

Supply of Human Allograft Tissue in Canada

Final Report 2010

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Executive Summary

The purpose of the National Survey for Supply of Human Allograft Tissue in Canada was to quantify the current supply of allograft tissue from Canadian tissue banks and to collect information on the characteristics and capabilities of these banks. Information was requested on tissue bank functions, donor activity, tissue recovery, processing and distribution activity, staffing, transmissible-disease testing, ancillary support and funding. The scope of this survey included human allograft bone, soft tissue, cardiovascular, skin, and ocular tissues. In addition to the supply survey work, interviews were conducted with representatives from Canadian tissue programs to obtain information on the programs' governance structure, roles and responsibilities, partnerships, strategic priorities, and funding models, as well as their end-user interactions. Quebec tissue banks, which are managed by Héma-Québec, were not included in the scope of the survey or in the interview process.

Survey responses were received from 22 tissue banks, including:

- Four comprehensive tissue banks;
- Seven surgical bone banks;
- Four musculoskeletal tissue banks;
- Five eye banks; and
- Two tissue-specific banks.

Of the 23 potential respondents, only one smaller musculoskeletal tissue bank did not provide a response to the survey. All 22 tissue banks that responded to the survey also participated in the interview process, with the exception of one musculoskeletal tissue bank.

The majority of tissue programs, 19/22 or 86.4%, operate within a hospital environment. The majority of deceased-donor programs report to the surgical function within their host hospital or health region. In the hospital context, the next most common function that tissue programs are aligned with is the transfusion medicine laboratory or the broader laboratory services group.

As reported by all survey respondents, the total number of staff dedicated directly to tissue services was 107.5 full-time equivalents (FTEs). Of this group, 62.5 FTEs were designated as technical staff involved in operational processes such as recovery, processing and distribution. Of the total 107.5 FTEs, 60.6 FTEs or 56.4% were associated with the four comprehensive tissue banks. In addition to FTEs, the respondents noted a total of 95 casual staff and 214 casual physicians performing recoveries. The majority of casual staff and casual physicians were associated with eye banks.

The majority of respondents, 18/22 or 81.8%, reported using a database to track some aspect of their operational activities. Database tools are most commonly used for tissue inventory management and tissue distribution activities. The majority of the information management tools used by tissue banks are stand-alone systems, developed in-house and based on standard database programs.

With the exception of transmissible-disease testing and courier services, the majority of programs rely on their host hospital or organization to provide support services, including finance, housekeeping, materials management and sterile supply services. The respondents indicated that there is generally no transfer of funds for services provided by their host hospitals or organization.

Six of the 17 (6/17) survey respondents that recover, process or distribute musculoskeletal, cardiovascular or skin allografts are AATB accredited (35.3%) and seven of the eight (7/8) banks processing and distributing ocular tissue are EBAA accredited (87.5%). There were no stand-alone surgical bone banks with AATB accreditation.

Survey respondents indicated that the majority of donor referrals to their programs originated from the hospital environment. Outside the hospital environment, the next highest source of referrals came from

medical examiners. Survey respondents reported an annual total of 4,593 donors (1,757 living and 2,957 deceased donors) in 2008. Approximately 135 of the 2,957 (4.6%) deceased donors were also organ donors. Within the group of 2,957 deceased donors, there were:

- 2,670 ocular recoveries;
- 278 bone and soft-tissue recoveries;
- 125 cardiac recoveries; and
- 156 skin recoveries.

The total number of recovered tissues was 12,343. The respondents reported a total of 10,550 tissues recovered from deceased donors and 1,793 tissues recovered from living donors. A total of 8,404 tissue allografts were processed within Canada in 2008; this total does not include femoral head allografts obtained from living surgical bone donors.

Fifteen of the 22 respondents indicated that they routinely distributed allografts outside of their host institution. Of the 15 programs distributing outside their host institution, eight programs indicated that they routinely distributed tissue outside their home province. A total of 8,181 allografts that were processed within Canada were distributed in 2008. Respondents indicated that corneas, skin allografts, ground and chipped bone and various types of tendons and large structural allografts are in high demand by the end-users they support.

In 2008, there were no ocular programs that were recovering costs for corneas distributed for transplantation. Although 33.3% of the tissue banks indicated that they recovered costs for processed allograft tissue, most Canadian tissue banks do not recover costs for allografts distributed to their host institution or within their health region. Given that most tissue banks distribute allografts primarily to local or regional end-users, each tissue bank's funding organization(s) covers the majority of the operating costs. The majority of programs noted that the greater part of their funding came from their host hospital. A few respondents indicated that all or most of their funding was provided directly by their province. One comprehensive tissue bank noted that a majority of their funds came from cost recovery, while another bank noted that it had developed a self-sustaining model.

The information obtained in the survey work and through the interview in process is very similar to the information presented in the *Supply of Human Allograft Tissue in Canada - 2003* report. For example:

- The comprehensive tissue banks in Canada continue to provide a significant portion of Canada's tissue supply, with the exception of ocular tissue.
- Stand-alone eye banks continue to provide the majority of ocular tissue for transplantation.
- Tissue activities continue to be locally managed, funded and monitored.

In addition, the concerns that were identified in the 2003 report largely remain the same. These issues include:

- Lack of a systematized, coordinated approach to the provision of tissue services.
- Regional disparities across Canada in the type and comprehensiveness of tissue services provided.
- No mechanism to coordinate supply with demand on a national basis.

Although much about the system has remained the same, there have been a number of notable changes in the tissue banking community since 2002. These changes include:

- A significant reduction in the number of stand-alone surgical bone banks; at least eight surgical bone banks have closed or halted recoveries of surgical bone.
- An increase in the number of Canadian tissue programs partnering with processors in the United States.
- The merging of tissue programs located in the same health region or province.
- An increased number of tissue programs involved in the management of tissue within their host hospital or health regions.

Although some individual programs have increased the number of tissue recoveries or number of allografts processed within their facilities in recent years, to date, overall growth in the number of recoveries and

processed allografts has been limited. Tissue programs across the country have clearly identified the challenges of the current environment, and the need for system improvement is generally accepted.

Background

In 2002, the Canadian Council for Donation and Transplantation (CCDT) engaged the Canadian Institute for Health Information (CIHI) to analyze the Canadian supply of allograft tissue. Twenty-nine Canadian tissue banks were surveyed, and responses were received from 28 tissue banks, for a 97% response rate. Results were compiled and presented in the *Supply of Human Allograft Tissue in Canada - 2003* report. This 2003 report also incorporated information from key informant interviews held with representatives from tissue banks, provincial networks and users of allograft tissue in Canada.

In August 2008, it was announced that Canadian Blood Services would take on some additional functions related to organ and tissue donation and transplantation. This included assuming the activities of the former Canadian Council for Donation and Transplantation (CCDT), as well as setting up registries for living donor paired exchange and urgent status and highly sensitized patients. Canadian Blood Services was also given the responsibility to develop a strategic plan for a national integrated organ and tissue donation and transplantation (OTDT) system, in collaboration with the OTDT community. To support these activities, funding was provided by both the federal and the provincial/territorial governments, excluding the government of Quebec.

Canadian Blood Services has taken a consultative approach and engaged stakeholders in the development of a nationally integrated Organ and Tissue Donation and Transplantation (OTDT) strategy. A Steering Committee, an Organ Expert Committee and a Tissue Expert Committee have been established to guide, and provide input regarding, the development of recommendations. In addition, there has been extensive expert and public engagement across Canada to provide input to the system design process.

In 2009, Canadian Blood Services initiated an environmental scan of tissue programs across the country, to gain a better understanding of the current tissue supply and the existing infrastructure. Information gathered in this environmental scan will be provided to the Tissue Expert Committee to assist with planning the design of the national system.

Introduction and Purpose

The environmental scan of the national tissue programs in 2009 included two initiatives:

1. Supply Survey
 - Quantify the current supply of human allograft tissue (bone, tendons, soft tissue, cardiovascular, ocular and skin) from tissue banks in Canada.
 - Collect information on the characteristics and capabilities of tissue banks. Information was requested on tissue bank functions, donor activity, tissue recovery, processing and distribution activity, staffing, transmissible-disease testing, ancillary support and funding.
2. Consultations with Tissue Programs
 - Conduct interviews with representatives from the Canadian tissue programs to obtain information on the programs' governance structure, roles and responsibilities, partnerships, strategic priorities and funding models, as well as their end-user interactions.

The purpose of this report is to compile the responses from the supply survey and to present the findings of the interviews conducted with Canadian tissue programs. The report will compile information from survey responses and from the consultations to provide a comprehensive review of the Canadian tissue system. The report will also compare data collected in previous years to the current information. Where possible, any changes in programs and activities over the past number of years will be highlighted.

Supply Survey Methodology and Limitations

Methodology

The survey was developed by the CBS project team and evaluated by key project stakeholders and representatives from the tissue bank community prior to finalization. The format and content of the survey was patterned after the survey conducted in 2003, to allow for comparison of 2002 data with 2008 data, where possible.

Potential survey respondent sites were identified through the past CCDT survey work and from Health Canada's List of Registered Cells, Tissues and Organs (CTO) Establishments. A total of 30 sites were initially identified as potential survey respondents. Although islet cells for transplantation are regulated under the CTO regulations, Canada's two islet banks were not included in the list of potential survey respondents. (Islet cells are recovered from heart-beating deceased donors, but are more closely aligned with cell-therapy products and organ-transplant programs.) The survey and cover letter were distributed electronically to all 30 sites.

Of the 30 sites that were initially identified:

- 23 tissue banks were confirmed to be potential survey respondents.
- Three surgical bone banks reported that they were no longer involved in tissue recovery or banking.
- One surgical bone bank had stopped surgical bone banking activities, but indicated that it was hoping to resume activities in the future.
- One program indicated that it was recovering surgical bone, but sending recovered tissue to another tissue bank.
- One program noted that it was recovering ocular tissue, but sending recovered tissue to another tissue bank.
- One eye bank had been incorporated into the local tissue program.

Data spreadsheets that corresponded to each survey section or subsection were developed. Data was entered for all completed surveys, along with any comments provided. The project team conducted telephone and email follow-up for incomplete data, unclear or contradictory information, and missing surveys. Any changes from the original responses, or clarifications of data based on follow-up activities, were clearly noted in the spreadsheets. Following data entry, all surveys were reviewed in detail to validate responses and statistics.

For the purposes of data analysis, tissue and eye banks were categorized as follows:

Comprehensive tissue banks: banks that retrieve/process/distribute two or more distinct tissue types (with the exception of ocular)

Surgical bone banks: banks that produce bone from surgical/living donors only

Musculoskeletal tissue banks: banks that produce bone and soft tissue from surgical and/or deceased donors

Eye banks: banks that retrieve/process/distribute only ocular tissue

Tissue-specific banks: banks that deal with one tissue type, other than bone or ocular tissue

For reporting of tissue statistics, the following tables outline the categorization of tissue types.

Table 1. Tissue Recovered

| Tissue Type: Deceased Donor | Tissues Recovered |
|------------------------------------|--|
| Musculoskeletal | Femur, fibula, hemi-pelvis, ilium, knee en bloc, tibia, other bone, meniscus, fascia lata |
| Tendons | Achilles tendon, patellar tendon, tibialis tendon, peroneus longus tendon, gracilis tendon, semi-tendinosus tendon, other tendon |
| Cardiovascular | Heart for valves, pericardium, ascending aorta, descending aorta, saphenous vein, femoral artery, other |
| Ocular | Whole eyes, corneas |

Table 2. Tissue Processed and Tissue Distributed

| Tissue Type | Tissues Processed/Distributed |
|-------------------------|---|
| Surgical Bone | Femoral heads |
| Ground and Chipped Bone | Cancellous ground/chipped bone, corticocancellous ground/chipped bone (excluding demineralized bone) |
| Cancellous Bone | Femoral condyle – hemi, femoral condyle – whole, femoral head (cadaveric), humerus head, tibia – proximal, other cancellous bone products |
| Small Structural Grafts | Uni/bi-cortical dowels, tri-cortical wedges/blocks, femoral or humeral rings/cross-sections, fibula wedge, iliac crest wedge/strip, other bone dowels/wedges |
| Large Structural Grafts | Acetabulum, hemi-pelvis, femur with head (whole femur), femur without head, proximal femur with head, proximal without head, distal femur with condyle, distal femur with flair, femoral shaft, femoral strut, fibula whole, fibula segment, proximal humerus with head and rotator cuff, proximal humerus with head, humerus shaft, tibia whole, distal tibia, proximal tibia, tibial strut, other large structural grafts |
| Tendons | Achilles tendon, patellar tendon – whole, patellar tendon – half, tibialis tendon anterior, tibialis tendon posterior, peroneus longus tendon, gracilis tendon, semitendinosus tendon, other tendons |
| Soft Tissue | Meniscus, fascia lata, other soft tissue |
| Cardiovascular | Aortic heart valves, pulmonary heart valve, mitral heart valve, non-valve conduit – aortic or pulmonary, ascending aorta, descending aorta, pericardium, saphenous veins, femoral veins, other cardiovascular tissue products |
| Ocular | Corneas, sclera (full globe, ½ globe, ¼ globe, ⅛ globe) |
| Amniotic Membrane | Amniotic membrane |

Limitations

It is important to present the limitations related to the information contained in this report, as well as the methods used to derive this information.

- Key project stakeholders and representatives from the tissue bank community evaluated the pilot survey prior to finalization. Enhancements were made to the final design and content of the survey; however, all respondents may not have interpreted each question consistently.

- The data provided by the respondents is subject to any pre-existing limitations or errors in their own record-keeping systems/processes.
- In certain cases, respondents provided estimates, as the specific data requested was not available.
- In some cases, questions were left blank, as the data was not available and could not reasonably be estimated.

In addition, the summary of the survey data presented in this report is a snapshot of the activity and characteristics of programs during the 2008 calendar or fiscal year. Several programs were in transition during this time period, and have subsequently undergone changes. A summary of program developments and anticipated future changes are noted throughout the report.

Supply Survey Results

Survey results are presented by major category as follows:

- Survey Response
- Characteristics of Respondent Tissue Banks
 - Location of Respondents
 - Tissue Bank Functions across Tissue Types
 - Accreditation
- Infrastructure of Respondent Tissue Banks
 - Staffing
 - Information Management
 - Ancillary Services
- Tissue Statistics
 - Donor Referrals
 - Number of Donors
 - Allograft Tissues Recovered
 - Allograft Tissues Processed
 - Allograft Tissues Distributed
 - Availability of Tissue
- Program Funding

Survey Response

Twenty-two out of 23 tissue programs completed and returned surveys. Table 3 presents the response rate by type of bank.

Table 3. Response Rate by Type of Bank

| Tissue Type | No. of Responses | No. of Potential Responses | Response Rate (%) |
|------------------------------|------------------|----------------------------|-------------------|
| Comprehensive Tissue Banks* | 4 | 4 | 100 |
| Surgical Bone Banks | 7 | 7 | 100 |
| Musculoskeletal Tissue Banks | 4 | 5 | 80 |
| Eye Banks | 5 | 5 | 100 |
| Tissue-Specific Banks | 2 | 2 | 100 |
| Total | 22 | 23 | 96 |

*One comprehensive tissue bank is involved only in the recovery and distribution of tissue. This tissue bank has established partnerships with external tissue banks to perform tissue processing activities.

Characteristics of Respondent Tissue Banks

Location of Respondents

Overall, 40.9% of banks that responded to the survey are located in Ontario (9/22). British Columbia and Saskatchewan each had three banks that responded to the survey, each representing 13.6% of the total number of banks responding. Alberta and Manitoba each had two banks that responded to the survey, while Nova Scotia had one tissue bank. There are no tissue programs in Prince Edward Island or Newfoundland and Labrador, and tissue banks in Quebec were not included in the scope of the survey work. The one tissue bank that did not provide a response to the survey was a smaller musculoskeletal program located within Ontario.

Table 4. Respondents by Province

| Province | Comprehensive Tissue Banks | Surgical Bone Banks | Musculoskeletal Tissue Banks | Eye Banks | Tissue-Specific Banks |
|-------------------------|---|---|---|---|---|
| British Columbia | | BC Tissue Bank Vancouver Island Health Authority Tissue Bank | | Eye Bank Of British Columbia | |
| Alberta | Comprehensive Tissue Centre Southern Alberta Tissue Program* | | | | |
| Saskatchewan | | Regina Qu'Appelle Health Region Bone Bank | Saskatoon Health Region Bone/Tissue Bank | Lions Eye Bank of Saskatchewan | |
| Manitoba | Tissue Bank Manitoba** | | | Lions Eye Bank of Manitoba & NW Ontario | |
| Ontario | | London Health Sciences Centre St. Michael's Hospital Tissue Bank Lake Superior Centre for Regenerative Medicine*** St. Joseph's Healthcare | Mount Sinai Allograft Technologies National Capital Regional Bone Bank | The Eye Bank of Canada | Sunnybrook Health Sciences Centre Skin Bank The Hospital for Sick Children Tissue Laboratory |
| New Brunswick | | | Dr. Donald MacLellan Tissue Bank | New Brunswick Eye and Tissue Bank | |
| Nova Scotia | Regional Tissue Bank | | | | |

*The Southern Alberta Tissue Program includes the Alberta Lions Eye Bank.

**Tissue Bank Manitoba recovers and distributes tissue. Processing activities are outsourced.

***The Lake Superior Centre for Regenerative Medicine is classified within this report as a surgical bone bank, based solely on the 2008 activity data.

The majority of tissue programs that responded (19/22, or 91%) operate within a hospital environment.

Tissue Bank Functions across Tissue Types

Table 5. No. of Tissue Banks Performing Functions across Tissue Types

| Function | Surgical Bone | Amniotic | Bone and Soft Tissue | Skin | Cardiac | Ocular |
|-----------------------------------|---------------|----------|----------------------|------|---------|--------|
| Donor Identification and Referral | 13 | 3 | 8 | 7 | 7 | 7 |
| Donor Screening | 15 | 3 | 9 | 7 | 9 | 11 |
| Consent | 15 | 3 | 8 | 7 | 7 | 10 |
| Recovery* | 15 | 3 | 8 | 6 | 8 | 10 |
| Processing | 9 | 3 | 6 | 4 | 3 | 8 |
| Distribution | 15 | 3 | 8 | 5 | 4 | 8 |

*A number of tissue banks indicated that they provide functions for specific tissue types, but did not perform those functions in 2008. For example, the number of tissue banks that recovered tissue in 2008, as presented in Figures 1–5, may vary from what is listed within this table.

In Table 5, “distribution” refers only to the distribution of tissue that is processed by the tissue bank; it does not refer to the distribution of allografts imported from other tissue banks. Several tissue banks indicated that they provide tissue management services for the surgical programs within their host institution or health region. The scope of tissues managed, as well as the level of involvement of the tissue bank in selecting or qualifying vendors, varies between tissue banks. Further discussion on tissue management services provided by specific tissue programs is provided within the interview summary section of this report.

Accreditation

Survey respondents were asked to indicate if their bank was accredited by the American Association of Tissue Banks (AATB) or Eye Bank Association of America (EBAA). Six of the 17 (6/17, or 35%) survey respondents that recover, process or distribute musculoskeletal, cardiovascular or skin allografts are AATB accredited. Of the six programs that are accredited, three are comprehensive tissue banks, two are musculoskeletal banks and one is a tissue-specific bank. There are no stand-alone surgical bone banks with AATB accreditation. Seven of the eight (7/8, or 85%) banks processing and distributing ocular tissue are EBAA accredited.

In a 2003 report,¹ five of the 20 tissue banks that were recovering, processing or distributing musculoskeletal, cardiovascular or skin allografts were AATB accredited. In the same report, 11 of the 20 tissue banks noted that they expected to be AATB accredited in the future. This anticipated shift in AATB accreditation status has not occurred in the six-year period between the two surveys.

Infrastructure and Resources of Respondent Banks

Staffing

As reported by all survey respondents, the total number of staff dedicated directly to tissue services was 107.5 full-time equivalents (FTEs). Of this group, 62.5 FTEs were designated as technical staff involved in operational processes such as recovery, processing and distribution. A total of 8.6 FTEs were dedicated to quality management activities.

¹ Supply of Human Allograft Tissue in Canada - 2003, Canadian Council for Donation and Transplantation

Table 6. Staffing by Type of Bank

| Tissue Type | No. of Responses | No. of Full-Time-Equivalents | No. of Casual Staff | No. of Casual Physicians |
|------------------------------|------------------|------------------------------|---------------------|--------------------------|
| Comprehensive Tissue Banks* | 4 | 60.6 | 17 | 0 |
| Surgical Bone Banks** | 7 | 16.3 | 0 | 0 |
| Musculoskeletal Tissue Banks | 4 | 9.3 | 8 | 11 |
| Eye Banks | 5 | 19.7 | 69 | 203 |
| Tissue-Specific Banks | 2 | 1.6 | 1 | 0 |
| Total | 22 | 107.5 | 95 | 214 |

*One comprehensive tissue bank is involved only in the recovery and distribution of tissue. This tissue bank has established partnerships with external tissue banks to perform tissue processing activities.

**Five of the seven (5/7) surgical bone banks were involved in providing tissue management services within their host institution or health region. The FTEs within these programs would be involved in both surgical bone banking and tissue management activities. Physicians recovering surgical bone from living donors as part of a surgical procedure were not included as "casual physicians."

In 2008, the four comprehensive tissue banks had 60.6 FTEs, representing 56.4% of the total number of FTEs noted by respondents. In addition to the 107.5 FTEs, tissue banks noted a total of 95 casual staff who were involved in their programs. The majority of the casual staff (69/95, or 72.6%) were associated with ocular programs and performed ocular recoveries. Respondents noted a total of 214 casual physicians performing recoveries, excluding surgeons that recovered surgical bone from living donors. Similar to the non-physician casual staff, the majority (203/214, or 94.9%) of the casual physicians were associated with ocular programs and performed ocular recoveries.

Information Management

Table 7. Information System Usage by Function

| | Function | | | | | |
|--|--------------------------|----------------------------|------------------------------|--|------------------------|--------------------------|
| | Tracking Donor referrals | Tracking Recovery Activity | Tracking Processing Activity | Tissue Inventory Management and Distribution | Recipient Traceability | Adverse Event Monitoring |
| No. of Tissue Banks (% of Overall Banks) | 7 (31.8%) | 10 (45.4%) | 11 (50.0%) | 16 (72.7%) | 18 (81.8%) | 7 (31.8%) |

The majority of respondents (18 or 72.7%) reported using a database to track some aspect of their operational activities. Database tools are most commonly used for tissue inventory management and tissue distribution activities. Tissue banks that are linked to laboratory or transfusion medicine services within the hospital often use the laboratory information system to track tissues in the same way blood and blood products are tracked. However, the majority of the information management tools used by tissue banks are stand-alone systems, developed in-house and based on standard database programs (e.g. FileMaker, Microsoft Access). One musculoskeletal program noted that it was planning to introduce a new customized information system in 2009 that would support recovery activity, inventory management and distribution, recipient traceability and ISBT 128 bar-coding.

Ancillary Services

The following table outlines the services provided to tissue programs by host hospitals or organizations. There were a total of 21 respondents for this particular question. One program did not provide details on ancillary services.

Table 8. Ancillary Service Provision

| Ancillary Service | Provided by Host Hospital or Organization | % of Tissue Banks where Service is Provided by Host Hospital or Organization |
|-----------------------------|---|--|
| Finance | 21 | 100.0% |
| Housekeeping | 19 | 90.5% |
| Human Resources | 21 | 100.0% |
| Information Systems | 21 | 100.0% |
| Infectious Disease Testing | 2 | 9.5% |
| Laboratories – Microbiology | 17 | 81.0% |
| Laboratories – Pathology | 16 | 76.2% |
| Legal and Risk Management | 20 | 95.2% |
| Materials Management | 20 | 95.2% |
| Shipping/Courier Services | 12 | 57.1% |
| Sterile Supply Dept. | 19 | 90.5% |

Most tissue banks are located within the hospital facility or are associated with a hospital or health region. With the exception of transmissible-disease testing and courier services, the majority of programs rely on their host hospital or organization to provide support services. The respondents indicated that

there is generally no transfer of funds for services provided by their host hospitals or organization. However, most programs noted that they pay for external transmissible-disease testing services (this excludes programs in Alberta, where testing is coordinated through the provincial testing laboratory). In addition, programs that distribute allografts outside of their region pay for shipping/courier services.

Table 9. Transmissible Disease Testing Service Providers

| Service Provider | No. of Tissue Banks Using Services | % of Tissue Banks Using Service |
|---|------------------------------------|---------------------------------|
| Mt. Sinai Hospital Laboratory* (Toronto, Ontario) | 11 | 50.0% |
| ViroMed Laboratories (Minnetonka, Minnesota) | 8 | 36.4% |
| Other** | 3 | 13.6% |

*One respondent noted "Provincial laboratory and Mt. Sinai" because the service provider was changed mid-year.

**Two respondents indicated "In-house and public laboratory"; one respondent noted "testing service providers determined by the tissue processors."

The Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations) do not mandate nucleic acid testing for HIV and HCV, and do not mandate West Nile virus (WNV) testing. One eye bank and three surgical bone banks do not perform nucleic acid testing (NAT) for HIV and HCV on donors. Nine banks perform WNV testing routinely, while another nine perform WNV testing seasonally. Four programs indicated that they do not perform WNV testing.

Survey respondents were asked to indicate how much time they require to receive transmissible-disease testing results for ocular donors.

- Six of the eight programs involved in processing ocular tissue indicated that they require a <48 hour turn-around-time (TAT) for their transmissible-disease testing results.
- One ocular program noted that it requires a 48 to 72 hour TAT.
- The remaining ocular program indicated that a 72 hour TAT is acceptable.

Survey respondents were asked to indicate how much time they require to receive transmissible-disease testing results for musculoskeletal, cardiac or skin donors.

- The majority of programs (12 of 18) processing musculoskeletal, cardiac or skin tissue indicated that either there is no TAT requirement, or that a >72 hour TAT is acceptable.
- Three programs indicated that they require a 48 to 72 hour TAT.
- One program noted that a 24 to 48 hour TAT requirement is specified by its tissue processors.
- One program noted that it requires a <24 hour TAT for fresh osteoarticular allografts, but that a >72 hour TAT is acceptable for all other allografts.
- One program indicated that a <24 hour TAT is required, but no explanation was provided.

Seven of the 22 programs (31.8%) noted specific challenges with transportation of samples for testing. The issues listed by these seven banks included courier availability and logistical problems with weather conditions.

Tissue Statistics

The respondents were requested to provide a variety of statistics and other information related to their tissue and eye banking functions. Tissue banks were asked to provide activity data from the 2008 calendar year or from the most recent fiscal-year data available.

Donor Referrals

Respondents were asked to identify the sources of their deceased-donor referrals. The programs indicated that the majority (76%–100%) of their referrals originated from the hospital environment. The distribution of the units/departments providing referrals within the hospital varied from program to

program. In some programs, the ICU provided the greatest number of referrals, while other programs noted that the emergency room or other hospital wards/units provided the greatest number of referrals.

Outside the hospital environment, the next highest source of referrals came from medical examiners. Three comprehensive tissue banks noted that medical examiners provided 6%, 7% and 13% of their total number of referrals. Of the potential referral sources listed in the survey, nursing homes, long-term care facilities and funeral homes provided the fewest referrals to the tissue programs.

Number of Donors

Survey respondents reported a total of 4,593 donors (1,757 living and 2,957 deceased donors) in 2008.

Table 10. Donor Activity by Tissue Type - 2008

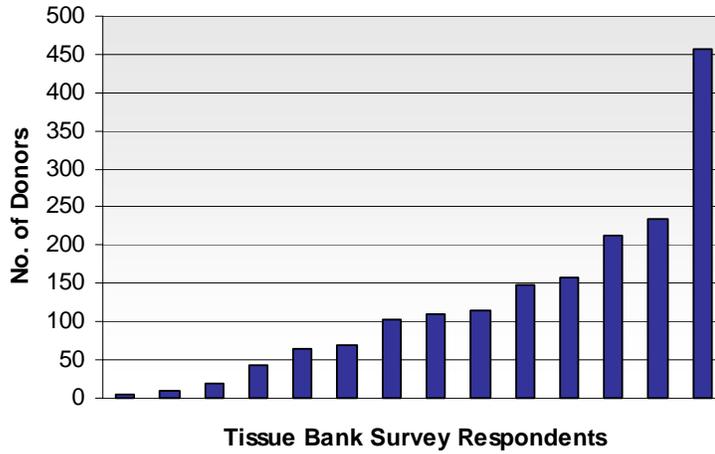
| Tissue Type | No. of Donors |
|----------------------------------|---------------|
| Surgical Bone (Living Donor) | 1,748 |
| Ocular Tissue | 2,670 |
| Bone and Soft Tissue | 278 |
| Cardiac | 125 |
| Skin | 156 |
| Amniotic Membrane (Living Donor) | 9 |

Since multiple tissue types may be recovered from deceased donors, a single donor may be counted under ocular tissue, bone and soft tissue, cardiac and skin categories in Table 10.

Each program provided the percentage of tissue donors that were also organ donors. Based on the responses, approximately 135 of the 2,957 (4.6%) deceased tissue donors were also organ donors. The Canadian Organ Replacement Registry² indicates that there were a total of 335 deceased organ donors in all provinces (with the exception of Quebec) in 2008. Based on this data, approximately 40.3% of all organ donors are also tissue donors. Each program also provided the percentage of "ocular only" tissue donors. Based on the responses provided, 2,335 of the 2,670 ocular donors (87.4%) were "ocular only" donors.

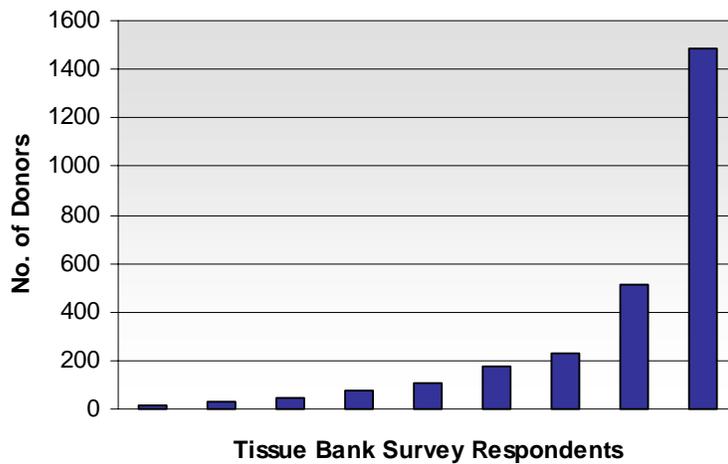
² Canadian Organ Replacement Registry: e-Statistics Report on Transplant, Waiting List and Donor Statistics – 2008 Summary Statistics, January 1 to December 31, 2008

Figure 1. Surgical Bone Recoveries from Living Donors - 2008



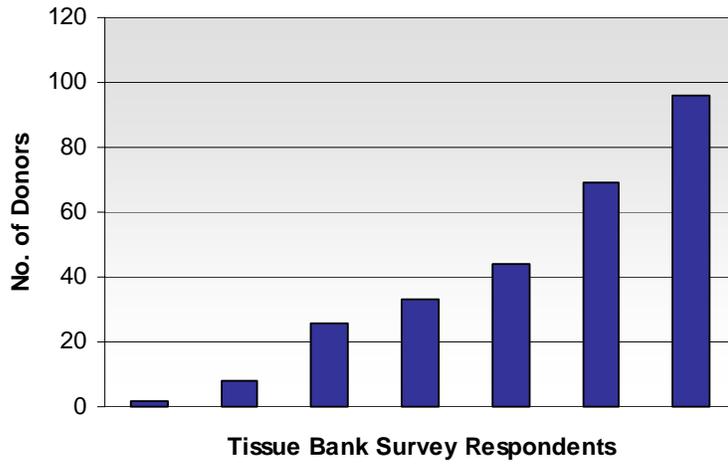
Based on the responses from the 14 programs involved in surgical bone banking, the average number of surgical bone donors per tissue bank is 125 (median: 107, range: 4–458).

Figure 2. Ocular Recoveries from Donors - 2008



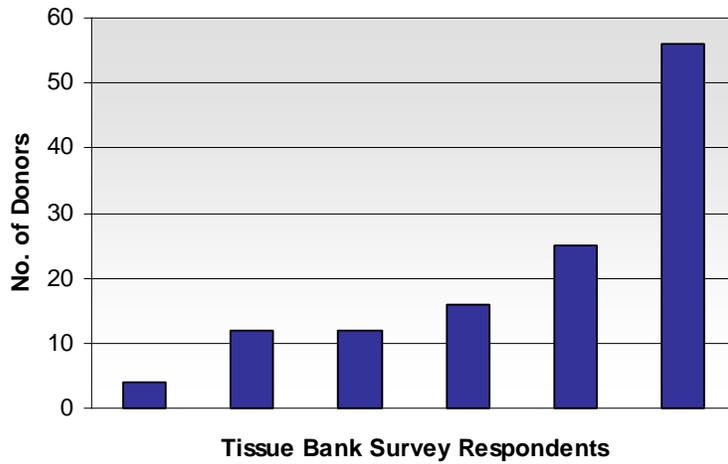
Based on the responses from the nine programs recovering ocular tissue, the average number of ocular donors recovered by each tissue bank is 297 (median: 111, range: 13–1484).

Figure 3. Musculoskeletal Tissue Recoveries from Deceased Donors -2008



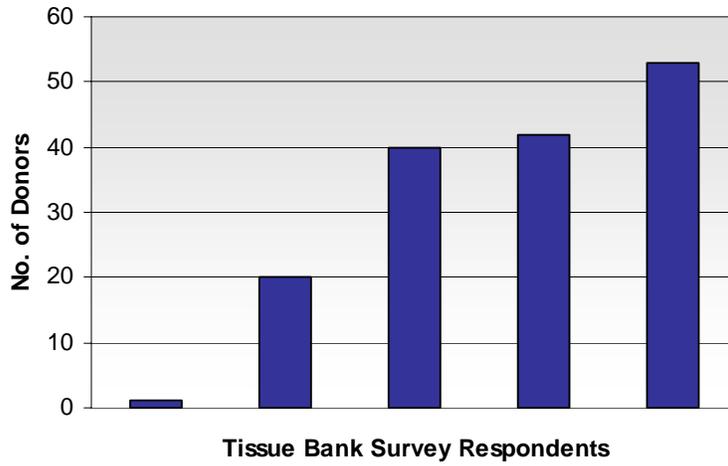
Based on the responses from the seven programs involved in recovering musculoskeletal tissue from deceased donors, the average number of musculoskeletal donors per tissue bank is 40 (median: 33, range: 2–96).

Figure 4. Cardiac Tissue Recoveries from Deceased Donors -2008



Based on the responses from the six programs involved in recovering cardiac tissue from deceased donors, the average number of cardiac donors per tissue bank is 21 (median: 33, range: 4–56).

Figure 5. Skin Tissue Recoveries from Deceased Donors -2008



Based on the responses from the five programs involved in recovering skin tissue from deceased donors, the average number of skin donors per tissue bank is 31 (median: 40, range: 1–53).

Allograft Tissues Recovered

The total number of recovered tissues was 12,343. The respondents reported a total of 10,550 tissues recovered from deceased donors and 1,793 tissues recovered from living donors.

Table 11. No. of Tissues Recovered

| Tissue Type | No. of Tissues Recovered | No. of Tissue Banks Recovering | % of Tissue Banks that Recover this Type of Tissue |
|-----------------------|--------------------------|--------------------------------|--|
| Surgical Bone | 1,784 | 14 | 63.6% |
| Ocular Tissues | 5,300 | 9 | 40.9% |
| Bone and Soft Tissue | 5,001 | 8 | 36.4% |
| Cardiovascular Tissue | 249 | 7 | 31.8% |
| Skin | N/A* | 7 | 31.8% |
| Amniotic Membrane | 9 | 3 | 13.6% |
| Total | 12,343 | – | – |

*Skin is recovered in varying sizes, limiting the ability to compare data. Data on skin is presented in the allograft processed and allograft distributed sections.

Table 12. No. of Tissues Recovered: Comparative Analysis – 2002 vs. 2008*

| Tissue Type | No. of Tissues Recovered in 2002 | No. of Tissues Recovered in 2008 | % Difference |
|-----------------------|----------------------------------|----------------------------------|---------------|
| Surgical Bone** | 1,524 | 1,784 | +17.0% |
| Ocular Tissues*** | 4,551 | 5,300 | +16.5% |
| Bone and Soft Tissue | 2,860 | 5,001 | +74.9% |
| Cardiovascular Tissue | 583 | 249 | -57.3% |
| Skin**** | N/A | N/A | N/A |
| Amniotic Membrane | 3 | 9 | – |
| Total | 9,521 | 12,343 | +29.6% |

*With the exception of one smaller musculoskeletal program that provided a survey response in 2009 but not in 2003, and one smaller musculoskeletal program that provided a survey response in 2003 but not in 2009, all deceased-donor tissue programs participated in both the 2003 and 2009 surveys.

**It is important to note that the 2003 survey did not reach out to all programs involved in surgical bone banking, and a number of the surgical bone programs that provided responses in 2009 were not surveyed in 2003. Also, a number of the surgical bone programs that provided information in 2003 are no longer involved in surgical bone banking. Although different surgical bone programs provided responses in 2003 and 2009, the total number of responses in both years stayed the same, at 14. For more information on surgical bone banking, refer to the Discussion section of this report.

***It is not clear from the 2003 *Supply of Human Allograft Tissue in Canada - 2003*³ if ocular tissue recovered and used for research and education purposes was included in the recovery numbers. The 2008 tissue recovery data includes tissue recovered for educational and research purposes. For more information refer to the Discussion section of this report.

****Skin is recovered in varying sizes, limiting the ability to compare data. Data on skin is presented in Table 13–16.

³ Supply of Human Allograft Tissue in Canada - 2003, Canadian Council for Donation and Transplantation

Allograft Tissues Processed

A total of 8,404 tissue allografts were processed within Canada in 2008. This total does not include femoral head allografts obtained from living surgical bone donors.

Table 13. Location of Processing Activities

| Tissue Type | Total No. of Tissue Banks Processing Tissue Type | Location of Processing Activities | | | |
|-----------------------|--|-----------------------------------|----------------------|---------------------------|----------------|
| | | Class 1000 Clean Room | Class 100 Clean Room | Biological Safety Cabinet | Operating Room |
| Bone and Soft Tissue | 6 | 1 | 2 | 1 | 2 |
| Cardiovascular Tissue | 3 | 0 | 1 | 2 | 0 |
| Skin | 4 | 0 | 1 | 3 | 0 |
| Ocular Tissues | 8 | 0 | 1 | 7 | 0 |
| Amniotic Membrane | 4 | 0 | 1 | 3 | 0 |

Two of the six tissue banks processing bone and soft-tissue allografts indicated that they performed sterilization, while two other tissue banks noted the use of a disinfection process for bone allografts. The remaining two programs did not indicate the use of a sterilization or disinfection process. Although there were no programs in 2008 that were preparing lyophilized or demineralized bone products, one of the six programs noted that it was planning to begin processing lyophilized and demineralized bone products. In addition to the six programs that were actively involved in processing musculoskeletal tissue from deceased donors in 2008, one program was planning to begin processing bone and soft tissue in a Class 100 clean room environment in 2009. This program also noted that it intended to introduce sterilization and chemical disinfection processes and the preparation of lyophilized and demineralized bone products.

All three programs processing cardiovascular tissue perform an antibiotic soak of allografts to reduce microbiological contamination. The four programs processing skin indicated that they used an antibiotic soak as part of a disinfection process.

Table 14. Total No. of Tissues Processed by Tissue Type

| Tissue Type | No. of Tissues Processed |
|------------------------------------|--------------------------|
| Ground and Chipped Cancellous Bone | 1,084 |
| Cancellous Bone | 754 |
| Small Structural Grafts | 139 |
| Large Structural Grafts | 869 |
| Tendons | 945 |
| Soft Tissue | 105 |
| Cardiovascular Tissue | 105 |
| Skin (packages) | 768 |
| Ocular | 3,423 |
| Amniotic Membrane | 212 |
| Total | 8,404 |

Table 15. No. of Tissues Processed: Comparative Analysis – 2002 vs. 2008*

| Tissue Type | No. of Tissues Processed in 2002 | No. of Tissues Processed in 2008 | % Difference |
|------------------------------------|----------------------------------|----------------------------------|---------------|
| Ground and Chipped Cancellous Bone | 541 | 1,084 | +100.4% |
| Cancellous Bone | 1,181 | 754 | -36.2% |
| Small Structural Grafts | 423 | 139 | -67.1% |
| Large Structural Grafts | 1,470 | 869 | -40.9% |
| Tendons | 466 | 945 | +102.8% |
| Soft Tissue | 416 | 105 | -74.8% |
| Cardiovascular Tissue | 249 | 105 | -57.8% |
| Skin (packages) | 2,210 | 768 | -65.2% |
| Ocular | 2,998 | 3,423 | +14.2% |
| Total | 9,954 | 8,192 | -17.7% |

*With the exception of one smaller musculoskeletal program that provided a survey response in 2009 but not in 2003, and one smaller musculoskeletal program that provided a survey response in 2003 but not in 2009, all deceased-donor tissue programs participated in both the 2003 and 2009 surveys. The number of amniotic membrane allografts produced in 2002 was not provided in the Supply of Human Allograft Tissue in Canada –2003.⁴ As a result, a comparison of the number of amniotic membrane allografts processed in 2002 and 2008 is not available.

Allograft Tissues Distributed

Fifteen of the 22 respondents indicated that they routinely distributed allografts outside of their host institution, and eight of these programs routinely distributed tissue outside their home province. Table 16 presents the total number of allografts that were processed and distributed within Canada. Allografts that were processed by tissue banks in the United States and distributed within Canada have not been included in the table.

Table 16. No. of Tissues Distributed by Tissue Type

| Tissue Type | No. of Tissues Distributed |
|------------------------------------|----------------------------|
| Surgical Bone | 820 |
| Ground and Chipped Cancellous Bone | 645 |
| Cancellous Bone | 1,016 |
| Small Structural Grafts | 164 |
| Large Structural Grafts | 860 |
| Tendons | 761 |
| Soft Tissue | 193 |
| Cardiovascular Tissue | 185 |
| Skin (packages) | 337 |
| Ocular | 3,052 |
| Amniotic Membrane | 148 |
| Total | 8,181 |

⁴ Supply of Human Allograft Tissue in Canada- 2003, Canadian Council for Donation and Transplantation

Availability of Tissue

Respondents were asked to indicate which allografts they considered to be in high demand, and they selected the following allografts as those where the number of requests from end-users exceeds the number of allografts available. The allografts included in Table 17 were noted as high-demand allografts by two or more programs. Note that this allograft demand information is based on the perspectives of representatives from Canadian tissue banks and the interactions they have with the end-users they support.

Table 17. High-Demand Allografts Provided by Canadian Tissue Banks

| Tissue Type | High-Demand Allografts | No. of Programs Indicating Allograft as High Demand |
|------------------------------------|---------------------------------|---|
| Surgical Bone | Femoral Heads (Living Donors) | 3 |
| Ground and Chipped Cancellous Bone | Cancellous 10–40 cc | 2 |
| | Cancellous >40 cc | 2 |
| | Corticocancellous <10 cc | 2 |
| Cancellous Bone | Femoral Heads (Deceased Donors) | 2 |
| Large Structural Grafts | Femoral Shaft | 2 |
| | Femoral Strut | 2 |
| | Fibula Segment | 3 |
| | Tibial Strut | 2 |
| Tendons | Achilles Tendon | 4 |
| | Gracilis Tendon | 2 |
| | Patellar Tendon – Half | 2 |
| | Patellar Tendon – Whole | 4 |
| | Peroneus Longus Tendon | 2 |
| | Semitendinosus Tendon | 2 |
| | Tibialis Tendon Anterior | 4 |
| | Tibialis Tendon Posterior | 4 |
| Skin (packages) | Frozen Skin | 3 |
| Ocular | Corneas | 6 |
| | Sclera | 4 |

Other allografts that were noted as high-demand allografts by a single program include:

- Ground and chipped cancellous bone (<10 cc);
- Ground and chipped corticocancellous (10–40 cc and >40 cc)
- Humerus head (cancellous)
- Tri-cortical wedge (small structural graft)
- Fascia lata (soft tissue)
- Aortic heart valve (cardiovascular)
- Pulmonary heart valve (cardiovascular)
- Non -valve conduit – aortic or pulmonary (cardiovascular)

Program Funding

The following table outlines the number of respondents who recover costs for unprocessed or processed tissue and/or pay recovery fees for tissue to other organizations. One program did not provide details on cost recovery and reimbursement practices within their survey response; therefore, the total number of banks reporting in this case is 21.

Table 18. Cost Recovery and Reimbursement Practices

| Cost Recovered or Reimbursed | No. of Tissue Banks | % of Tissue Banks Recovering Costs or Reimbursing |
|--|---------------------|---|
| Costs recovered for unprocessed tissue sent to other tissue programs | 4 | 80.0%* |
| Costs recovered for processed allograft tissue | 7 | 33.3% |
| Hospitals receive compensation for expenses related to tissue recovery | 4 | 19.0% |
| Reimbursement provided to hospitals or teams that recover tissue | 8 | 38.1% |
| Costs recovered for tissue sent to research programs | 4 | 19.0% |

*Only five programs were providing unprocessed tissue to other tissue programs.

In 2008, there were no ocular programs that were recovering costs for corneas distributed for transplant. However, some programs were recovering costs for sclera and amniotic membrane allografts. Although 33.3% of the tissue banks recover costs for processed allograft tissue, it is important to note that most Canadian tissue banks do not recover costs for allografts distributed to their host institution or within their health region. Given that most tissue banks distribute allografts primarily to local or regional end-users, each tissue bank's funding organization(s) covers the majority of the operating costs.

Survey respondents were asked to identify the source of their funding. Sources listed as options within the survey included: hospital, provincial government, charitable/hospital foundations, private corporations, cost recovery or other sources. One respondent did not provide information on funding sources. Of the 21 responses provided on funding:

- 11 respondents indicated that they receive 100% of their funding from their host hospital;
- Four respondents indicated that they receive over 90% of their funding from their host hospital, with a small percentage received from other sources;
- Two respondents indicated that they receive 100% of their funding from their respective province;
- One respondent indicated that they receive 80% of their funding from their province, with the remaining 20% received from their host hospital;
- One respondent noted that 100% of their funding was from an "other" source and that they had established a self-sustaining model;
- One respondent noted that 70% of their funding was from cost recovery, with the remaining 30% received from their host institution; and
- One respondent reported a mix of funding sources.

Survey respondents were asked to provide their actual operational expenditures or an estimate of their operational expenditures. The survey noted that the operational budget includes staff, overtime, supplies and non-capital equipment costs. Data was provided by 16 of the 23 respondents, with the sum of all operational budgets totaling \$11,076,937. A breakdown of each tissue bank's operational budget was not requested.

Interviews with Tissue Banks – Methodology and Limitations

Methodology

A set of questions was developed by the CBS project team to guide interviews with representatives from Canadian tissue programs. The 23 tissue programs that were identified during the survey work were contacted to participate in the interview. In-person or telephone interviews were set up with tissue program representatives, and the list of questions was provided in advance. A total of 17 interviews were conducted between June and October of 2009. Three of the interviews included representatives from two tissue programs, so that a total of 20 programs participated in the interview process. The 20 programs included:

- Four comprehensive banks;
- Six surgical bone banks;
- Three musculoskeletal banks;
- Five eye banks; and
- Two tissue-specific banks.

Notes from the interviews were recorded and forwarded to the tissue programs after the interview to ensure that the discussions were accurately documented. Representatives from three provincial organ-procurement organizations were interviewed to obtain additional perspectives on the donation process and on system design. These included Trillium Gift of Life, Saskatchewan Transplant and Nova Scotia Legacy of Life.

Limitations

The majority of the questions that were asked were specific questions relating to program structure or characteristics. However, in some cases, information obtained through tissue bank representatives reflected their personal preferences, opinions, observations and/or local processes and practices. The information provided by these individuals does not represent the opinion of any particular health care organization or of Canadian Blood Services.

Summary of Interviews

The following section provides a summary of the interview responses from deceased-donor programs and organ-procurement organizations. The sub-headings of this section reflect the topics explored in the interview questions.

Organizational and Governance Structure

The majority of deceased-donor programs report to the surgical function within their host hospital or health region. In the hospital context, the next most common function that tissue programs are aligned with is the transfusion medicine laboratory or broader laboratory services group. Many of the smaller tissue programs – for example, stand-alone surgical bone banks – are operationally aligned with the hospital's laboratory service. Although surgical bone banks may be a part of the laboratory services group, they often have physicians within the orthopaedic programs who provide medical leadership and support to the tissue bank.

Two of three comprehensive tissue programs that process and distribute ocular tissue have an ocular medical director, in addition to the medical director for tissue. A number of eye banks also have a board of directors that help to administer or provide input to the program. Lions Clubs continue to provide some financial support to eye banking in Canada. Certain eye banks are administratively linked to the Lions Club through the board of directors, while others simply obtain funding and support from the Lions Club for specific activities or capital purchases.

There are several unique governance structures that exist within the Canadian system. One comprehensive tissue bank reports directly to the executive management group within the health region; one eye bank

reports to the Department of Medicine at the local university, and one tissue bank is an independent, non-profit and incorporated tissue bank with a board of directors.

Support of Donor Families

In most jurisdictions, support is limited to providing the donor families with letters of appreciation after the donation and invitations to donor-recognition events. Organ-procurement programs or organizations often provide some form of bereavement support to donor families if the donor is both an organ and tissue donor, but less often when it is a "tissue only" donor. In one province, the OPO provides support to all tissue donor families. Several tissue programs noted that they have their own processes established to support tissue donor families.

Public Awareness and Education

There are currently no tissue banks that manage comprehensive, coordinated public awareness programs. The majority of tissue banks rely on their provincial or regional organ-procurement organization or transplant program for public awareness efforts. These efforts are primarily focused on organ donation. Tissue banks will often participate or provide input to provincial or regional activities, if requested. A number of eye banks noted that they had received support for public awareness and education activities from the Lions Club.

Education of Health Professionals

A number of tissue banks rely on the provincial or regional organ-procurement organizations to develop and deploy awareness and education programs for health professionals. In some cases, tissue banks will support provincial or regional efforts and, when requested, present information specific to tissue. However, a number of tissue banks indicated that they have limited contact and relations with organ-procurement organizations.

Eye banks are often involved in education initiatives for health professionals that focus on ocular donation. These efforts are frequently directed toward non-acute centres or palliative care programs that are outside the scope of regionally or provincially coordinated organ/tissue education programs. Ocular donation education efforts also often extend outside of the eye bank's local area into other regions within its province.

Staff from surgical bone banking programs are usually involved in the education of orthopaedic clinic staff involved in the surgical bone banking process.

Donor Identification, Referral and Initial Donor Screening

The majority of tissue donors in Canada are identified within the hospital environment. Two of the larger comprehensive tissue programs noted that they received support from the medical examiner's office in the identification and referral of donors. Many of the eye banks have established referral networks that extend beyond acute care hospitals, and often cover a wide geographic area within their province.

For provinces where there is legislation governing the required referral of donors (British Columbia, Ontario, Manitoba, New Brunswick and Alberta), deaths are reported to the OPOs or tissue programs defined within the legislation. The detailed requirements within the legislation often designate the target hospitals where required referral is mandatory. These requirements are put in place to define the hospitals where donation potential is highest, and to ensure there are resources in place to handle the referrals. In regions where the capacity for tissue recovery does not exist, potential tissue donors are not referred. For example, in British Columbia, potential musculoskeletal, cardiovascular and skin donors are not referred, as there is no recovery infrastructure.

The majority of the provinces with required referral legislation have established referral hubs or call centres to receive information on hospital deaths. Generally, OPOs and tissue programs rely on front-line health care providers to identify and refer potential tissue donors. Within Manitoba, the recommended process within the legislation is for departments or functions that record death within the facility (e.g. Medical Information, Admitting, Death Registration) to provide notification of death. This unique process removes the requirement for front-line health care providers to identify and refer potential donors. In New Brunswick, the tissue

programs involve morgues in their notification process, to identify donors from deaths occurring outside the hospital environment.

Obtaining Consent and Medical/Social History

Within one province, consent for donation and medical/social history information is obtained from the next of kin by OPO staff members in the hospital environment or over the telephone. In other jurisdictions, tissue programs have their own staff involved in obtaining consent and medical/social history information. Several tissue banks indicated that they routinely obtain consent over the telephone. When a tissue donor is also an organ donor, the regional or provincial organ procurement organization often obtains the consent and medical/social history from the next of kin for the tissue program. One comprehensive tissue program noted that consent was most often obtained by front-line health care providers, and that the program's own staff is not involved.

Staffing Models

Tissue programs were asked to discuss their staffing models relating specifically to recovery, processing and distribution activities.

1. Recovery
 - a) Most ocular programs have both full-time equivalents and casual staff recovering ocular tissue. Casual staff involved in ocular recoveries often work in outlying areas or are distributed throughout the region or province, and can include technicians, nursing staff and physicians. In some provinces, physicians are able to bill for their recovery activities through the provincial billing plans, while in other provinces eye banks will provide physicians with a per diem rate. Most eye banks also provide non-physician casual staff with per diem rate for recovery activities.
 - b) Musculoskeletal, cardiac and skin recoveries are usually performed by either full-time or casual tissue bank staff trained in multi-tissue recovery. Each program has defined the size of recovery teams based on the type of tissue recoveries, and each has its own approach. One program noted that it uses laboratory assistants to support tissue bank specialists in recovery activities, while another program noted that its recovery staff includes foreign-trained physicians.
 - c) Surgical bone banking programs rely on orthopaedic surgeons to recover and package femoral heads that are obtained from living donors during surgical procedures.
2. Processing
 - a) Ocular processing activities are performed by eye bank staff within the eye bank or comprehensive tissue bank facilities. The majority of ocular programs do not prepare partial-thickness grafts as part of their processing activities.
 - b) Musculoskeletal, cardiac and skin processing activities are usually performed by tissue bank specialists within the tissue bank facility. For a few programs that are only involved in processing musculoskeletal tissue, basic processing activities are performed within the operating room after recovery of the tissue.
 - c) Most programs that are involved in surgical bone banking do not perform processing activities for recovered femoral heads, although some programs will send out femoral heads for irradiation.
3. Distribution
 - a) For eye banks, the distribution of ocular tissue is managed by eye bank staff.
 - b) For many of the larger tissue banks, distribution is managed by tissue bank staff. For tissue banks that operate within the context of hospital laboratory service groups, including many of the surgical bone banks, distribution of allografts are often managed by transfusion medicine laboratory staff.

Recovery, Processing and Distribution Partnerships

There are very few recovery partnerships between Canadian tissue programs. The partnerships that have been established involve three separate tissue banks that recover and provide cardiovascular and skin tissue

to two of the comprehensive tissue banks. In addition, one eye bank has established partnerships for ocular recovery in two other provinces that do not have ocular tissue programs.

One tissue program within Canada has established partnerships with two American tissue processors for musculoskeletal, soft-tissue and skin processing. Two other Canadian tissue programs were exploring this type of processing partnership with processors in the United States. For distribution, one tissue bank collaborates with US processors to distribute processed tissue within its province.

One eye bank distributes ocular allografts to an eye bank in an adjacent province, where all cornea transplants for patients from the eye bank's home province are performed. Another eye bank noted it was exploring potential distribution partnerships with a consortium of eye banks in the United States.

Allocation and Distribution of Allografts

Most tissue banks in Canada were established to meet the needs of surgeons within their hospital or health care region. For the most part, there are no formal policies in place for allocation or distribution of tissue. Requests are usually filled on a first-come, first-served basis, and local needs are often given priority. The process for the allocation and distribution of ocular tissue to end-users is more formalized, but the actual process varies from region to region. Corneal wait-list management is most often managed by transplanting surgeons.

Management of Imported Allografts

A number of tissue banks indicated that they manage allograft and allograft products imported from domestic or foreign suppliers. Some tissue banks assess tissue suppliers to ensure they are on the list of registered CTO establishments, but do not have formal vendor qualification processes. Only two programs have established a formal vendor qualification process to assess tissue suppliers. The cost of imported allografts used within hospitals is usually assigned to the surgical programs and not covered by the tissue bank's budget. The scope of products managed by tissue banks is usually limited to base tissue grafts. More advanced products that are classified as medical devices are usually managed by surgical groups or end-users. Only two tissue banks noted that it managed all types of tissue products, including advanced grafts and demineralized bone matrix products. Most of the larger programs, including three of the four comprehensive tissue banks, noted that they were not actively involved in managing tissue products used within their institution or health region. In contrast, the majority of stand-alone surgical bone banks that were interviewed indicated that they were involved in managing tissue products used within their hospital or health region.

There is one health region that does not have a program for recovering or processing tissue but has a CTO-registered tissue bank that manages all imported allografts and allograft products. It is important to note that there may be other hospitals and health regions that may have centralized programs for management of allografts within their transfusion medicine laboratory, or as a separate function. The summary of tissue management practices within Canadian hospitals in this report is limited to those hospitals or health regions with tissue banks that participated in the interview process.

End-User Communities Served

The majority of programs continue to provide allografts primarily to end-users in their own hospital or health region. One exception is a comprehensive tissue bank that routinely distributes to over 100 hospitals in all 10 provinces. Some programs indicated that they would like to distribute tissue outside of their institution or health region, but do not recover and process enough tissue to support wider distribution.

Customer Relationships

The majority of programs did not have formal mechanisms for engaging customers/end-users (i.e., surgeons) and analyzing their needs. Many programs noted that they informally obtain input and feedback from users through meetings or discussions. A few programs routinely prepare and deploy customer surveys. One comprehensive tissue bank, distributing tissue to all 10 provinces, employs a dedicated customer-care

representative who, as the point of contact with end-users, ensures that surgeons receive the appropriate allografts. Another program that is collaborating with processors in the United States and distributes allografts employs a sales manager who is responsible for developing relationships with surgeons within the province.

The majority of programs did not have processes or mechanisms in place to support demand forecasting or to align production with forecasted demand.

Research and Development Activities

The majority of programs are not involved in research and development activities. Three programs indicated that they provide tissue to the National Disease Research Interchange (NDRI), an American organization that provides tissue to researchers on a cost recovery basis. A few programs noted that they provided tissue to local researchers and one comprehensive tissue bank indicated that they had established a partnership with the local university in support of collaboration in basic research. One program noted that research and development activities need to be coordinated on a national level and expressed the opinion that the Canadian tissue industry is decades behind the tissue industry in United States.

Quality Systems

The Canadian tissue programs that process heart valves are required to hold a Canadian Medical Device License. In order to obtain a license, tissue programs must be registered to the ISO 13485 quality system standard for medical devices. As a result, these programs generally have more advanced quality systems in place and often have staff dedicated to maintaining the quality program. One of these programs noted that it considered itself a leader in quality within their host institution. The six programs that have AATB accreditation also have established quality programs that meet AATB standards. In contrast, many of the other smaller programs within Canada indicated that they have quality control focus, but have not established coordinated quality assurance activities. For example, most programs perform audits of donor records, but would not routinely assess their own quality program through measurement, monitoring or audit activities (e.g., assessing the effectiveness of their own corrective/preventive action (CAPA) program).

Strategic Planning and Priorities

Many Canadian tissue programs do not have a formal strategic planning process. During the interviews, many programs highlighted operational or organizational plans that they felt were a priority. These plans ranged from increasing tissue donations or introducing new processing techniques to establishing processing relationships for advanced tissue products. A number of programs have developed business cases to secure funding for business models that will allow them to expand their services.

Operational and Capital Funding Models

As noted within the survey section of the report, most Canadian tissue programs receive operational funding through their host hospital or health region. Cost recovery for musculoskeletal, skin and cardiac allografts processed in Canada is limited due to the local distribution of allografts, with no transfer of funds. One exception is a comprehensive program that has a large portion of its operational expenses covered by cost recovery from allografts distributed in all 10 provinces. For programs that do recover costs, revenue is usually not protected, and is provided back to the hospital or host institution. With the exception of one eye bank, there are no costs recovered for corneal tissue provided to end-users from Canadian programs.

Other Input from Interviews

Other feedback on the current tissue system and the national system design process from tissue programs and OPOs is listed in this section.

- Two comprehensive tissue programs noted the importance of having access to experienced staff. They highlighted the value of employees trained in tissue banks in the United States, where there is a business and manufacturing focus.

- The design of any new system should recognize that ocular tissue has distinct differences from other tissue, and this should be reflected in future operational plans.
- Existing provincial plans/reports (e.g., Strategic Plan to Increase Tissue Donation in Ontario) and programs that have been established (Héma-Québec) can provide insight during the planning process and should be referenced.
- The knowledge and expertise of front-line tissue bank staff can provide value to the system design process.
- The national system should emphasize safety and quality, and not just aim to meet minimum regulatory standards.
- Hospital and tissue bank management often lack a business approach.
- Promotion of tissue donation needs to be paired with the appropriate infrastructure for recovery.
- Tissue banks are under-resourced and isolated within the hospital environment.
- The location of a manufacturing function (tissue banking) within the hospital service delivery model presents funding challenges. Several programs indicated they have not received the support to meet quality standards or develop their programs, due to competition for limited hospital resources.

Perspectives on the Value of a Nationally Coordinated System

The majority of the tissue programs suggested that a nationally coordinated system could help to increase tissue donations through unified, national public awareness activities that focus on tissue. The need for support of health professional education activities was also frequently mentioned. One program that did not have access to a provincial intent to donate registry mentioned that a national consent or intent to donate registry could be part of the national system. Two programs mentioned the option of having a centralized referral service/call centre to support the donation process.

Many programs suggested that on an operational level, a national system could help standardize processes within the system. It was noted that standardized processes would allow for better data collection and provide opportunities for benchmarking and performance improvement. In the discussions, it was noted that certain areas in the system could benefit from standardization. These areas included donor criteria, forms, product classifications, coding and labelling. Two programs noted that the system could help to interpret the regulatory and accreditation standards and assist with the design and implementation of a standardized quality system or standardized quality processes. One program mentioned that a national system could bring leadership in cost recovery standardization. A number of smaller programs noted that a nationally coordinated system could also assist with the management of transmissible-disease testing services.

At the system level, many programs indicated that a nationally coordinated system could help to better align supply and demand. Suggestions of mechanisms that would support this objective included the development of a coordinated approach to understand customer needs, creation of a national inventory system or other support tools for information management and sharing, and provision of a coordinated approach to system delivery. A coordinated approach to system delivery could include defining the programs that are providing various services, taking advantage of economies of scale and breaking down provincial barriers that exist. One program specifically identified the need for the system to create a better understanding of the business model that has been successful in the United States, and to foster partnerships between programs in Canada and the United States. Several surgical bone banks mentioned that the role of surgical bone banking could be clarified or better coordinated and standardized within the system.

Several programs pointed out that a nationally coordinated system could also help in providing a united approach to research and development activities. Two programs suggested that the system could also provide leadership in the assessment and response to emerging issues or ethical/legal concerns within the tissue banking community. Several programs involved in managing allograft and allograft products for end-users within their hospital or health region noted that there could be a role for a centralized supply and inventory of tissues where all vendors have been qualified. It was mentioned that centralized supplier qualification could avoid duplication of qualification activities by multiple hospitals.

Two interviewees highlighted that the national system should build on the success of provincial or regional systems. Overall, the majority of respondents recognized the potential benefits that a nationally coordinated system could offer to the tissue community.

Discussion

Donor Referrals

Identification of potential tissue donors and timely referral to tissue banks or Organ Procurement Organizations (OPOs) are critical to increasing the Canadian supply of tissue for processing. Unlike organ donors, who are generally identified in emergency departments or intensive care units (ICUs), tissue donors may be referred from a variety of in-hospital units, as well as from medical examiner's offices or funeral homes.

Based on the survey data, the majority of tissue donor referrals originate from Canadian hospitals. These referrals are often received from ICUs and emergency departments. Based on the survey data, the number of referrals received from other in-hospital units varies between tissue banks. There is an opportunity to increase donation within the hospital environment by coordinating the identification and referral of potential donors from hospital units outside of ICUs and emergency departments. In addition, most OPOs and tissue programs target a specific subset of hospitals within their region or province. If resources were available, there may be an opportunity to extend identification and referral activities to a larger set of hospitals.

Medical examiner cases are recognized as a good source of tissue. Three of the comprehensive tissue banks indicated that they had established relationships with the medical examiners in their region and consequently received between 6%–13% of their referrals from this source. One eye bank and one musculoskeletal tissue bank also noted that they received referrals from medical examiners. OPOs and tissue programs that currently do not receive referrals from medical examiners could establish links with medical examiners in their area to increase tissue donations.

There is a significant opportunity to increase the number of potential tissue donors identified in both hospital and non-hospital settings. Unlike barriers that exist for vital organs, tissue donation appears not to be curtailed by a lack of available donors, but with system/process issues and a lack of infrastructure to realize donor potential.

Supply of Surgical Bone

In 2008, there were 15 Canadian tissue programs that were involved in surgical bone banking (excluding Quebec programs). Seven of these programs were considered "stand-alone" surgical bone banks that were not involved in recovering or processing tissue from deceased donors. None of the seven stand-alone surgical bone banks indicated they were AATB accredited. Based on the responses from 14 of the 15 surgical bone programs, the total number of femoral heads recovered in 2008 was 1,748, with the average number per bank at 125 (min. 4, max. 458). Of the 1748 femoral heads, 778 (45%) were recovered by the seven stand-alone surgical bone banks. Survey respondents indicated that 1271 femoral heads were released into usable inventory and 820 femoral heads were distributed from their programs to end-users in 2008. In 2002, Canadian programs (excluding Quebec) released a total of 1,883 femoral heads into usable inventory, indicating that a 33% decrease in surgical bone production had taken place by 2008.

The number of surgical bone programs in Canada has decreased significantly in the last number of years. In 2006, a report on surgical bone banking in Canada identified 14 programs banking surgical bone within Ontario.⁵ There are currently only six programs that are recovering and banking surgical bone in Ontario; eight programs have closed or halted their surgical bone banking activities. In addition, one other surgical

⁵ Evaluation of Surgical Bone Banking and Utilization in Canada, 2006, Canadian Council for Donation and Transplantation

bone banking program outside of Ontario has decided to stop their surgical bone banking activities due to the increased operational costs for serological donor testing. In-hospital surgical bone banks often find it difficult to maintain quality assurance systems with limited hospital resources. This is certainly one factor in the closure of surgical bone banks in recent years.

The roles and responsibilities for identification and referral of donors, obtaining consent and donor screening activities vary between programs. The majority of programs do not perform any processing activities with surgical bone grafts (e.g., depletion of blood and marrow components or washing). The practice of irradiating surgical bone grafts varies between programs. In 2008, five of the 14 respondents were irradiating femoral head grafts. The decision to irradiate or not to irradiate femoral head grafts is often related to the historical practice of the program and the preference of its end-users.

Supply of Musculoskeletal Tissue

The results of the supply survey showed that of all grafts produced by tissue banks in Canada from deceased donors (excluding ocular allografts), 3,896 or 81.7%, are musculoskeletal allografts.

Supply of Allograft Bone

The respondents indicated that a total of 2846 bone allografts were produced in Canada from deceased donors. The three comprehensive tissue programs produced 2,226 of the 2,846 of the total number of bone allografts, or 78.2%. Packages of ground and chipped bone were the most commonly processed bone allografts in 2008. Only one comprehensive tissue program in Canada indicated that it was processing this type of allograft. Two musculoskeletal programs indicated that they were planning on producing ground and chipped bone products in the future. One of these programs projected that it would produce over 1000 packages of both cancellous and cortico-cancellous bone in 2009.

A total of 836 large structural grafts were processed in 2008, representing a 40.9% decrease from the number of large structural grafts processed in 2002. The number of large structural grafts being processed by the three comprehensive tissue banks did not change significantly between 2002 and 2008, but there was a significant reduction in the number of large structural allografts processed by one musculoskeletal bank in 2008. In 2008, the most commonly processed large structural allografts were fibula segment, fibula whole, femoral strut, tibia strut, tibia whole, distal tibia and proximal femur with head. These seven large structural grafts make up 60.8% of all large structural allografts processed.

A total of 139 small structural grafts were processed in 2008, representing a 67.1% decrease from the 423 small structural grafts processed in 2002. The overall decrease can be attributed to a decrease of small structural graft processing by two comprehensive tissue banks and one musculoskeletal bank that processed this category of graft in 2002, but not in 2008. Tri-cortical wedges made up 91.4% of all small structural grafts processed, and bi-cortical dowels made up the remaining 8.6% of the small structural grafts processed in 2008. One musculoskeletal program that did not produce small structural grafts in 2008 indicated that it was planning on producing both tri-cortical wedges and femoral rings along with other types of small structural grafts in 2009. This program's projected 2009 production numbers for small structural grafts would more than triple the number of small structural grafts produced by all Canadian tissue programs in 2008.

The use of sterilization and disinfection processes vary between banks that process bone grafts.

In 2008, there were no Canadian tissue programs processing demineralized or lyophilized bone products. However, two programs noted that they were planning to begin processing both demineralized and lyophilized bone products.

Supply of Tendons and Soft Tissue

A total of 945 tendons were processed in Canada in 2008, representing a twofold increase over the 466 tendons processed in 2002. The increase can be attributed to two comprehensive tissue banks that have significantly increased the number of tendons processed. Of the 945 tendons processed in Canada in 2008, 783 tendons (82.9%) were produced by three comprehensive tissue banks. The most commonly processed tendons were tibialis tendon anterior, tibialis tendon posterior, achilles tendon and patellar tendon – whole; these made up 81.5% of all tendons processed. A total of 105 soft tissue grafts were produced, with allograft fascia lata comprising the largest component (43.8%). However, one program noted that fascia was not commonly used by surgeons, due to a synthetic substitute.

Supply of Skin Tissue

Based on the survey data, a total of 745 packages of frozen skin were produced in 2008. The percentage breakdown of the size of skin packages that were processed in 2008 is as follows: 32.8% were >200 cm², 40.0% were 100–200 cm², 24.7% were <100 cm² and 2.5% of the packages were listed as “various sizes.” Three comprehensive tissue banks produced 97.5% of the total number of skin packages.

The respondents indicated that a total of 339 packages of skin were distributed to end-users in 2008. This indicates that the supply of Canadian-processed frozen skin allografts exceeded the demand in 2008. However, one cannot conclude that supply exceeds the overall demand, as Canadian end-users may be purchasing skin and allograft skin products from tissue processors in the United States to meet their needs.

Supply of Ocular Tissue

Of the 5,300 ocular tissues recovered from donors, 4,614 or 87.1% were whole eye recoveries. The remaining 686 tissues, or 12.9%, were “cornea only” recoveries. A number of the stand-alone eye banks indicated that they did not process all the tissue recovered from donors. Recovery is performed if consent is obtained, and any tissue that is not acceptable for transplantation is used for education or research purposes. The five stand-alone eye banks noted that a total of 526 eyes were used for education or research purposes.

Based on the survey data, stand-alone eye banks produced 2,662 grafts, or 77.8% of the Canadian supply of ocular tissue. The comprehensive tissue programs produced the remaining 761 ocular grafts, or 22.2%. During the interviews it was noted that, although the number of partial-thickness cornea transplants is increasing, there are a limited number of Canadian eye banks providing pre-cut tissues to surgeons. If pre-cut tissues are not available for procedures requiring partial-thickness grafts, surgeons are required to perform extra processing steps in the operating room setting.

Although amniotic membrane is not ocular tissue it is primarily used for ocular surgeries. In 2008, there were two comprehensive tissue banks and two eye banks involved in recovering and processing amniotic membrane. The two comprehensive tissue banks processed 183/212 (86.3%) of all amniotic membrane allografts produced.

Supply of Cardiovascular Tissue

Cardiovascular tissue, including heart valves and non-valve conduits, were produced by two comprehensive tissue banks and one tissue-specific bank in 2008. The three banks processed a total of 105 allografts. The number of hearts recovered and cardiovascular allografts processed in 2008 is significantly lower than the 2002 numbers; there was a 57.3% decline in the number of recovered cardiovascular tissue and a 57.8% decline in the number of allografts processed.

Conclusion

There have been a number of changes within the tissue banking environment since the *Supply of Human Allograft Tissue In Canada - 2003* report, which provided a summary of Canadian tissue banks and their activities in 2002. The regulatory changes in the Canadian tissue environment since 2002 include:

- The introduction of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations), which took effect in 2007.
- The regulation of allograft heart valves under the Medical Device Regulations. Programs processing heart valves are now required to obtain a Canadian Medical Device License.

The changes in Canadian tissue banking community since 2002 include:

- A significant reduction in the number of stand-alone surgical bone banks; at least eight surgical bone banks have closed or halted recoveries of surgical bone.
- An increase in the number of Canadian tissue programs partnering with processors in the United States.
- The merging of tissue programs located in the same health region or province.
- An increased number of tissue programs involved in the management of tissue within their host hospital or health regions.

Even with these changes, the current tissue banking system is very similar to the system as described in the 2003 report. The comprehensive tissue banks in Canada continue to provide a significant portion of Canada's tissue supply, with the exception of ocular tissue. Stand-alone eye banks continue to provide the majority of ocular tissue for transplantation. Tissue activities continue to be locally managed, funded and monitored. In addition, the concerns that were identified in the 2003 report largely remain the same. These issues include:

- Lack of a systematized, coordinated approach to the provision of tissue services;
- Regional disparities across Canada in the type and comprehensiveness of tissue services provided; and
- No mechanism of coordinating supply with demand on a national basis.

The majority of tissue banks are operating within a hospital environment and are funded by their local hospital or health region. In this context, there are often limited resources to improve operational processes or to develop and implement business plans. Having multiple, independent tissue programs operating with limited resources is a contributing factor to the following:

- Tissue donation potential is not being realized. Donor identification, referral and tissue recovery processes are not coordinated across agencies and programs.
- Musculoskeletal, cardiac and skin recovery capacity is very limited and is often focused only in regions in close proximity to the tissue bank.
- Efforts to engage with a broad base of end-users, in order to understand their current and future allograft needs, are not consistently undertaken.
- The ability to align supply with demand by increasing production of current products or introducing new product lines is very limited.
- The ability to perform research and development activities is limited. Tissue banks cannot lead in the development of innovative products or invest in defining and implementing best practices.

It is important to note that there are specific programs within Canada that have developed business plans to improve infrastructure or expand tissue services. However, these plans have not always been supported or given priority by funding organizations. Programs that have been able to obtain support for their plans may further help to increase the overall supply of allografts within Canada.

Although specific individual programs have increased the number of tissue recoveries or number of allografts processed within their facilities in recent years, to date, overall growth in the number of recoveries and processed allografts has been limited. Tissue programs across the country have clearly identified the challenges of the current environment, and the need for system improvement is generally accepted.

Appendix A



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National Survey for Supply of Human Allograft Tissue in Canada

Canadian Blood Services

May 2009

Instructions

The purpose of this survey is to quantify the current supply of human allograft tissue from Canadian tissue programs and to obtain an understanding of the existing tissue banking environment. It is comprised of questions related to:

- Tissue Donor Activity
- Tissue Recovery Activity
- Tissue Processing Activity
- Tissue Distribution Activity
- Ancillary Services, and
- Funding

The scope includes **musculoskeletal, cardiovascular, skin and ocular tissues**. Other tissues, solid organs, xenograft tissues and biosynthetic tissues are outside the scope of this survey.

Aggregate data compiled from the survey will be provided to each of the programs who participate. Program specific data will not be shared.

Please complete responses to all sections. If for some reason you do not have the information requested, please note this in the relevant section along with any other information you consider to be applicable. Although we anticipate that you will be able to complete a number of the sections quickly, Sections 3, 4, 6, and 7 require activity statistics from January 2008 to December 2008 and may take more time. If data is collated by fiscal year, please provide data from the most recent fiscal 12 month period that is available.

The survey can be completed electronically using Microsoft Word:

- Open the file in Microsoft Word
- Click on the first shaded text field () where information is required and enter your response.
- Use the Tab key or the mouse to move to the next field.
- Enter the requested information for each text field
- For questions where response options are provided, click on the appropriate check box (→)
- When the survey is complete, save the file to your computer and send via email to: paul.derksen@blood.ca

Please complete and return the survey by Friday, May 29th.

If you have any questions please do not hesitate to contact the program manager:

Paul Derksen
Program Manager, Organs & Tissues
Canadian Blood Services
Tel: 416 313-3298
Email: paul.derksen@blood.ca

We recognize the time required to complete the survey and thank you in advance for your assistance!



General Information

Name of Tissue Bank:

Mailing Address:

Website:

Tissue Bank Director:

Contact Email:

Contact Phone Number:

Medical Director:

Senior Administrator:

(Bank Director reports to)

AATB Accreditation: Yes No

EBAA Accreditation: Yes No

Questions in this survey generally focus on activity for the 2008 calendar year.

- If your data is collated by fiscal year (i.e. April to March), please provide data for the most recent fiscal year you have available and record the fiscal year.

Fiscal Year:



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Throughout this survey, we will be using tissue categories as noted in the following tables:

Musculoskeletal

| Category | Tissues included |
|--|---|
| Surgical Bone | Femoral heads retrieved from total hip replacements. |
| Cancellous, and corticocancellous bone | Chips, ground bone, crushed bone, cubes, other |
| Small structural grafts | Uni/bi-cortical dowels, tri-cortical wedges/blocks, femoral or humeral rings/cross-sections, fibula wedge, iliac crest wedge/strip, other bone dowels/wedges |
| Large structural grafts | Acetabulum, hemi-pelvis, fibula whole/segment, femoral whole/proximal/distal/shaft, humerus whole/proximal/distal/shaft, tibia whole/proximal/shaft, rib, other |
| Tendons | Achilles (with/without bone strut), patellar, tibialis anterior/posterior, peroneus longus, gracilis, semi-tendinosus tendon, other |
| Meniscus | Lateral and medial meniscus |
| Soft tissues | Fascia lata |
| Demineralized bone matrix products | Demineralized grafts, cancellous or corticocancellous chips or powders, cancellous cubes, corticocancellous granules, putty, gels, paste, pellets, other |

Cardiovascular

| Category | Tissues included |
|-----------------|---|
| Heart Valves | Pulmonary, aortic, mitral |
| Conduits | Non-valved aortic conduit, non-valved pulmonary conduit |
| Pericardium | Pericardium |
| Vascular grafts | Ascending and thoracic aorta, saphenous veins, femoral arteries |

Skin tissues

| Category | Tissues included |
|----------------|-------------------------|
| Skin allograft | Frozen and fresh Grafts |

Ocular tissues

| Category | Tissues included |
|------------|--|
| Whole eyes | Whole eyes |
| Cornea | Cornea for penetrating keratoplasty, cornea for lamellar keratoplasty, cornea for endothelial keratoplasty |
| Sclera | Whole globe, half globe, one-third globe, quarter globe, eighth globe |

Amniotic tissues

| Amniotic Category | Tissues included |
|-------------------|-------------------|
| Amniotic Tissues | Amniotic Membrane |

1. Staffing

In order to better understand your staffing model, please complete the following questions.

- 1.1. How many full-time equivalent (FTE) staff does your bank have dedicated directly to tissue services? This should include FTE's performing any of the following activities: donor referral and screening, donor recovery, processing, distribution, training, management, quality systems, administration and information services, management and medical director functions assigned directly to your tissue bank.

No. of FTEs:

- 1.2. Please provide a FTE breakdown by the following categories. If the position is not dedicated full time please indicate the allotment e.g. 0.2 FTE.

| Position | FTE Allotment |
|---|---------------|
| Management | |
| Tissue Bank Director (if separate position from management) | |
| Medical Director | |
| Administrative | |
| Quality Management | |
| Technical (referral, recovery, processing and distribution) | |
| Education | |

- 1.3. How many casual allied health professionals are dedicated to tissue services e.g. casual staff performing tissue recoveries? *A casual employee is defined as an employee who has no guarantee of hours and is called in as work is identified.*

- 1.4. How many casual physicians perform tissue recoveries?

2. Functions

2.1. In order to better understand the activities your bank performs, please check off all applicable functions by tissue type.

| Functions Your Bank Performs | Surgical Bone | Amniotic Membrane | Bone and Soft Tissue | Skin | Cardiac | Ocular |
|-----------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Donor Identification and Referral | <input type="checkbox"/> |
| Donor Screening | <input type="checkbox"/> |
| Consent | <input type="checkbox"/> |
| Recovery | <input type="checkbox"/> |
| Processing | <input type="checkbox"/> |
| Distribution | <input type="checkbox"/> |

3. Donor Activity

3.1. Please detail the total number of donor referrals in 2008. A **donor referral** is defined as a communication to, or contact with your program regarding a potential donor for consideration of donation. This includes donors that are deferred and donors that proceed to recovery.

| Type of Donor | Total No. of 2008 donor referrals |
|----------------------------------|-----------------------------------|
| Cadaveric Donor | |
| Living Donor - Surgical Bone | |
| Living Donor - Amniotic Membrane | |

3.2. Please detail donation activity for 2006, 2007 and 2008 numerically in the following chart. **Recovery** is defined as any donor where tissue was recovered whether or not it was released to transplant.

| Type of Donor | Total No. of 2006 donors which proceeded to recovery | Total No. of 2007 donors which proceeded to recovery | Total No. of 2008 donors which proceeded to recovery |
|----------------------------------|--|--|--|
| Cadaveric Donor | | | |
| Living Donor - Surgical Bone | | | |
| Living Donor - Amniotic Membrane | | | |



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3.3. Please detail the total number of cadaveric donors in 2008 by tissue type recovered.

Recovery is defined as any donor where tissue was recovered whether or not it was released to transplant.

| | Total No. of donors where <u>bones/tendons</u> were recovered | Total No. of donors where <u>cardiac tissue</u> was recovered | Total No. of donors where <u>skin</u> was recovered | Total No. of donors where <u>ocular tissue</u> was recovered |
|-------------------------|---|---|---|--|
| Cadaveric Donors | | | | |

3.4. What percentage of your tissue donors are also organ donors? %

3.5. If your bank processes ocular tissue, what percentage of your tissue donors are "ocular only" donors? %

3.6. In order to better understand your bank's source of **cadaveric donor** referrals, please estimate the percentage of your 2008 donor referral activity by source. **Source** is defined as the location where the potential or actual tissue donor was identified.

| | Medical Examiner | Hospital ICU | Hospital Emergency Department | Hospital other Units /Wards | Funeral Directors | Nursing Homes/Long Term Care Facilities | Other |
|---------------------------------------|------------------|--------------|-------------------------------|-----------------------------|-------------------|---|-------|
| % of Donor Referrals by Source | % | % | % | % | % | % | % |

If other, please specify:

4. Allograft Tissue Recovery

In order to better understand your bank's recovery activities, please answer the following questions.

- 4.1. Does your tissue bank have dedicated recovery facilities? Yes No
 If yes please detail: On-site recovery suite Dedicated operating room access Other
- 4.2. If you do not have dedicated recovery facilities, do you have difficulty in accessing hospital operating rooms for recovery procedures? Yes No
 If yes, does this occur: Infrequently Occasionally Frequently
- 4.3. Please provide the number of tissues **recovered** from cadaveric donors **in 2008**. **Recovered tissue** is defined as tissue surgically removed from the donor whether or not grafts were subsequently deemed suitable for transplant.

Musculoskeletal Tissue

| Tissue Type – Cadaveric Donor | No. Recovered |
|-------------------------------|---------------|
| Musculoskeletal | |
| Femur | |
| Fibula | |
| Hemi-pelvis | |
| Ilium | |
| Knee en Bloc | |
| Tibia | |
| Other Bone | |
| Meniscus | |
| Fascia Lata | |
| Tendons | |
| Achilles Tendon | |
| Patellar Tendon | |
| Tibialis Tendon | |
| Peroneus longus Tendon | |
| Gracilis Tendon | |
| Semi-tendinosus Tendon | |
| Other Tendon | |

Cardiovascular

| Tissue Type – Cadaveric Donor | No. Recovered |
|-------------------------------|---------------|
| Heart for valves | |
| Pericardium | |
| Ascending aorta | |
| Descending aorta | |
| Saphenous vein | |
| Femoral artery | |
| Other | |

Ocular

| Tissue Type – Cadaveric Donor | No. Recovered |
|-------------------------------|---------------|
| Whole eyes | |
| Corneas only | |

The quantity of skin recovered from cadaveric donors and any amniotic membrane tissue recovered will be captured in Question 6.5 under “Allograft Processing”.

5. Transmissible Disease Testing

5.1. Where is your transmissible disease testing currently performed?

- In-House Laboratory Mount Sinai Laboratory Viromed
 Labs at Bonfils Public Health Laboratory Other

5.2. Do you routinely perform NAT HIV and HCV on all donors? Yes No

5.3. Do you perform routine WNV testing on all donors? Yes No
 If no, do you perform WNV seasonally? Yes No

5.4. In what time period do you require results for your **musculoskeletal, cardiac and skin donor** transmissible disease testing? *The **time period** is defined as the interval between tissue recovery and receiving test results.*

- < 24 hour 24-48 hours 48-72 hours >72 hours acceptable
 Not Applicable

What are the factors that influence this requirement?



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5.5. In what time period do you require results for your **corneal donor** transmissible disease testing? *The **time period** is defined as the interval between tissue recovery and receiving test results.*

- < 24 hour 24-48 hours 48-72 hours >72 hours acceptable
 Not Applicable – ocular tissue not recovered

What are the factors that influence this requirement?

5.6. Transmissible disease testing often requires the transportation of blood samples to testing sites outside your institution or jurisdiction. Have you identified any challenges related to the transportation of samples for testing?

- Yes No

What are the challenges related to the transportation of samples for testing?

6. Allograft Tissue Processing

In order to better understand your bank’s processing activity please answer the following questions.

6.1. **Does your program process musculoskeletal tissue?** Yes No

If yes,

a) Please indicate the location(s) where musculoskeletal (MS) processing takes place?

- | | |
|---|---|
| <input type="checkbox"/> Operating room | <input type="checkbox"/> Biological Safety Cabinet |
| <input type="checkbox"/> Class 100 (ISO 5) clean room, or cleaner | <input type="checkbox"/> Class 1000 (ISO 6) clean room, or less clean |
| <input type="checkbox"/> Dedicated processing suite, no clean room classification | |

b) Do your MS processing practices include sterilization by irradiation? Yes No

c) Do your MS processing practices include sterilization by chemical processes? (e.g., licensed wash technology) Yes No

d) Please describe your disinfection/decontamination process for musculoskeletal tissue.

e) Do your MS processing practices include lyophilisation (freeze drying)? Yes No

f) Do your MS processing practices include demineralization of bone? Yes No

6.2. **Does your program process cardiovascular tissue?** Yes No

If yes,

a) Please indicate the location(s) where cardiovascular tissue processing takes place?

- Biological Safety Cabinet Class 100 (ISO 5) clean room, or cleaner
 Other

b) Please describe your disinfection process for cardiovascular tissue?

6.3. **Does your program process skin?** Yes No

If yes,

a) Please indicate the location(s) where skin tissue processing takes place?

- Operating room Biological Safety Cabinet
 Class 100 (ISO 5) clean room, or cleaner Class 1000 (ISO 6) clean room, or less clean
 Dedicated processing suite, no clean room classification

b) Please describe your disinfection process for skin.

6.4. **Does your program process ocular tissue?** Yes No

If yes,

a) Please indicate the location(s) where ocular tissue processing takes place?

- Operating room Biological Safety Cabinet
 Class 100 (ISO 5) clean room, or cleaner Class 1000 (ISO 6) clean room, or less clean
 Dedicated processing suite, no clean room classification

b) Please indicate the ocular processing activities your bank supports:

- Cornea for penetrating keratoplasty Sclera
 Cornea for lamellar keratoplasty Research Tissue
 Cornea for endothelial keratoplasty

- 6.5. Please provide the number of final allograft tissue products **released for distribution** in **2008**. Please provide an entry for each category. If you did not release grafts into usable inventory for a specific graft type, please enter 0.

Musculoskeletal Tissue

| Tissue Type | No. of Grafts Released |
|--|------------------------|
| Surgical Bone | |
| Femoral Heads from Living Donors | |
| Ground and Chipped Bone | |
| Cancellous ground/chipped bone (excluding demineralized bone) | |
| < 10 cc | |
| 10-40 cc | |
| > 40 cc | |
| Corticocancellous ground/chipped bone (excluding demineralized bone) | |
| < 10 cc | |
| 10-40 cc | |
| > 40 cc | |
| Cancellous Bone | |
| Femoral Condyle – Hemi | |
| Femoral Condyle – Whole | |
| Femoral Head from Cadaveric Donors | |
| Humerus Head | |
| Tibia – Proximal | |
| Other cancellous bone products (please specify) | |
| Small Structural Grafts | |
| Uni-Cortical Dowel | |
| Bi-Cortical Dowel | |
| Tri-Cortical Wedge | |
| Femoral Rings | |
| Other small structural grafts | |



Musculoskeletal Tissue, continued.

| Tissue Type | No. of Grafts Released |
|---|-------------------------------|
| Large Structural Grafts | |
| Acetabulum | |
| Hemi Pelvis | |
| Femur with Head (whole femur) | |
| Femur without Head | |
| Proximal Femur with Head | |
| Proximal Femur without Head | |
| Distal Femur with Condyle | |
| Distal Femur with Flair | |
| Femoral Shaft | |
| Femoral Strut | |
| Fibula Whole | |
| Fibula Segment | |
| Proximal Humerus with Head and Rotator Cuff | |
| Proximal Humerus with Head | |
| Humerus Shaft | |
| Tibia Whole | |
| Distal Tibia | |
| Proximal Tibia | |
| Tibial Strut | |
| Other large structural grafts | |



Musculoskeletal Tissue, continued.

| Tissue Type | No. of Grafts Released |
|---------------------------|-------------------------------|
| Tendons | |
| Achilles Tendon | |
| Patellar Tendon – Whole | |
| Patellar Tendon – Half | |
| Tibialis Tendon Anterior | |
| Tibialis Tendon Posterior | |
| Peroneus longus Tendon | |
| Gracilis Tendon | |
| Semi-tendinosus Tendon | |
| Other tendons | |
| Soft Tissue | |
| Meniscus | |
| Fascia Lata | |
| Other soft tissue | |

Cardiovascular Tissue

| Tissue Type | No. of Grafts Released |
|---|-------------------------------|
| Aortic Heart Valve | |
| Pulmonary Heart Valve | |
| Mitral Heart Valve | |
| Non Valve Conduit – Aortic or Pulmonary | |
| Ascending Aorta | |
| Descending Aorta | |
| Pericardium | |
| Saphenous Veins | |
| Femoral Veins | |
| Other cardiovascular tissue products | |



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Skin Tissue

| Tissue Type | Package Size (cm ²) | No. of Packages Released (list for each package size) |
|-------------|---------------------------------|--|
| Frozen | | |
| | | |
| | | |
| | | |
| Fresh | | |
| | | |
| | | |
| | | |

Ocular Tissue

| Tissue Type | No. of Grafts Released |
|------------------------------------|---|
| Corneas – penetrating keratoplasty | |
| Corneas - lamellar keratoplasty | |
| Corneas - endothelial keratoplasty | |
| Sclera | 1/8 globe: 1/4 globe: 1/3 globe: 1/2 globe: full globe: |
| Eyes for Research | |

Amniotic membrane

| Tissue Type | Package Size (cm ²) | No. of Packages Released (list for each package size) |
|-------------------|---------------------------------|--|
| Amniotic Membrane | | |
| | | |
| | | |
| | | |

7. Allograft Tissue Distribution

7.1. Do you routinely distribute allografts outside of your host institution? Yes No

If yes,

a) Please indicate the type of allografts that you routinely distribute outside your host institution.

- Surgical Bone Musculoskeletal Cardiovascular
 Skin Ocular Amniotic Membrane

b) Please indicate the jurisdiction(s) where you routinely distribute allografts for transplantation.

- BC AB SK MB ON QC
 NB NS PE NL NWT YK
 NU United States Other country – please name:

7.2. Please provide the number of final allograft tissue products that your bank **distributed** in **2008**. This refers to all tissues distributed to end users in 2008. Please provide an entry for each category. If you did not distribute any grafts please enter 0.

In addition, please indicate which allografts, in your experience, are in high demand. *The definition for **high demand** is – “allografts where often there is not the supply to meet the requests/demands”.*

Musculoskeletal

| Tissue Type | No. of Grafts Distributed for Transplant | High Demand (Select if yes) |
|--|--|-----------------------------|
| Surgical Bone | | |
| Femoral Heads | | <input type="checkbox"/> |
| Ground and Chipped Bone | | |
| Cancellous ground/chipped bone (excluding demineralized bone) | | |
| < 10 cc | | <input type="checkbox"/> |
| 10-40 cc | | <input type="checkbox"/> |
| > 40 cc | | <input type="checkbox"/> |
| Corticocancellous ground/chipped bone (excluding demineralized bone) | | |
| < 10 cc | | <input type="checkbox"/> |
| 10-40 cc | | <input type="checkbox"/> |
| > 40 cc | | <input type="checkbox"/> |



Musculoskeletal, continued.

| Tissue Type | No. of Grafts Distributed for Transplant | High Demand (Select if yes) |
|---|--|--------------------------------|
| Cancellous Bone | | |
| Femoral Condyle – Hemi | | <input type="checkbox"/> |
| Femoral Condyle – Whole | | <input type="checkbox"/> |
| Femoral Head | | <input type="checkbox"/> |
| Humerus Head | | <input type="checkbox"/> |
| Tibia – Proximal | | <input type="checkbox"/> |
| Other cancellous bone products | | <input type="checkbox"/> |
| Small Structural Grafts | | |
| Uni-Cortical Dowel | | <input type="checkbox"/> |
| Bi-Cortical Dowel | | <input type="checkbox"/> |
| Tri-Cortical Wedge | | <input type="checkbox"/> |
| Femoral Rings | | <input type="checkbox"/> |
| Other small structural grafts | | <input type="checkbox"/> |
| Large Structural Grafts | | |
| Acetabulum | | <input type="checkbox"/> |
| Hemi Pelvis | | <input type="checkbox"/> |
| Femur with Head (whole femur) | | <input type="checkbox"/> |
| Femur without Head | | <input type="checkbox"/> |
| Proximal Femur with Head | | <input type="checkbox"/> |
| Proximal Femur without Head | | <input type="checkbox"/> |
| Distal Femur with Condyle | | <input type="checkbox"/> |
| Distal Femur with Flair | | <input type="checkbox"/> |
| Femoral Shaft | | <input type="checkbox"/> |
| Femoral Strut | | <input type="checkbox"/> |
| Fibula Whole | | <input type="checkbox"/> |
| Fibula Segment | | <input type="checkbox"/> |
| Proximal Humerus with Head and Rotator Cuff | | <input type="checkbox"/> |
| Proximal Humerus with Head | | <input type="checkbox"/> |
| Humerus Shaft | | <input type="checkbox"/> |



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Musculoskeletal, continued.

| Tissue Type | No. of Grafts Distributed for Transplant | High Demand (Select if yes) |
|--|---|------------------------------------|
| Large Structural Grafts, continued. | | |
| Tibia Whole | | <input type="checkbox"/> |
| Distal Tibia | | <input type="checkbox"/> |
| Proximal Tibia | | <input type="checkbox"/> |
| Tibial Strut | | <input type="checkbox"/> |
| Other large structural grafts | | <input type="checkbox"/> |
| Tendons | | |
| Achilles Tendon | | <input type="checkbox"/> |
| Patellar Tendon – Whole | | <input type="checkbox"/> |
| Patellar Tendon – Half | | <input type="checkbox"/> |
| Tibialis Tendon Anterior | | <input type="checkbox"/> |
| Tibialis Tendon Posterior | | <input type="checkbox"/> |
| Peroneus longus Tendon | | <input type="checkbox"/> |
| Gracilis Tendon | | <input type="checkbox"/> |
| Semi-tendinosus Tendon | | <input type="checkbox"/> |
| Other tendons | | <input type="checkbox"/> |
| Soft Tissue | | |
| Meniscus | | <input type="checkbox"/> |
| Fascia Lata | | <input type="checkbox"/> |
| Other soft tissue | | <input type="checkbox"/> |



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Cardiovascular

| Tissue Type | No. of Grafts Distributed for Transplant | High Demand (Select if yes) |
|---|--|-----------------------------|
| Aortic Heart Valve | | <input type="checkbox"/> |
| Pulmonary Heart Valve | | <input type="checkbox"/> |
| Mitral Heart Valve | | <input type="checkbox"/> |
| Non Valved Conduit- Aortic or Pulmonary | | <input type="checkbox"/> |
| Ascending Aorta | | <input type="checkbox"/> |
| Descending Aorta | | <input type="checkbox"/> |
| Pericardium | | <input type="checkbox"/> |
| Saphenous Veins | | <input type="checkbox"/> |
| Femoral Veins | | <input type="checkbox"/> |
| Other cardiovascular | | <input type="checkbox"/> |

Skin

| Tissue Type | Package Size (cm ²) | No. of Packages Distributed (list for each package size) | High Demand (Select if yes) |
|-------------|---------------------------------|--|-----------------------------|
| Frozen | | | <input type="checkbox"/> |
| | | | |
| | | | |
| | | | |
| Fresh | | | <input type="checkbox"/> |
| | | | |
| | | | |
| | | | |



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Ocular

| Tissue Type | No. of Grafts Distributed for Transplant | High Demand (Select if yes) |
|------------------------------------|---|-----------------------------|
| Corneas – penetrating keratoplasty | | <input type="checkbox"/> |
| Corneas - lamellar keratoplasty | | <input type="checkbox"/> |
| Corneas - endothelial keratoplasty | | <input type="checkbox"/> |
| Sclera | 1/8 globe: 1/4 globe: 1/3 globe: 1/2 globe: full globe: | <input type="checkbox"/> |
| Research Eyes | | <input type="checkbox"/> |

Amniotic Membrane

| Tissue Type | Package Size (cm ²) | No. of Packages Distributed (list for each package size) | High Demand (Select if yes) |
|-------------------|---------------------------------|--|-----------------------------|
| Amniotic Membrane | | | <input type="checkbox"/> |
| | | | |
| | | | |
| | | | |

8. Information Management

8.1. Please indicate which of the following functions are supported by information systems. An **information system** includes any database system but does **not** include spreadsheets that are used for tracking.

| Function | Supported by database system(s)? (Select if yes) |
|--|---|
| Tracking donor referrals | <input type="checkbox"/> |
| Tracking recovery activity | <input type="checkbox"/> |
| Tracking processing activity | <input type="checkbox"/> |
| Tissue inventory management and distribution | <input type="checkbox"/> |
| Recipient traceability | <input type="checkbox"/> |
| Adverse event monitoring | <input type="checkbox"/> |
| Materials management – supplies | <input type="checkbox"/> |

8.2. Please indicate the name(s) of the information system(s) used:

8.3. Are these system(s) linked or integrated with institutional or health region information systems?

Yes No

9. Ancillary Support

9.1. Providing tissue recovery and processing requires the support of ancillary services. Please complete the following chart indicating who provides those services to your tissue program and the cost/financial processes related to those services.

| Ancillary Service/Department | Provided by host hospital or organization (Select if yes) | Provided by external organization (Select if yes) | Are funds exchanged or transferred for these services? (Select if yes) |
|------------------------------|--|--|---|
| Finance | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Housekeeping | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Human Resources | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Information Systems | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Infectious Disease Testing | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Laboratories - Microbiology | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Laboratories -Pathology | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Legal and Risk Management | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Materials Management | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Shipping/Courier Services | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Sterile Supply Dept. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

10. Funding

In order for us to better understand your organization's funding model and the resources required to support your tissue program, please answer the following questions.

10.1. Do you receive reimbursement or recover costs for unprocessed tissues you recover and send to other tissue processing programs or organizations? Yes No

10.2. Do you receive reimbursement or recover costs for processed allograft tissues and tissue products that you send to other organizations, programs and end users? Yes No

10.3. Do your donor hospitals receive compensation for expenses related to tissue recovery such as operating room use? Yes No

If yes, who provides the compensation?

10.4. Do you provide reimbursement for expenses to other hospitals or teams who recover tissue and send it to your program? Yes No



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10.5. Do you receive reimbursement or recover costs for allograft tissues that you send to research programs? Yes No

10.6. What is the source of funding for your operational budget? (please estimate the % by source):

| | | | |
|---------------------------------|---|-----------------------|---|
| Hospital | % | Provincial Government | % |
| Charitable/Hospital Foundations | % | Cost Recovery | % |
| Private Corporations | % | Other | % |

If other please specify:

10.7. What is your actual **or** estimated annual operational budget? **Operational budget includes staff, overtime, supplies and non-capital equipment costs.**

Actual annual operational budget:

Estimated annual operational budget:

Thank you for taking the time to complete this survey!

For further information, please contact:

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