close to the surgeons and in ideal positions to bring new allograft ideas back to the processing centre. Proposals for collaborative work will materialize, with medical industry partners approaching the processing centre for product development and processing needs.

RESOURCES NEEDED IN YEAR 5
Resource Description
• Additional employees up to full complement of 33 full time staff.

7.13.6 Appendix: Financials

Trillium Gift of Life Network

Work Plan for Consolidation of Processing In One Centre

Summary Pro Forma Financial Report for Work Plan

Multi Tissue Donor Processed	YEAR ONE	YEAR TWO	YEAR THREE	YEAR FOUR	YEAR FIVE
Musculoskeletal			0	250	500
Skin			0	50	100
Heart Valve			0	75	150
Total MULTI DONORS			0	300	600
Operating Expenses					
Planning and Start Up Costs	$ 110,000	$ 210,000	$ 210,000	$ 75,000	$ -
Salaries and Compensation	-	-	-	1,089,934	1,847,460
Operating Expenses	-	-	10,000	948,000	1,881,000
Administrative and Other Expenses	-	-	-	807,300	963,600
Depreciation / Amortization Expense	-	-	-	379,455	758,909
TOTAL OPERATING EXPENSES	$ 110,000	$ 210,000	$ 220,000	$ 3,299,688	$ 5,450,969
Capital Budget					
Medical and Office Equipment / Furnishings				$ 2,744,546	
Build out / Leasehold Improvement			$ 1,050,000	$ 1,050,000	
Total Capital			$ 1,050,000	$ 3,794,546	

Assumptions:

Overhead for an operation of this kind is not included - e.g. executive management, insurance, accounting and administrative support, HR, etc.,

The costs of donor material - including shipping - is not included.

Certain costs associated with donor recovery and processing are not included e.g.. serology testing costs, microbiology testing costs.

Cost to market the allografts (other than basic distribution) are not included.

7.14 System Re-Design Work Plan to Implement Pre-cutting of Corneas

7.14.1 Executive Summary

The Eye Bank of Canada Ontario Division (EBC) will precut and supply lamellar corneal allografts to all surgeons who request this service in the province. This will be implemented over a two year period. The benefits will include: better surgical outcomes, shorter patient wait times and lower costs per procedure.

7.14.2 Background and Important Information

Posterior lamellar keratoplasties are corneal transplant procedures that replace only the patient's compromised corneal layer. Since 2006, these lamellar procedures (referred to by the acronyms DSAEK, DMEK and DALK) have been replacing the traditional, full thickness corneal transplant (which replaces all layers of the patient's cornea) as the preferred surgical indication for most patients. EBC tissue distribution data for full thickness or lamellar corneal transplants indicate that between April and December 2013, approximately 65% of the corneal tissues in Ontario were used in posterior lamellar corneal transplants.

Currently, corneal lamellar grafts in Ontario are prepared by the surgeon in the operating room just prior to the corneal transplant procedure. In North America, the vast majority of eye banks prepare or precut these lamellar grafts in the eye bank and deliver them to the surgical site ready to be transplanted. This is considered best practice, and the benefits include: better uniformity in preparing the allograft; more exacting specifications for thickness and other attributes; less waste/loss of corneal tissue; and freeing up Operating Room time as the surgeon no longer manually cuts the cornea in the OR immediately prior to surgery. The EBC has incorporated space for tissue processing suites, which are available for precutting tissue, in their new laboratory facility. Indications are that corneal transplant surgeons strongly support the precutting of corneas by the EBC.

7.14.3 Goals and Objectives

Complete the transition to a new standard of practice in the province under which all lamellar corneas are precut by EBC. Specific goals that will be achieved are:

- Better patient care, as precut cornea allografts better adhere to surgeon specifications and are more uniformly prepared by a technician who is expert in the process. In addition, Optical Coherence Tomography assures better quality.
- Less waste of donated corneas. The EBC loss rate will be a fraction of the loss occurring when individual surgeons cut corneas in the Operating Room.
- More efficient utilization of Operating Room time. Approximately thirty minutes of OR time per procedure will be saved. With more than 1,000 procedures per year, significant OR time will be freed up, moderating the pressure of inadequate OR time on scheduling, and contributing to lower patient wait times.
- The EBC's performance at a state of art level of practice and technology will better position it to evolve and respond to future, inevitable changes in corneal transplantation.

7.14.4 Resources and Constraints

1. The new location occupied by the EBC already encompasses sufficient square footage to accommodate the clean rooms and ancillary space needed for precutting all of the lamellar grafts needed in the province.
2. One or more microkeratomes, the special equipment to cut corneas, already in place and used by surgeons, may be transferred to the EBC. Additional expenses must be budgeted for:
    a. A total of four microkeratome systems complete with artificial chambers to be transferred in or purchased;
    b. An Optical Coherence Tomography unit which is used to verify corneal thickness;
    c. Maintenance and repair expenses for the medical equipment.
3. Supplies to perform the precutting.
4. Technicians specializing in the precutting processes will be recruited, employed and trained.

7.14.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	Communicate the details of the Work Plan to ophthalmic surgeon customers of the EBC.
2	Identify a group of surgeons/individuals (e.g. a subcommittee of the Provincial Corneal Transplant Working Group) who can mentor the EBC toward effective implementation of the Work Plan.
3	Transfer in or purchase the first microkeratome system.
4	Purchase supplies for precutting
5	Recruit, employ and train 2.5 full time equivalent medical technicians for precutting corneal tissue.
6	Precut 350 (about 1/3 of the provincial need) lamellar allografts and distribute to surgeons in Ontario.

YEAR 2: ACTION PLAN	
Step	**Activity Description**
7	Transfer in or purchase three additional microkeratome systems.
8	Purchase the Optical Coherence Tomography unit.
9	Purchase supplies for precutting all lamellar grafts need in the province
10	Precut 1,100 (100% of the provincial need) lamellar allografts and distribute to surgeons in Ontario.

7.14.6 Appendix: Financials

Trillium Gift of Life Network Precutting Corneas at the Eye Bank of Canada **Summary Pro Forma Financial Report for Work Plan**					
	YEAR ONE	YEAR TWO	YEAR THREE	YEAR FOUR	YEAR FIVE
Volume					
Precut Tissue	*350*	*1,100*	*1,100*	*1,100*	*1,100*
Salaries and Compensation	185,625	185,625	185,625	185,625	185,625
Operating Expenses	77,820	170,880	170,880	170,880	170,880
Depreciation Expense	5,500	37,500	64,000	64,000	64,000
TOTAL OPERATING EXPENSES	$ 268,945	$ 394,005	$ 420,505	$ 420,505	$ 420,505
Capital Budget	$ 55,000	$ 265,000	$ -	$ -	$ -

7.15 System Re-Design Work Plan to Improve Information Systems and Data Management

7.15.1 Executive Summary

Information collection and exchange for tissue donation and transplantation in Ontario is limited, and stakeholders do not share data electronically. TGLN's Information Systems Department and associated IT resources are a foundation for improving and automating the exchange of medical and other information concerning donors, tissues, and allografts. This Work Plan parallels several others and is central to their implementation. Significant improvement in information systems is fundamental to reaching the primary goal of an integrated, efficient, enlarged system for tissue donation and processing.

7.15.2 Background and Important Information

With few exceptions, information systems and data management for tissue donation and transplantation are disconnected in Ontario, with limited ability to share information electronically. Reports over the full continuum of activities: referral > donation > recovery > processing > distribution > surgery, cannot be compiled on a timely, regular basis and only capture limited data. For shared tissue donors, several donor identification systems are used, which hinders expedient tracking and tracing of tissues and allografts.

A system capturing surgical use and outcome data would involve tracking thousands of allografts and integrating data from hospital Operating Room systems with provincial surgical coding databases. This is an enormous undertaking and is not addressed in the presented redesign.

However, capturing in-province data from tissue referral through tissue distribution is an attainable goal. Information from referral to consent, as well as some elements of recovery, is already captured in the TGLN iTransplant systems. Implementing data management systems at Ontario's tissue processing sites will provide data on recovery, processing, inventory, and distribution. Our recommendations include adding such a system at the EBC, followed by a comparable system at the Central Processing Center for multi tissue donors in Year Four.

Integrated data will allow tissue processors to improve donation specifications communicated to recovery technicians. Recovered tissues will better match the needs of processors and support improved allograft production, inventory management, distribution, and required tracking and tracing from referral through surgical implant. From a macro point of view, province wide data will be more easily attainable, more accurate and complete, and sourced from fewer entities. This will enable better planning and review by management and expanded public reporting.

7.15.3 Goals and Objectives

Goals and objectives for information systems are:

1. Extend the TGLN Donor Management System to the Eye Bank of Canada – including the iTransplant Eye Bank Module for Processing.

2. In conjunction with the newly established Tissue Donor Recovery Department, expand data capture using the iTransplant Tissue Recovery Module for collecting all information needed by processors.
3. Transition to an identification system for donors sourced in Ontario so that there is one and only one donor identification number used per donor, per tissue and per allograft.
4. Adopt ISBT 128 for the identification, defining, referencing and labeling of all allografts recovered and processed in Ontario.
5. Extend the TGLN Donor Management System to the Consolidated Processing Centre for multi tissue donors.

7.15.4 Resources and Constraints

1. The Trillium Gift of Life Network has software, systems and human resources that may be further leveraged to improve and expand donation and transplantation activities in Ontario.
2. Additional hardware, software and human resources will be needed to achieve the Work Plan goals.
3. Software for tissue processing will be purchased/customized for the Consolidated Processing Centre for multi tissue donors, which is to be operational in Year Four.

7.15.5 Strategies and Actions

YEAR 1: ACTION PLAN	
Step	**Activity Description**
1	Install the Eye Bank Processing Module for use by the Eye Bank of Canada and interface with TGLN referral and recovery activities data.
2	TGLN determines if the iTransplant tissue recovery module can be further leveraged to support the new Tissue Donor Recovery Department.
3	The MOHLTC and TGLN introduce the concept and begin planning for adoption of a unique identification numbering system for donors, tissues and allografts.

RESOURCES NEEDED IN YEAR 1
Resource Description
• Acquisition and annual licensing of iTransplant's Eye Bank Module • Consultation services for Information Systems enhancements and for introduction of a unique identification system for donors, tissues, and allografts. Existing resources of TGLN Information Systems Department will be leveraged when feasible.

YEAR 2: ACTION PLAN	
Step	**Activity Description**
3	Initiate the use of a single donor/allograft identification system for donors recovered and processed in Ontario and plan for full adoption of ISBT 128.
4	Begin planning and determine specifications of information system for Consolidated Processing Centre for multi tissue donors.

RESOURCES NEEDED IN YEAR 2
Resource Description
• Consultation services to move forward with ISBT 128 adoption.

• Consultation services and planning resources for Information Systems for Consolidated Processing Centre information systems.

YEAR 3: ACTION PLAN	
Step	**Activity Description**
5	For the Consolidated Processing Centre for multi tissue donors, complete requirements document, develop and issue request for proposals, complete bid process, select vendor, prepare system to come online simultaneously with the Centre in Year Four.
6	Adopt ISBT 128 standards for defining, referencing, and labeling ocular allografts.

RESOURCES NEEDED IN YEAR 3
Resource Description
• Consultation services to move forward with ISTB 128; professional services for completing specifications and requirements, and engaging vendors for selection of Information Systems for Consolidated Processing Centre for multi tissue donors. • Fees for ISBT 128 (ocular allografts).

YEAR 4: ACTION PLAN	
Step	**Activity Description**
7	The Information Systems for Consolidated Processing Centre comes online. The new Centre will adopt ISBT 128 standards for defining, referencing, and labeling allografts.

RESOURCES NEEDED IN YEAR 4
Resource Description
• Implementation costs and licensing fees for software and related systems for Consolidated Processing Centre for multi tissues. • Fees for ISBT 128 (all allografts)

YEAR 5: ACTION PLAN	
Step	**Activity Description**
8	Activities continue

RESOURCES NEEDED IN YEAR 5
Resource Description
• Licensing fees continue for software.

7.15.6 Appendix: Financials

Trillium Gift of Life Network Improve Information Systems and Data Management **Summary Pro Forma Financial Report for Work Plan**					
	Year 1	Year 2	Year 3	Year 4	Year 5
Consultation and professional services (Existing resources of TGLN Information Systems Department will be leveraged when feasible.)	$10,000	$10,000	$10,000	$10,000	$10,000
iTransplant or other OS licensing fees	$84,000	$84,000	$84,000	$168,000	$252,000
ISBT 128 licensing fees	$200	$310	$310	$510	$1,310
Hardware maintenance and repair	$2,000	$2,000	$2,000	$2,000	$2,000
Subtotal	**$96,200**	**$96,310**	**$96,310**	**$180,510**	**$265,310**
Depreciation and Amortization of Capital Items	$26,000	$52,000	$52,000	$96,000	$140,000
Total	**$122,200**	**$148,310**	**$148,310**	**$276,510**	**$405,310**
Capital	**$244,000**	**-**	**$220,000**	**$220,000**	**-**

Appendix F: About the GJC Consulting Group

The GJC Consulting Group Baltimore, Maryland USA

The GJC Consulting Group provides consulting services in various business sectors with an emphasis in the fields of transplantation, tissue banking, eye banking, biotechnology and non-profit management utilizing an extensive network of experienced professionals to customize the knowledge and expertise required for each assignment. The GJC Consulting Group team contributors to this report are:

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Appendix G: Glossary of Terms and Abbreviations

AATB – American Association of Tissue Banks, Washington D.C.

ADM – Acellular Dermal matrix; a soft tissue allograft processed from donated skin typically used for soft tissue repair; wound healing and surgical site containment.

Adverse Outcome - An undesirable effect or untoward complication in recipient consequent to or reasonably related to cells and/or tissue transplantation

Allograft - Cells and/or tissue intended for transplantation into another individual of the same species.

AOPO – Association of Organ Procurement Organization, Washington DC

Aseptic Processing – The processing of cells and/or tissue using methods to prevent, restrict or minimize contamination with microorganisms from the environment, processing personnel.

Aseptic Retrieval - The processing of cells and/or tissue using methods to prevent, restrict or minimize contamination with microorganisms from the donor, environment, retrieval personnel.

Autograft – Cell and/or tissue intended for implantation, transplantation or infusion into the individual from whom it was recovered.

Approached –family approached for consent for donation of organs and/or medically eligible tissue donation candidates.

Bone – see musculoskeletal tissue.

Cancellous bone – the meshwork of spongy bone typically found within the heads of the femur and humerus and iliac crests.

CDC – Center for Disease Control and Prevention, Atlanta Georgia, United States of America

Clean Room – a room in which the concentration of airborne particles is monitored and controlled to defined specifications.

Cortical bone – the dense outer surface of the bone providing skeletal structure and strength.

Cross-Contamination – The transfer of infectious agents from cells and/or tissue to other cells and/or tissue or from one donor's tissue to another donor's tissue.

Cryopreserved – Tissue frozen with the addition of, or in a solution containing, a cryprotectant agent such as glycerol or dimethylsulfoxide.

Compliance Rate – ratio of patient's deaths referred to the Routine Notification Requirement (RNR) to the total deaths in a hospital.

CV – abbreviation for cardiovascular tissue (heart valves and certain veins).

DBM – Demineralized Bone Matrix

DSAEK – Descemet's Stripping Automated Endothelial Keratoplasty. A corneal transplant procedure using only the posterior cornea layers when prepared by an eye bank;

DSEK - – Descemet's Stripping Endothelial Keratoplasty**.** A corneal transplant procedure using only the posterior cornea layers when prepared by corneal transplant surgeon (in the operating room).

DMEK - Descemet's Membrane Endothelial Keratoplasty. A corneal transplant procedure using only the Descemet's membrane and endothelial layers of the cornea prepared by either an eye bank or corneal transplant surgeon (in the operating room).

DALK - Deep Anterior Lamellar Keratoplasty. A corneal transplant procedure using anterior donor cornea lamella prepared by an eye bank or corneal transplant surgeon (in the operating room).

Distribution – A process that includes receipt of a request for cells and/or selection and inspection of appropriate cells and/or tissue, and inspection and subsequent shipment and delivery of cells and/or tissue bank, tissue distribution intermediary, or tissue dispensing service (i.e. . Hospital)

Donation – an anatomical gift of organ and/or tissue for transplantation or research.

Donor – A deceased individual who is the source of cells and/or tissue for transplantation in accordance with established medical criteria and procedures.

Donor Medical History Questionnaire – A documented dialogue with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior.

Donor Referral – A call made to Trillium Gift of Life Network -Provincial Resource Center (PRC) by a hospital on a patient's death with the potential to donate organ and/or tissue.

EBAA – Eye Bank Association of America, Washington DC

Enucleation – the tissue recovery technique to obtain the whole eye from the donor.

Excision – In the context of this report, the tissue recovery technique to remove only the cornea from a donor instead of enucleating the whole eye or a tissue processing step performed at the eye bank laboratory.

EBC – Eye Bank of Canada, Ontario Division

FDA – The United States Food and Drug Administration

Freeze Dried/Lyophilized – Tissue dehydrated for storage by conversion of the water content of frozen tissue to a gaseous state under vacuum that extracts moisture.

Homograft – see allograft.

HSCTL – Hospital for Sick Children Tissue Laboratory is a source agency tissue bank located at the Hospital for Sick Kids, Toronto, ON.

HV – Heart Valve.

ISBT 128 - a global standard for the identification, labeling, and information transfer of human blood, cell, tissue, and organ products across international borders and disparate health care systems.

MS – musculoskeletal tissue.

Musculoskeletal tissue- relating to or involving the muscles and the skeleton tissue typically including bone, ligaments, tendons, cartilage and fascia lata.

Next of Kin – The person (s) most closely related to a deceased individual as designated by applicable law.

NGO – Non-Government Organization

OHIP – Ontario Health Insurance Plan

OPFSB – Ontario Professional Firefighters Skin Bank

OPO – Organ Procurement Organization is a non-profit organization that is responsible for the evaluation and procurement of deceased donor organ and/or tissue for transplantation.

OTC – Organs, Tissues and Cells as defined by Health Canada.

PRC – Provincial Resource Center is the central 24/7 communication center operated by TGLN in which all organ and tissue donor referrals and transplantation activity is coordinated.

Medically Eligible – a donor referral that has been screened and deemed to have met medical eligibility criteria for transplantation for at least one tissue type.

MOHLTC – Ministry of Health and Long-Term Care (Province of Ontario)

MSAT - Mount Sinai Allograft Technologies (MSAT), is a source agency tissue bank located in the pathology Department of Mt Sinai Hospital, Toronto, ON

Multi-tissue Recovery – A donor procedure where more than one tissue type is recovered

Organ and Tissue Donation Coordinator (OTDC) – A person assigned to coordinate and manage the organ donation process at one of the 21 Tier I hospital.

OCT - Optical Coherence Tomography is microscopic system widely used in ophthalmology to obtain sub-surface images of the cornea at a much higher level than MRI or ultrasound.

RegenMed - Lake Superior Centre for Regenerative Medicine is one of source agency musculoskeletal tissue bank serving Ontario, Thunder Bay, ON.

Referral – A decedent notification (typically from a hospital) to the Trillium Gift of Life Network to screen for potential donation of organs and tissues. Timely Referral – a donor referral made within one hour of documented asystole.

Recovery – Obtaining cells and/or tissue from donor that is intended for use in human transplantation and/or research.

Retrieval – The removal, acquisition, recovery, harvesting, or collection of donor cells and/or tissues.

Routine Notification Requirement (RNR) – All designated hospital in Ontario have been mandated legislatively to call Trillium Gift of Life Network with all imminent death to assess the potential for organ and tissue donation.

Skin for burns – the thin epidermal and partial dermal layers of the skin recovered for the treatment of severe burn wounds. Sometimes referred to as split thickness skin.

Sterilization – A validated process to destroy, inactivate, or reduce microorganisms to a sterility assurance level of 10^{-6}.

Structural Grafts – Those tissue grafts that contribute biomechanical strength to a surgical construct.

Tertiary care hospital – a hospital providing health and surgical care in one of more medical specialties.

TGLN – Trillium Gift of Life Network is the designated Organ Procurement Organization in Ontario as well as an OTC establishment.

Tissue – A functional group of cells. The term is used collectively in most standards to indicate both cells and tissue. In the context of this report, the primary tissues addressed are eye, heart valves, musculoskeletal, pericardia and skin.

Tissue Bank – An entity that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes. These services include assessing donor suitability, recovery, processing, storage, labeling, and distribution of cells and/or tissue. Other references may be made to "free standing tissue bank" (a bank that is its own distinct organization); "hospital based tissue bank" (a bank that is part of a hospital or hospital department) and "blood bank based tissue bank" (a tissue bank that is part of a blood bank).

Traceability – The ability to locate cells and/or tissue during any step of its donation, collection, processing, testing, storage, distribution, disposition or transplantation.

TRC – Tissue Recovery Coordinator is responsible for the coordination and/or recovery of tissue

USP – United States Pharmacopoeia, the United States Pharmacopeial Convention, Inc., Rockville, Maryland

USPHS – United States Public Health Services

Validation – The process of establishing documented evidence that provides a high degree of assurance that specific process will consistently produce a predetermined outcome.

Xenograft - A graft of tissue taken from a donor of one species and grafted into a recipient of another species.

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