Supply of Human Allograft Tissue in Canada

Final Report

April 2003

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Acknowledgements

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Executive Summary

In November 2002, the Canadian Council for Donation and Transplantation engaged the Canadian Institute for Health Information (CIHI) to conduct the *CCDT Project 4.1—Supply and Demand for Human Tissue in Canada.* This project is the first phase of a multi-phase, multi-year process to make recommendations for a Tissue Banking and Transplantation model of services for Canada. This model would address tissue donation, processing, distribution, access, quality, informatics, safety and governance.

The CCDT Project 4.1 is considered a foundation phase to document the "lay of the land" with regard to Canadian tissue banking and related activities, as they exist today. These initiatives will position the CCDT Tissue Committee to identify areas of focus for future initiatives deemed necessary to gather the additional data and information required to recommend an appropriate Canadian model.

This report, *Supply of Human Allograft Tissue in Canada,* is a deliverable for the CCDT Project 4.1. The findings of the Supply study are presented in this report in three major sections:

- Supply Survey of Known Tissue Banks,
- Key Informant Interviews, and
- Estimation Methods of Canadian Tissue Supply from Unknown Sources.

The ***Discussion*** **and** ***Summary*** sections integrate the findings and the report concludes with a section on ***Considerations for Canadian Tissue Banking Model.***

Supply Survey

The purpose of the survey was to quantify the current supply of human allograft tissue from Canadian tissue banks and to collect information on the characteristics and capabilities of tissue banks. The scope of this survey included human allograft bone, soft tissue, cardiovascular, skin and ocular tissues.

Twenty-nine (29) tissue banks were surveyed. A total of twenty-eight (28) banks (97%) completed and returned surveys. Survey respondents represented a range of tissue banks:

- **Comprehensive Tissue Banks (CTB)** — banks that retrieve/process/distribute two or more distinct tissue types (with the exception of ocular) (4 banks).
- **Surgical Bone Banks (SSB)** — banks that produce bone from surgical/living donors only (7 banks).
- **Musculoskeletal Tissue Banks** — banks that produce bone and soft tissue from surgical and/or cadaveric donors (6 banks).
- **Eye Banks (EB)** — stand-alone eye banks (8 banks).
- **Tissue Specific Banks (TSB)** — banks that deal with one tissue type that is other than surgical bone or ocular tissue (3 banks).

Survey respondents reported a total of 5,691 donors (1,550 living and 4,141 cadaveric donors). From the total donors 13,974 tissues were retrieved, of which 7,597 or 54% were ocular tissues. The remaining 46% of tissues included a variety of bone, soft tissue, cardiovascular and skin. The Eye Banks recovered tissue from over 3,600 cadaveric donors or 63% of all donors.

Volume of Tissues Recovered

Tissue	#	% of Total
Amniotic Membrane	3	<1%
Surgical Bone	1,581	11%
Bone	1,914	14%
Soft Tissues (tendons, fascia, meniscus)	946	7%
Cardiovascular Tissue	583	4%
Skin	1,350	10%
Ocular Tissues	7,597	54%
Total	**13,974**	**100%**

The respondents reported a total of 10,729 allograft tissues processed as follows:

Volume of Tissues Processed

Tissue Product	#	% of Total
Cancellous Ground Bone	541	5%
Cancellous Bone	1,503	14%
Small Structural Grafts	423	4%
Large Structural Grafts	1,534	14%
Tendons	466	4%
Soft Tissues (fascia, meniscus, pericardium)	416	4%
Cardiovascular Tissues	249	2%
Skin Grafts	2,210	21%
Ocular Tissues	3,387	32%
Total	**10,729**	**100%**

Supply of Allograft Bone

The results of the Supply Survey showed that, of all grafts produced by known tissue banks in Canada (excluding ocular tissue), 55% of grafts are bone. There are no tissue banks in Canada producing demineralized bone products (DMB) but it is clear from Key Informant Interviews and other investigations that DMB is commonly purchased from the U.S. and used in Canada by a variety of specialists (orthopaedic surgeons, neurosurgeons, and the dental industry). As well, it is clear that other types of bone grafts (small and large structural bone) are imported to supplement supply. Finally, it is understood that there are a number of “unknown” Surgical Bone Banks (SBB) that produce bone grafts.

Supply of Allograft Tendons and Soft Tissue

Of the survey respondent banks, only Comprehensive Tissue Banks and Musculoskeletal Tissue Banks produced tendons. The majority of tendons (84%) were produced by the 4 CTB’s.

A total of 416 soft tissue grafts were produced of which fascia comprised the largest component (85%). Only 9 grafts or 2% of this total was menisci. According to users, menisci transplants are becoming more common. If more than 9 transplants were done in Canada in the past year, it is likely that there is a quantity of allograft menisci being obtained from international sources.

The majority of fascia lata is produced by two Comprehensive Tissue Banks (>82%). Approximately 50% of the menisci are produced at one CTB and the other 50% by two Musculoskeletal Tissue Banks. Pericardium is produced at two centres that process heart valves.

Supply of Cardiovascular Tissue
Cardiovascular allograft tissue for transplantation was produced by two CTB's and one TSB.

Supply of Skin Grafts
The results of the Supply Survey indicate that 99% of skin grafts are being produced by three of the Comprehensive Tissue Banks.

Supply of Ocular Tissue
The Supply Survey indicates that stand-alone Eye Banks produce 83% of Canada's supply of ocular tissue. The other significant portion is produced by Comprehensive Tissue Banks (14%). Only two banks are producing amniotic membrane and the majority (68%) is produced at one CTB. Information gathered through interviews indicated that this tissue was not always accessible and the need for it would increase in the future.

Estimation of Canadian Tissue Supply from Unknown Sources
There is currently no system for directly measuring the supply of allograft tissue in Canada. For the purposes of this report "allograft tissue supply" is defined as being comprised of two components:

- "Known Supply"—tissue produced by known tissue banks in Canada; and
- "Unknown Supply"—tissue produced by unknown tissue banks (surgical bone banks) that may exist at hospitals across Canada, and tissue products directly imported by health care organizations and users.

For the purposes of this report Known Supply was measured directly through the Supply Survey sent to known tissue and eye banks across Canada. Unknown Supply is much more difficult to quantify.

Through research, and Key Informant Interviews, the project team determined that there are several tissue types for which Canadian supply is augmented through importation and Surgical Bone Banks (Unknown Supply). Where a basis of estimation could be established, the project team attempted to measure the components of Unknown Supply. The following components of Unknown Supply have been estimated in this report.

Estimated Components of Unknown Supply

Estimation Method	Component of Unknown Supply	Source
#1	Cancellous Bone	Unknown Surgical Bone Banks
#2	Cancellous Bone	Imports required for total hip and knee joint replacement revisions
#3	Demineralized Bone (DMB) Products	Sales by commercial companies to Canadian clients
#4	Demineralized Bone and Bovine/Synthetic Bone Products	Purchases by Canadian hospitals
#5	Cardiovascular Tissue	Imports

Canadian Tissue Supply

The results of this study, *Supply of Human Allograft Tissue in Canada,* have provided a snapshot of the current Canadian supply of allograft tissue grafts. As measured directly using the Supply Survey, 10,729 grafts comprised of various tissue types, were produced by "known" tissue banks in Canada.

Using estimation methods for the Unknown Supply of various tissue types (bone, cardiovascular), the following ranges of Canadian tissue supply were derived:

1. When incorporating the method based on purchases of bone products from commercial companies (Method #3), additional tissue supply in Canada is estimated to be in the range of 15,877 to 29,814 grafts. Combining the Known and Unknown Supply provides an estimate of total supply in the range of 26,606 to 40,543 grafts.
2. When incorporating the method based on purchases of bone products by Canadian hospitals (Method #4), additional tissue supply in Canada is estimated to be in the range of 8,822 to 12,349 grafts. Combining the Known and Unknown Supply provides an estimate of total supply in the range of 19,551 to 23,078 grafts.

It is clear from this study that a significant portion of the Unknown Supply is Demineralized Bone Product imported into Canada. These products are not currently produced in Canada and they are a product preference of many Canadian users including orthopaedic surgeons, neurosurgeons and the Dental Industry. The Dental Industry, comprising periodontists and oral and maxillo-facial surgeons have been identified through this study as common users of these products.

Current Tissue Banking System in Canada
The results of the Supply Survey, Key Informant Interviews and the Environmental Scan reveal that the tissue domain as it exists today in Canada is fragmented, unregulated, undocumented, lacks national coordination and is underdeveloped.

This was evidenced in responses to the Supply Survey and Key Informant Interviews as follows:

- There are regional disparities across Canada in the type and comprehensiveness of tissue services provided.
- There appears to be a general lack of knowledge and awareness of various stakeholders regarding availability and access to Canadian allograft tissue.
- Tissue activities are generally locally managed, funded and monitored with little or no coordination between services and only a minor amount of activity in tissue related research and development agencies.
- Information sharing and data management standards are lacking.
- Potential for tissue donation will not be realized until there are improved processes in place to coordinate tissue procurement activities across agencies and programs.
- There is no mechanism of coordinating supply with demand on a national basis.

Benefits of Comprehensive Tissue Banks in Canada
Of the range of tissue bank types included in this study, the 4 Comprehensive Tissue Banks (CTB's) in Canada produce a significant portion of Canada's tissue supply with the exception of ocular tissue which is provided by well developed stand-alone Eye Banks across Canada.

This comprehensive model of tissue banking appears to be very efficient, achieving high volumes of production and maximization of resources. At the same time, CTB's provide services that meet internationally accepted standards for tissue banking through staff certification and accreditation of banks and are able to transport tissue across Canada in a safe and timely fashion

Surgical Bone Banks
Surgical Bone Banks (SBB's) are typically located in health care organizations where procedures are performed that consistently require allograft bone (e.g. hip and knee joint replacement revisions).

These banks are typically established as a response to local demand. As their users (mainly orthopaedic and neurosurgeons) typically perform procedures that require ongoing supply of allograft bone, it is likely that unknown SBB's comprise a significant portion of the Unknown Supply of allograft bone in Canada.

SBB's surveyed did not have certified Tissue Banking Specialists on staff and were not AATB accredited with no plans to obtain accreditation in the future. It is unlikely that these tissue banks will have the resources to comply with Canadian tissue banking standards once they are mandatory. At the same time, users are highly dependent on these banks as a source of what they perceive to be convenient and inexpensive cancellous bone.

Safety

The results of the Supply Survey and Key Informant Interviews highlight a number of concerns related to the safety of the Canadian tissue supply. Tissue bank representatives, users and others have stated their frustration with the time it is taking to implement national standards for the tissue domain.

Potential users of tissue products express concern regarding safety and the potential liability/risk involved. There is also some lack of awareness and acknowledgement that a properly managed system of tissue banking would result in extremely low risk for disease transmission.

The results of the Supply Survey substantiate the concerns for the current safety of Canadian tissue as levels of staff certification and bank accreditation are inconsistent across bank types and alarmingly low for some bank types.

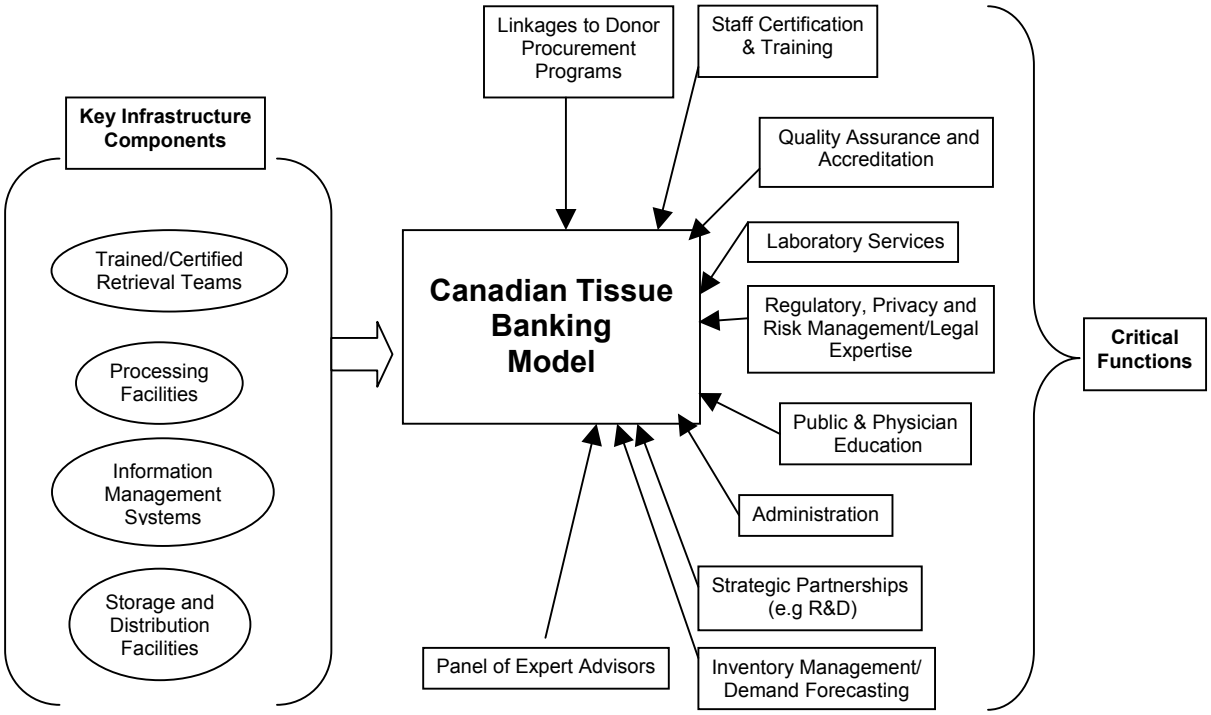
Considerations for a Tissue Banking Model

The Supply Survey and Key Informant Interviews provided information and data that could contribute to the CCDT's recommendations for a Tissue Banking Model for Canada. This section provides an overview of some of the considerations that have been highlighted by this study including:

- Infrastructure Components
- Critical Functions
- Other Considerations

Key components that will be critical to establishing a safe, accessible supply of allograft tissue that will benefit all Canadians are depicted in the diagram below.

Critical Components for a Safe, Accessible, Allograft Tissue Supply



Background

In November 2002, the Canadian Council for Donation and Transplantation engaged the Canadian Institute for Health Information (CIHI) to conduct the *CCDT Project 4.1—Supply and Demand for Human Tissue in Canada.* This project is the first phase of a multi-phase, multi-year process to make recommendations for a Tissue Banking and Transplantation model of services for Canada. This model would address tissue donation, processing, distribution, access, quality, informatics, safety and governance.

The CCDT Project 4.1 is considered a foundation phase to document the "lay of the land" with regard to Canadian tissue banking and related activities, as they exist today. These initiatives will position the CCDT Tissue Committee to identify areas of focus for future initiatives deemed necessary to gather the additional data and information required to recommend an appropriate Canadian model.

This foundation phase, *Supply and Demand for Human Tissue in Canada* comprises three major components:

- Environmental Scan (December 2002),
- Supply of Human Allograft Tissue in Canada (April 2003), and
- Demand of Human Allograft Tissue in Canada (May 2003).

The Environmental Scan was a critical step in preparing for the core project activities of studying Supply and Demand of human tissue in Canada. The findings of this Scan were used to develop the data collection instruments for both Supply and Demand studies.

Key Informant Interviews were conducted for all components of the project and played a major role in the development of data collection instruments and in identifying survey respondent groups.

The Supply component of the project focuses on existing services and tissue banks in Canada known to recover, process and distribute allograft tissue to users. The Demand component focuses on the range of key users of allograft tissue in Canada (primarily surgical specialists), their product preferences and predicted use of tissue in the future.

Introduction and Purpose

This report provides the methods, findings and results of the *Supply of Human Allograft Tissue in Canada.*

The purpose of this study is:

- to quantify the current or "Known Supply" of human allograft tissue (bone, tendons, soft tissue, cardiovascular, ocular and skin) from known tissue banks in Canada; and
- to estimate the "Unknown Supply" of human allograft tissue available to Canadian users from other sources and to investigate the nature and source of these tissue products.

The findings of the Environmental Scan and Interviews with Key Informants pointed the consultants to a number of methods for studying Supply. These included:

- a structured survey instrument for Known Supply from tissue banks in Canada;

- methods for estimating Unknown Supply of allograft tissue in Canada; and
- Key Informant Interviews.

The literature review conducted for the Environmental Scan and new sources of information have also contributed to the results of this study of Supply.

This report is organized as follows:

- Methodology, Results and Limitations
  - Supply Survey for Known Tissue Banks in Canada
  - Key Informant Interviews
  - Estimation of Canadian Tissue Supply from Unknown Sources
- Discussion
- Summary
- Considerations for a Canadian Tissue Banking Model
- Bibliography
- Appendices:
  - Appendix A—Supply Survey (Tissue Banks), Supply Survey (Eye Banks)
  - Appendix B—CCDT/CIHI Cover Letter
  - Appendix C—Authorization Forms (Tissue Banks, Eye Banks)

Methodology, Results and Limitations

Supply Survey for Known Tissue Banks in Canada

Methodology

The survey was developed by the CIHI project team in conjunction with key stakeholders from the CCDT Tissue Committee and Health Canada after completion of the Environmental Scan, the first project deliverable. This Environmental Scan informed the process and influenced the content of the survey. In addition, information compiled from Key Informant Interviews and site visits in November and December 2002 contributed to the development of the survey instrument.

Two surveys were developed—one for tissue banks processing one or more tissue types and the other specific to eye banks. The purpose of the survey was to quantify the current supply of human allograft tissue from known Canadian tissue and eye banks and to collect information on the characteristics and capabilities of these banks. The scope of this survey included human allograft bone, soft tissue, cardiovascular, skin and ocular tissues. Key project stakeholders and tissue bank representatives pilot tested both surveys prior to finalization. Enhancements were made to the final design and content of the surveys based on this feedback.

Potential survey respondent sites were identified through various means:

- the Canadian Association of Transplantation Web Site;
- the Canadian Tissue Bank Interest Group;
- CCDT/Health Canada project stakeholders; and

through interviews conducted by the CIHI project consultants during the Environmental Scan phase of the project.

39 Sites were initially identified as potential tissue bank respondent sites. A contact person for each site was established and this individual was contacted by telephone. He or she was provided with information about the project and requested to contribute to the work through the completion of the supply survey. The majority of individuals either agreed or indicated that the background information should be forwarded and they would decide whether to complete the survey upon receiving it.

Of the 39 sites:

- 29 sites indicated that they were interested in participating or would consider completing the survey.
- 5 sites indicated that they imported tissue from other banks but were not involved in tissue banking.
- 2 sites were not involved in tissue banking but had plans for the future.
- 2 sites were not reachable.
- 1 site had been involved in tissue banking in the past.

Each of the contacts at the 29 interested sites was electronically sent a joint cover letter from CCDT and CIHI, as well as an authorization form to be signed by the medical or program

director. The purpose of this form was to authorize the release of site-specific survey data. Copies of the cover letters and authorization forms can be found in Appendices B and C.

On January 15, 2003, a survey package and a self-addressed courier envelope were couriered to each of 29 sites. A three week response time with a return date of February 14, 2003 was indicated.

Excel spread sheets that corresponded to each survey section (and in some cases subsections) were developed. Data was entered for this report for all completed surveys. Spread sheets were designed for ease of review and inclusion as appendices. All comments noted on surveys were included.

The project consultants conducted telephone and email follow-up for incomplete data, confusing or contradictory information and for missing surveys. Following data entry, all surveys were reviewed a second time to validate responses and statistics.

For the purpose of data analysis for these survey results, an approach to categorizing the different types of tissue and eye banks was used. These categories are used frequently throughout this report to assist in highlighting meaningful information. The following categories are utilized:

CTB: Comprehensive Tissue Banks—banks that retrieve/process/distribute two or more distinct* tissue types (with the exception of ocular). All of these banks would deal with cadaveric donors.

*Distinct tissue types—include musculoskeletal (bone, tendons, soft tissue), cardiovascular, skin.

SBB: Surgical Bone Banks—banks that produce bone from surgical/living donors only.

MSB: Musculoskeletal Tissue Banks—banks that produce bone and soft tissue from surgical and/or cadaveric donors.

EB: Eye Banks—stand-alone eye banks.

TSB: Tissue Specific Banks—banks that deal with one tissue type that is other than surgical bone or ocular tissue (these banks don't fall into the other groups and have unique combinations of tissue products).

Note: Some CTB's and MSB's may retrieve and process ocular tissue.

Where appropriate, the banks have been grouped by regions within Canada as follows:

- Atlantic (provinces and territories east of Quebec)
- Central (Quebec and Ontario)
- West (provinces and territories west of Ontario)

For reporting of tissue statistics, the following tables outline the types of tissue included under major headings for Tissues Recovered and Tissues Processed.

Table 1. Tissues Recovered—Tissue Types

	Tissues Recovered
Amniotic Membrane	Amniotic membrane
Surgical Bone	Femoral heads
Bone	Femur, fibula, hemi-pelvis, humerus, ilium, knee-en-bloc, tibia, other
Soft tissue	Achilles, hamstring, patellar, tibialis anterior and posterior tendons, fascia lata, meniscus, other
Cardiovascular	Hearts for valves, pericardium, descending and ascending veins, saphenous and femoral veins
Skin	Skin
Ocular	Whole eyes, corneas in situ

Table 2. Tissues Processed—Tissue Types

	Tissues Processed
Cancellous ground bone	Packages
Cancellous bone	Femoral condyle hemi and whole, femoral head, humerus head, tibia proximal, other
Small structural grafts	Uni-cortical and bi-cortical dowels, tri-cortical wedge, femoral rings, other
Large structural grafts	Acetabulum, hemi-pelvis, femur with and without head, proximal femur with and without head, distal femur with condyle, distal femur with flair, femoral shaft and strut, fibula whole and segment, proximal humerus with rotator cuff, proximal humerus with head, humerus shaft, tibia whole, tibial shaft and strut, distal and proximal tibia, other
Tendons	Achilles, patellar whole and half, tibialis anterior and posterior, other
Soft tissue	Fascia lata, meniscus, pericardium
Cardiovascular	Aortic and pulmonary valves, ascending and descending aorta, other
Skin	Skin
Ocular	Corneas, sclera (whole, half and quarter), amniotic membrane

Limitations

As the project was completed over a fairly aggressive time frame, it was not possible to perform a complete census of current supply of allograft tissues in Canada. The number of organizations, facilities, users and other stakeholders is vast and, in some cases (e.g. small surgical bone banks), not clearly known.

It is therefore important that the limitations related to the information contained in this report, as well as the methods used to derive this information, are noted by readers of this report.

- The potential sample for the Supply Survey was identified through a number of means including documented listings of "known" tissue banks. The project consultants were able to identify additional banks (primarily Surgical Bone Banks) through Key Informant Interviews and other key contacts. It is understood that the Supply Survey sample is not fully representative of tissue banks in Canada as it does not include all surgical bone banks.
- Key project stakeholders and tissue bank representative's pilot tested the survey prior to finalization. Enhancements were made to the final design and content of the surveys; 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 limited cases questions were left blank as the data was not available and could not reasonably be estimated.

Results—Supply Survey for Known Tissue Banks in Canada

Survey results are presented by major category as follows:

- Survey Response
- Characteristics of Respondent Tissue Banks
  - Respondent Identification
  - Tissue Bank Functions by Tissue Type
  - Accreditation
  - Partnerships and Affiliations
- Resources of Respondent Tissue Banks
  - Staffing and Certification
  - Program Funding and Resources
  - Information Systems
  - Resources Required to Double Capacity
- Tissue Statistics
  - Donor Referral
  - Allograft Tissues Recovered
  - Final Allograft Tissues Processed
  - Export of Unprocessed Tissue
  - Export of Final Allograft Tissue Products
  - Availability of Tissue
- Key observations—this section provides some high level observations with regard to the data reported.

Survey Response

Twenty-eight (28) of 29 sites (97%) completed and returned surveys. Table 3 presents the response rate by type of bank.

Table 3. Response Rate by Type of Bank

Type of Bank	# Surveys Mailed	# Surveys Returned	% Returned
Comprehensive Tissue Banks	4	4	100
Surgical Bone Banks	8	7	88
Musculoskeletal Tissue Banks	6	6	100
Eye Banks	8	8	100
Tissue Specific Banks	3	3	100

Characteristics of Respondent Tissue Banks

Respondent Identification

Of the surveys received, 50% of banks are located in Ontario (14 of 28). Two provinces had 3 banks (11% each). Eye Banks have the best coverage across Canada, existing in 7 provinces. All of the Surgical Bone Banks responding to the survey were located in one province.

Tissue Functions by Tissue Type

In Section #3 of the Supply Survey, respondents indicated the range of tissue bank functions that they were involved in. The following table provides the number of banks that reported involvement in each function and the % that this represents of the 28 responses.

Table 4. Tissue Bank Functions across Tissue Types

Function	Bone	% of Total	Soft Tissue	% of Total	Skin	% of Total	Cardiac	% of Total	Ocular	% of Total
Screening of Donor Referrals	17	61	7	25	7	25	8	29	15	54
Retrieval	16	57	7	25	6	21	7	25	15	54
Processing	16	57	6	21	5	18	3	11	10	36
Storage	19	68	6	21	6	21	4	14	10	36
Distribution	18	64	5	18	6	21	3	11	10	36
Data Management	16	57	6	21	6	21	3	11	13	46
Q/A	15	54	5	18	6	21	4	14	11	39
Public Education	15	54	7	25	6	21	8	29	15	54
Staff Training	15	54	6	21	5	18	8	29	13	46
R&D	3	11	-		-		-		4	14

Accreditation

Survey respondents were asked to indicate if their bank was accredited by one of the recognized standards setting bodies (i.e. AATB, EBAA, ISO).

Table 5 illustrates the percentages of banks currently accredited and the percentage of banks that will be accredited in the future.

Table 5. Accreditation Status of Survey Banks—Current and Future

Accreditation	Current	Total in Future *
AATB	5 of 20** / 25%	11 of 20 / 55%
EBAA	6 of 15*** / 40%	10 of 15 / 67%
ISO	1 of 28 / 4%	4 of 28 / 14%

*Includes those currently accredited and those planning for it.
**Total of 20 banks (4 CTB, 7 SBB, 6 MSB, 3 TSB) with potential for AATB accreditation
*** Total of 15 banks (8 EB, 3 CTB, 1 SBB, 3 MSB) with potential for EBAA accreditation

Table 6 illustrates the current status of compliance with CSA standards and estimated time to comply with these standards.

Table 6. Current Compliance with CSA Standards and Estimated Time to Comply

CSA Standards	Current	Time to Comply
General	3 of 28 / 11%	Min 1 mo, Max 24 mo
Tissue	2 of 20 / 10%	Min 1 mo, Max 24 mo
Ocular	2 of 15 / 13%	Min 1 mo, Max 12 mo

The following table details the status of accreditation by bank type, including both the current status and accreditation plans for the future. For each accreditation the number of banks currently accredited by bank type is noted with a percentage. The “Total Future” and percentage incorporates those banks that indicated plans to become accredited in the future.

Table 7. Accreditation Status by Bank Type

Bank Type (#)	AATB				EBAA				ISO			
	Current	%	Total Future	%	Current	%	Total Future	%	Current	%	Total Future	%
CTB*(4)	2	50	4	100	1	33	2	66	1	25	1	25
SBB** (7)	0	0	0	0	0	0	0	0	0	0	0	0
MSB (6)	2	33	5	83	0	0	0	0	0	0	2	33
EB (8)	n/a		n/a		5	63	8	100	0	0	0	0
TSB (3)	1	33	2	66	n/a		n/a		0	0	1	33

* 3 of 4 CTB’s deals with ocular tissue
** 1 of 7 SBB’s deals with ocular tissue and is not accredited by EBAA

Partnerships and Affiliations
Survey respondents were asked to indicate any partnerships and/or affiliations they have with other organizations, and the nature of that relationship.

Numbers of partnerships/affiliations:

- the number of partnerships/affiliations reported by respondent banks ranged from 0 to 5;
- 22 of 28 (79%) banks reported at least one relationship with another organization; and
- 43% of banks reported one relationship only.

Nature of partnerships/affiliations:

- 5 banks reported relationships with U.S. companies;
- 4 banks reported relationships with universities;
- out of a total of 47 partnerships reported, approximately 50% were related to donor referral and coordination of procurement/tissue retrieval; and
- other types of relationships included—teaching and research, charitable/funding support, publicity and education.

Resources of Respondent Tissue Banks

Staffing and Certification
The following table summarizes the staffing levels and associated certifications reported by the survey respondents.

Table 8. Staffing Levels and Certification

	# FTE's	Full-Time Staff	Part-Time Staff	# Staff AATB Certified	# Staff EBAA Certified	# Staff ISO Trained
Total for all Types of Tissue Banks	**58.9**	**52**	**143**	**34**	**17**	**4**

Program Funding and Resources
The following table outlines the number of respondents who receive fees for tissue and/or pay retrieval fees for tissue.

Table 9. Fees Received and Paid

Fee Type	# Yes Responses	% of Total	# No or n/a Responses	% of Total
Received Fees for Unprocessed Tissue	8	29%	20	71%
Received Fees for Processed Tissue	10	36%	18	64%
Receive Fees for Research Tissue	6	21%	22	79%
Pay Retrieval Fees	7	25%	21	75%

Of the 28 survey respondents:

- 18, or 64%, indicated that they receive 100% their funding from their home hospital;
- 3 respondents indicated that they receive 100% of their funding from their respective province; and
- the remainder, or 7 respondents, reported a mix of funding sources.

Information Systems
The majority of the respondents, 21 or 75%, reported some level of automation in terms of information management. The remaining 7, or 25%, reported that they are using a manual system.

Of those using automated systems, the majority are in-house developed using products such as Microsoft Access, FoxPro, and Filemaker Pro. A few reported utilizing a combination of in-house developed and hospital systems. Several employ office automation tools such as Microsoft Word and Excel.

Resources Required to Double Capacity
Survey respondents were asked to estimate the resources (FTE's, one-time capital and annual operating funds) that they would require to double their current capacity.

Of the survey respondents:

- 8 (primarily EB's and SBB's) could not provide information concerning the number of FTE's, or the one-time capital and annual operating budget that they would require to double their current capacity; and
- 3 provided incremental FTE's of 1.2 and 3 respectively but no associated costs.

A summary of the information that was provided appears in the table below.

Table 10. Resources Required to Double Capacity

Respondents	# of FTEs	One Time Capital $	Annual Operating $
Comprehensive Tissue Banks (3 of 4)	14.0	$ 737,000	$ 1,225,000
Surgical Bone Banks (4 of 7)	3.7	$ 100,000	$231,500
Musculoskeletal Tissue Banks *	18.2	$2,060,000	$2,336,000
Eye Banks (4 of 8)	10.0	$ 450,000	$1,166,550
Tissue Specific Banks (3 of 3)	7.5	$152,500	$950,000
Total	**53.4**	**$ 3,499,500**	**$ 5,909,050**

*****All banks reported on FTE's, 3 of 6 reported on costs

Tissue Statistics

The respondents were requested to provide a variety of statistics and associated information related to their tissue and eye banking functions. Data for the January to December 2002 period, or for the most recent 12-month period for which it was available, was requested.

Donor Referral

For the most recent 12-month period respondents reported a total of 5,691 donors. This represents 1,550 living donors and 4,141 cadaveric donors.

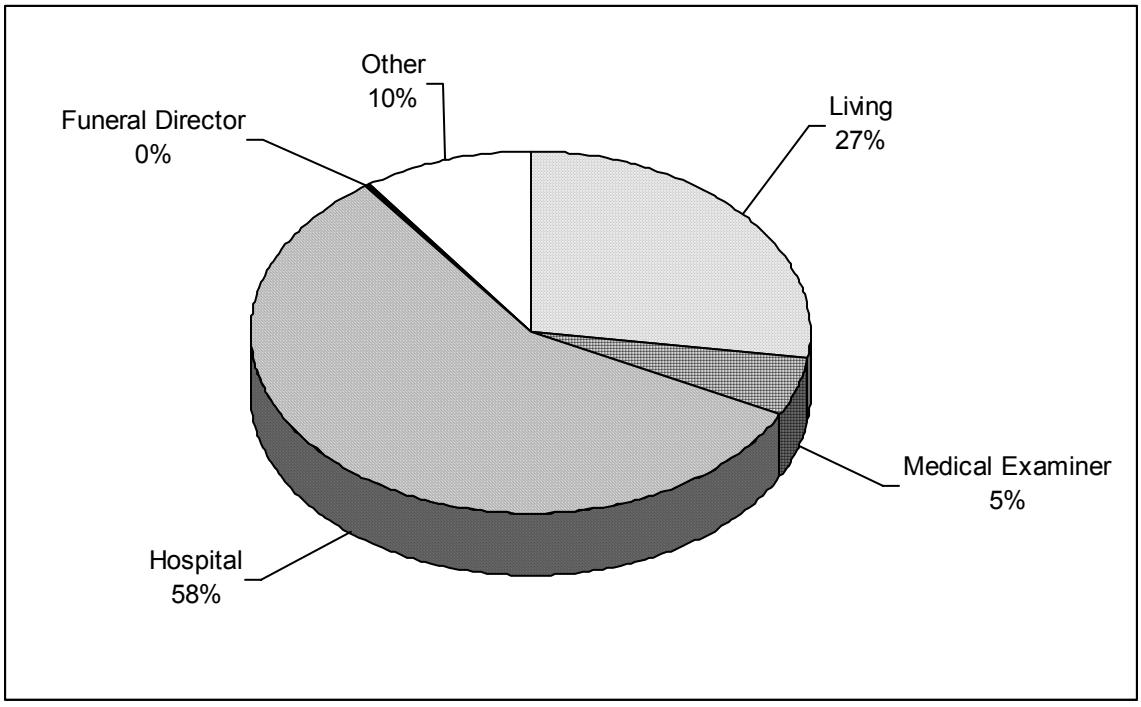


Figure 1. Percentage of Donors by Source

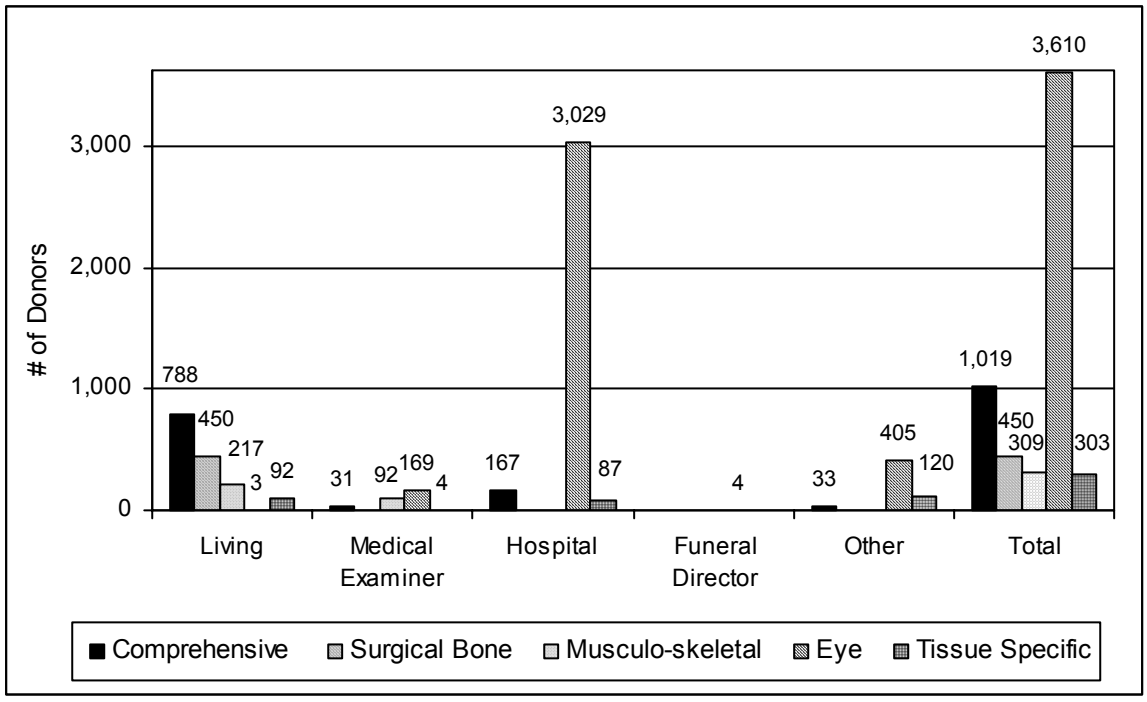


Figure 2. Donor Type (Donor Source by Bank Type)

Allograft Tissues Recovered

The total number of recovered tissues was 13,974. The respondents reported a total of 12,390 tissues recovered from cadaveric donors and 1,584 recovered from living donors. The tables below provide the breakdown by major tissue type.

Table 11. Volume of Tissues Recovered

Tissue	#	% of Total
Amniotic Membrane	3	<1%
Surgical Bone	1,581	11%
Bone	1,914	14%
Soft Tissues (tendons, fascia, meniscus)	946	7%
Cardiovascular Tissue	583	4%
Skin	1,350	10%
Ocular Tissues	7,597	54%
Total	**13,974**	**100%**

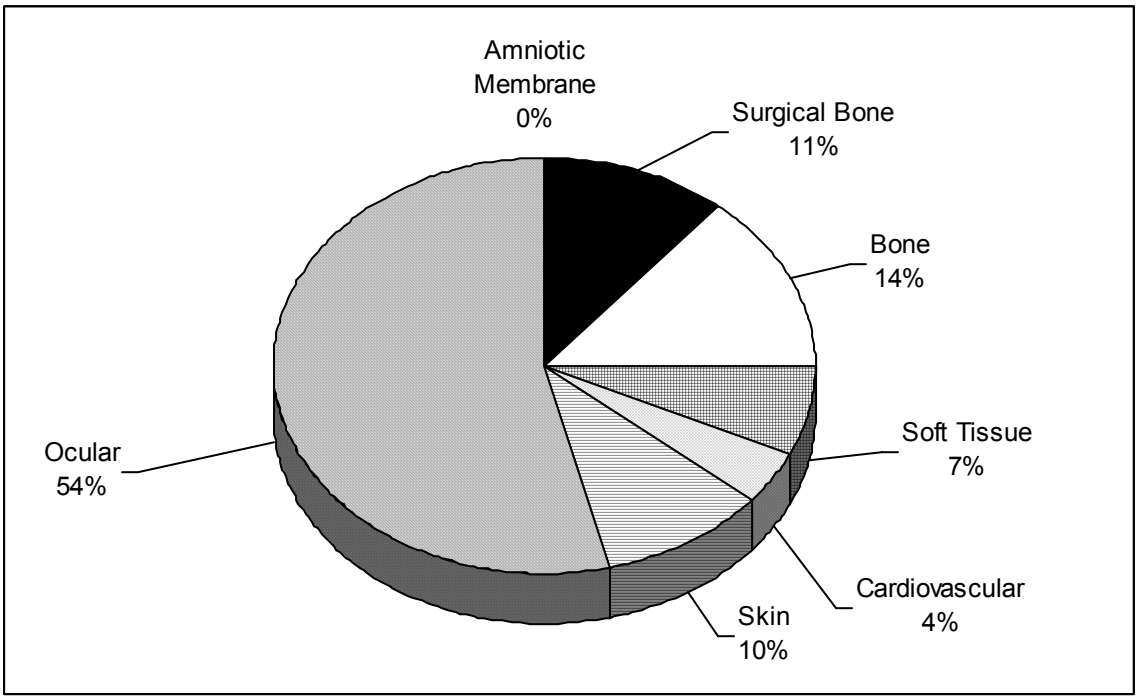


Figure 3. Allograft Tissues Recovered by Tissue Type

Table 12. Tissues Recovered by Major Tissue Type

Source	Amniotic Membrane	Surgical Bone	Bone	Soft tissue	Cardiac	Skin	Ocular
Comprehensive Tissue Banks							
Total	2	786	930	821	222	1,343	257
% of Type	67%	50%	49%	87%	38%	99%	3%
Surgical Bone Banks							
Total		455					74
% of Type		29%					1%
Musculoskeletal Tissue Banks							
Total		248	984	125	18	1	100
% of Type		15%	51%	13%	3%	0.1%	1%
Eye Banks							
Total	1						7,036
% of Type	33%						93%
Tissue Specific Banks							
Total		92			343	6	130
% of Type		6%			59%	0.9%	2%
Grand Total	**3**	**1,581**	**1,914**	**946**	**583**	**1,350**	**7,597**

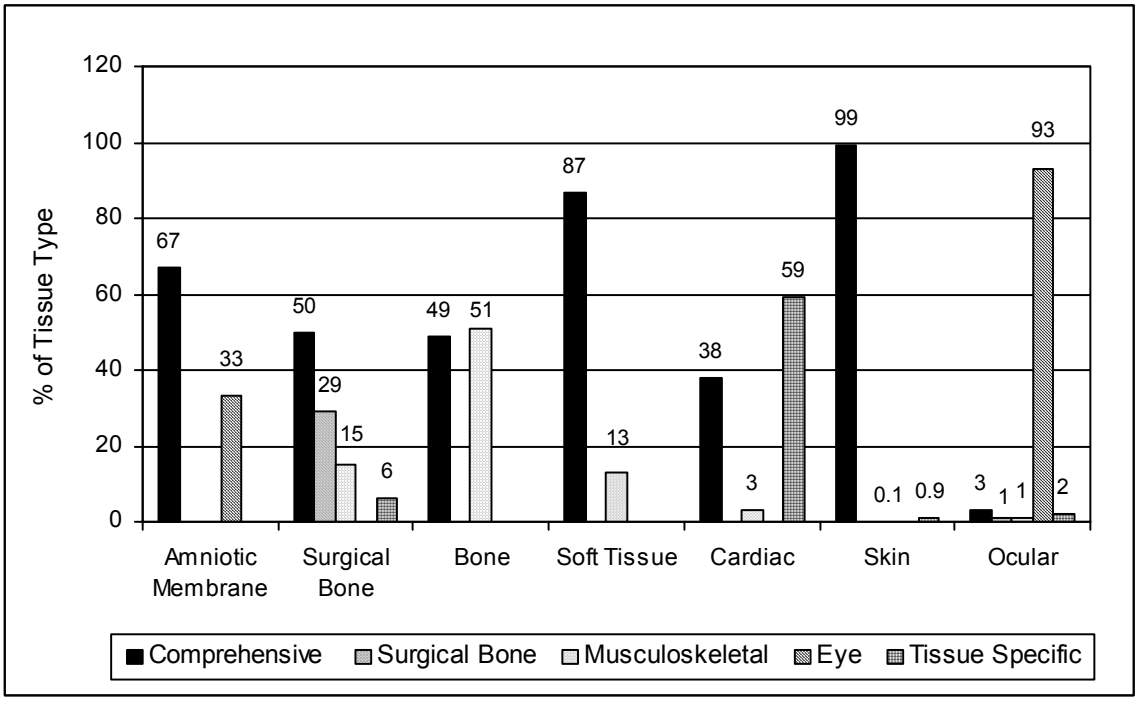


Figure 4. Percentage of Tissues Recovered by Tissue Type and Bank Type

The respondents were asked about recovery of tissue in conjunction with other banks:

- 57% of all respondent banks indicated that they routinely recover tissue in conjunction with other banks.
- 100% of CTB's reported that they routinely recover tissue in association with other banks.
- 66% of MSB's reported that they routinely recover tissue in association with other banks.
- 1 SBB reported recovering tissue (ocular) with other banks.
- 63% of EB's reported that they routinely recover tissue in association with tissue banks.

Final Allograft Tissues Processed
The respondents reported a total of 27,090 cc's or 541 packages of cancellous ground bone (based on 50 cc packages) processed over the past year.

The survey respondents reported a total of 10,729 allograft tissues processed. Table 14 presents the total number of tissue products and percentages by tissue type. Table 15 provides a detailed breakdown of tissues produced by bank type and for each bank.

Table 13. Volume of Tissues Processed and Percentage by Tissue Type

Tissue Product	#	% of Total
Cancellous Ground Bone	541	5%
Cancellous Bone	1,503	14%
Small Structural Grafts	423	4%
Large Structural Grafts	1,534	14%
Tendons	466	4%
Soft Tissues (fascia, meniscus, pericardium)	416	4%
Cardiovascular Tissues	249	2%
Skin Grafts	2,210	21%
Ocular Tissues	3,387	32%
Total	**10,729**	**100%**

Note: For cancellous ground bone statistics, the total number of grafts was calculated using a standard volume of 50 cc's per graft.

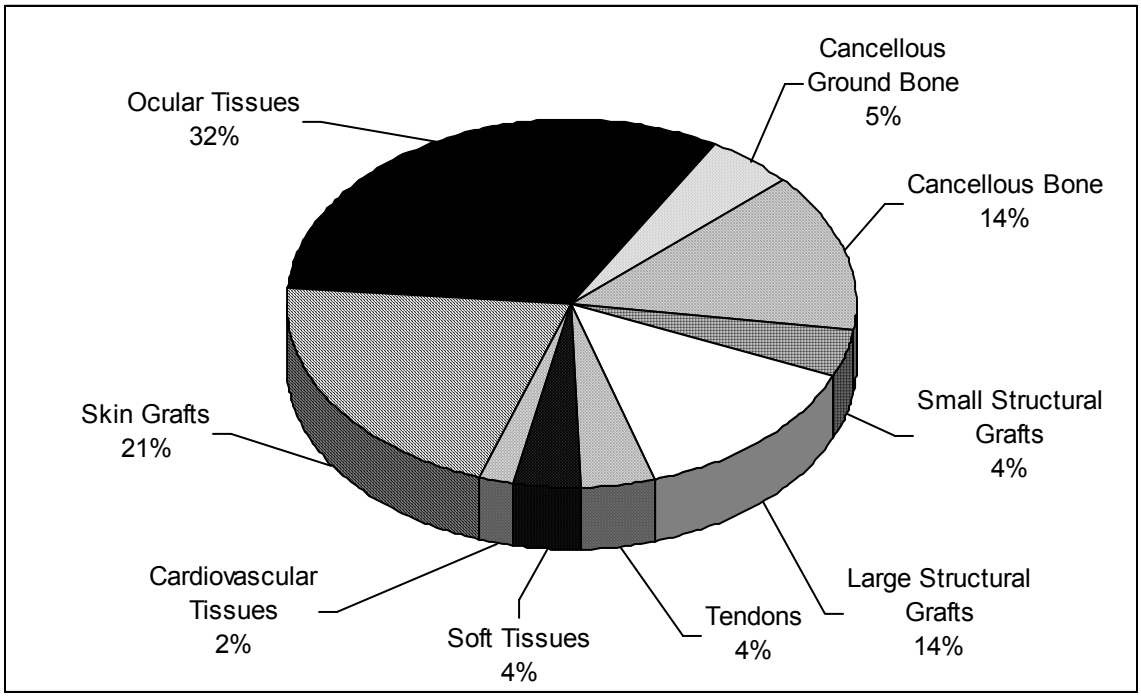


Figure 5. Allograft Tissues Produced as Percentage of Total

Table 14. Volume of Tissues Processed by Bank Type and Each Bank

Source	Cancellous Ground Bone	Cancellous Bone	Small Structural	Large Structural	Tendons	Soft Tissue	Cardiac	Skin	Ocular
Comprehensive Tissue Banks									
Total	538	576	315	595	393	340	97	2,189	468
% of Type	99%	38%	74%	39%	84%	82%	39%	99%	14%
Surgical Bone Banks									
Total		281							
% of Type		19%							
Musculoskeletal Tissue Banks									
Total	3	626	108	939	73	36			20
% of Type	1%	42%	26%	61%	16%	8%			1%
Eye Banks									
Total									2,810
% of Type									83%
Tissue Specific Banks									
Total		20				40	152	21	89
% of Type		1%				10%	61%	1%	2%
Grand Total	**541**	**1,503**	**423**	**1,534**	**466**	**416**	**249**	**2,210**	**3,387**

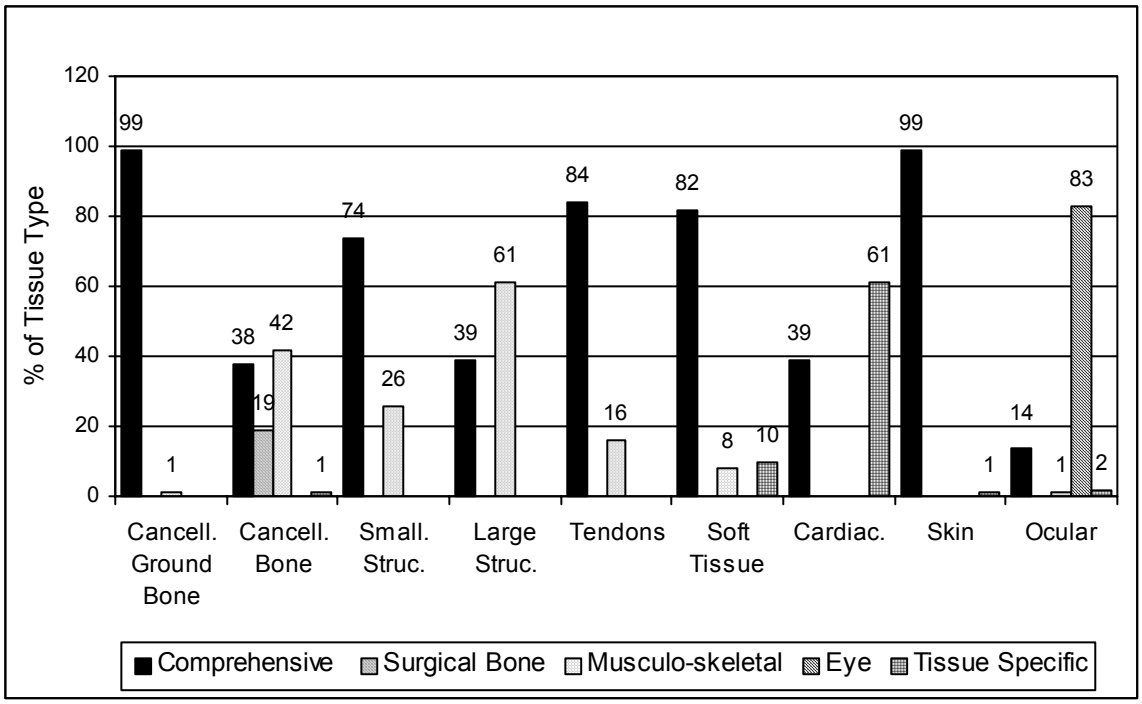


Figure 6. Percentage of Tissues Processed by Tissue Type and Bank Type

Export and Distribution of Unprocessed Tissue

The survey respondents were asked for data regarding the number of unprocessed tissues distributed within Canada and exported to international/U.S. destinations:

- 7 of the survey respondents reported exporting unprocessed tissue within Canada; and
- 6 reported exporting unprocessed tissue internationally or to the U.S.

Table 15. Unprocessed Tissue Exports

Tissue Type	# Tissues	Exported To
Cardiovascular	70	Canada
Ocular	630	Canada
Total Distributed within Canada	**700**	
As a % of Total Tissues Recovered	**5%**	
Cardiovascular	131	Int'l/U.S.
Ocular	30	Int'l/U.S.
Bone	21	Int'l/U.S.
Soft tissue	80	Int'l/U.S.
Total Exports to Int'l/U.S.	**262**	
As a % of Total Tissues Recovered	**2%**	
Total Tissues Distributed and Exported	**962**	

Table 16. Unprocessed Tissue Exports to Int'l/U.S. as Percentage of Tissue Type

Tissue Type	# Tissues Exported to Int'l/U.S.	Total # Tissues Recovered	Int'l/U.S. Exports as % of Tissues Recovered
Cardiovascular	131	583	22%
Ocular	30	7,597	<1%
Bone	21	1,914	1%
Soft tissue	80	946	8%
Total Exports to Int'l/U.S.	**262**		

Export and Distribution of Final Allograft Tissue Products

The survey respondents were asked for data regarding the number of final allograft tissues distributed within Canada and exported to international/U.S. destinations:

- 16, or 57% of the survey respondents reported distribution of processed tissue products within Canada (2 of these banks did not have activity in 2002); and
- 3 reported exporting final allograft tissue products internationally or to the U.S; another bank indicated that although they did not export any processed tissue during 2002, they have done so in past years.

Table 17. Final Allograft Tissue Distribution and Exports

Tissue Product	# Products	Distribution or Export To
Cancellous—Ground Bone (20cc packages)	32	Canada
Cancellous—Ground Bone (40cc packages)	263	Canada
Cancellous—Ground Bone (60cc packages)	51	Canada
Cancellous—Chips (30cc packages)	231	Canada
Cancellous—Chips (60cc packages)	88	Canada
Cancellous Bone Grafts	234	Canada
Small Structural Grafts	166	Canada
Tendons	164	Canada
Large Structural Grafts	212	Canada
Soft Tissues	173	Canada
Ocular Tissues	530	Canada
Cardiovascular Tissues	129	Canada
Skin	419	Canada
Total Distribution within Canada	**2,692**	**Canada**
As a % of Total Tissues Processed (including packages of cancellous bone)	**25%**	
Cancellous bone	6	Int'l/U.S.
Large structural grafts	14	Int'l/U.S.
Soft Tissue	12	Int'l/U.S.
Tendons	10	Int'l/U.S.
Cardiovascular Tissue	2	Int'l/U.S.

Tissue Product	# Products	Distribution or Export To
Ocular Tissues	55	Int'l/U.S.
Total Exports to Int'l U.S.	**99**	**Int'l/U.S.**
As a % of Total Tissues Processed (including packages of cancellous bone)	**1%**	
Total Tissue Products Distributed and Exported	**2,791**	

Table 18. Final Allograft Tissue Exports to Int'l/U.S. as Percentage of Tissue Type

Tissue Product	# Products Exported to **Int'l/U.S.**	Total # Tissues Processed	Int'l/U.S. Exports as % of Tissues Processed
Cancellous Bone	6	1,503	<1%
Large Structural Grafts	14	1,534	1%
Soft Tissue (fascia)	12	416	3%
Tendons	10	466	2%
Cardiovascular Tissues	2	249	1%
Ocular Tissues	55	3,387	2%
Total Exports to Int'l U.S.	**99**		

Availability of Tissue

The survey respondents were asked to indicate the tissue type they most frequently were unable to supply in sufficient quantities to meet demand.

Table 19. Frequently Unavailable Tissue by Type of Bank

Tissue Type	CTB	SBB	MSB	EB	TSB	Total
Cancellous Bone	2	1	4	-	-	**7**
Small Structural Grafts	-	2	1	-	-	**3**
Large Structural Grafts	1	2	1	-	-	**4**
Tendons	1	-	2	-	-	**3**
Soft Tissue	-	-	-	-	1	**1**
Skin	1	-	-	-	1	**2**
Cardiac Valves	1	-	1	-	1	**3**
Cardiac, Other	-	-	-	-	-	**-**
Corneas	1	1	-	8	-	**10**
Sclera	-	-	-	1	-	**1**
Amniotic Membrane	1	-	-	-	-	**1**

Of all 15 banks processing ocular tissue, 10 (67%) indicated a lack of corneal tissue. Three (3) banks reported frequent inability to meet demand for cardiac valves. Forty-one percent (41%) of CTB's, MSB's and SBB's indicated a lack of cancellous bone.

Key Observations

Based on review and analysis of the supply survey respondent data the following key observations have been made:

Survey Response

- Based on the number of sites approached to participate in the survey (29), the response rate was considered to be excellent. Twenty-eight (28) of 29 surveys have been received. Only one site did not agree to participate, citing survey fatigue. Overall, survey respondents were very cooperative and supportive of this initiative. A number of contacts offered to provide further assistance later in the project if required.
- Survey respondents represented a range of tissue banks. Review of the data pointed to natural groupings of banks as follows:

  Comprehensive Tissue Banks (CTB) — banks that retrieve/process/distribute two or more distinct tissue types (with the exception of ocular).

  Surgical Bone Banks (SBB) — banks that produce bone from surgical/living donors only.

  Musculoskeletal Tissue Banks (MSB) — banks that produce bone and soft tissue from surgical and/or cadaveric donors.

  Eye Banks (EB) — stand-alone eye banks.

  Tissue Specific Banks (TSB) — banks that deal with one tissue type that is other than surgical bone or ocular tissue.
- These groupings facilitated meaningful comparisons and presentation of the data.

Characteristics of Respondent Tissue Banks

- On review of the banks across Canada who responded to the survey, Eye Banks are most geographically dispersed, existing in 7 provinces.
- Data on the range of tissue functions by type of tissue bank highlighted one area with minimal involvement of tissue banks. Research and development was an integral component of only 2 CTB's, 1 SBB and 4 of 8 EB's.
- On review of current and future planning for accreditation, EB's appear to have the highest accreditation rates (63%). CTB's have a current rate of 50% with AATB, which is expected to rise to 100% with future plans for accreditation. MSB's and TSBs have a current rate of 33% for AATB, which is expected to rise to 83% and 66% respectively. None of the surveyed SBB's are AATB accredited or have future plans to do so.
- Compliance with CSA draft standards is relatively low ranging from 12% to 14% across bank types. Respondents indicated a wide range of time required to comply, from 1 month to 24 months.
- Of the 47 partnerships reported by 28 respondents, 50% of these were related to donor referral and coordination of tissue retrieval.
- Only 3 banks reported relationships with universities, which is consistent with the low number of banks involved in research and development.

Resources of Respondent Tissue Banks

- 26% of the 195 staff reported, held either AATB or EBAA certification. The majority of certified staff are located in CTB's and EB's.
- 2% reported ISO training.
- Although there was a mix of funding sources reported, the majority of tissue banks are funded locally. This is not surprising given the fragmented range and nature of tissue services in Canada. Three respondents reported receiving 100% of funding from the province.
- As most banks do not pay or receive fees for tissue services, their funding organizations bear the majority of operating costs.
- Although almost 75% of banks reported some level of automation in terms of information management, the majority of these systems are stand-alone, and developed in-house. As a result there is currently no mechanism to share or compile comprehensive data for tissue banking activities in Canada.
- Overall, survey respondents had most difficulty responding to the question on resources required to double capacity. Several banks were unable to respond to the question at all and there was a wide variation in the range of responses. Those who did respond, reported a total requirement of 53.4 FTEs, $3.5 million for one-time capital and $5.9 million for annual operating budget. Should demand increase in the absence of a comprehensive Canadian model, it is highly likely that the overall cost will be greater than would be the case if there were more opportunities to achieve economies of scale.

Tissue Statistics

Tissue Recovery

- Over the past year, respondents reported a total of 5,691 donors (1,550 living and 4,141 cadaveric donors). From the 1,550 living donors, 1,584 tissues were retrieved. From the total donors 13,974 tissues were retrieved, of which 7,597 or 54% were ocular tissues. The remaining 46% of tissues included a variety of bone, soft tissue, cardiovascular and skin.
- Eye Banks recovered tissue from over 3,600 cadaveric donors or 63% of all donors.
- Based on the number of cadaveric donors and the tissues retrieved, an average of 3 tissues was retrieved from each donor. It is important to note that this survey did not address donation specific information such as the % of donors who consented to donate multiple tissues vs. specific tissue (e.g. eyes) nor did the survey address the screening process.

Tissue Processing

- Including cancellous ground bone, there were 10,729 tissue products produced by the respondent banks. Of these, 7,610 or 71% were produced by accredited banks.
- Of the 10,729 tissues, 3,387 or 32% were ocular tissues. Of the ocular tissues, 55% were produced by accredited banks.
- Of all grafts produced by known tissue banks in Canada (excluding ocular tissue), 55% of grafts are bone.
- CTB's produce 82%–84% of all tendons and soft tissue.
- Five types of tendons were reported with the most common (~60%) being the achilles tendon and the whole patellar tendon.

- The majority of tendons (84%) were produced by the 4 CTB's together; 1 of the MSB's produced 14% of the total tendons.
- A total of 416 soft tissue grafts were produced of which fascia comprised the largest component (85%). The majority of fascia lata is produced by two CTB's (>82%).
- Cardiovascular allograft tissue for transplantation was produced by 2 CTB's and 1 TSB. The majority of grafts (61%) were processed at one centre.
- 99% of skin grafts are produced by 3 CTB's.
- Stand-alone Eye Banks produce 83% of Canada's supply of ocular tissue; CTB's produce 14%.
- At one EB there was a significant discrepancy between eyes retrieved and tissues processed (2,595 eyes recovered compared to 177 tissues processed). The EB policy is to recover all eyes when families request donation. Many of these are not suitable for transplant and are used for research/education.
- Two banks produce amniotic membrane—1 EB and 1 CTB. 68% is produced by the CTB.
- Based on the mix of tissues processed in different regions (Atlantic, central and west) there appeared to be no relationship between apparent demand and processing capacity. For example, a large burn centre in Central Canada had access to only 21 skin grafts, whereas over 2,189 skin grafts were processed in the Atlantic and Western regions.
- Problems with the availability of tissue were most commonly cited for corneas, cardiac valves and cancellous bone.

Distribution and Export of Canadian Tissue

- Distribution of unprocessed and final tissue products occurred primarily within Canada. The majority of these were final tissue products.
- Exports to international/U.S. of unprocessed tissue totaled 262. It should be noted that 131 were cardiovascular tissues, which amounted to 22% of the total cardiovascular tissues recovered.
- Export of processed tissue to international/U.S. totaled 99 spread across various tissue types, the majority (55) being ocular tissue.

Key Informant Interviews

Methodology

In the initial planning phases of the CCDT 4.1 project on Supply and Demand of Human Allograft Tissue in Canada, Key Informant Interviews were identified as an important method. The strategy for planning interviews was based on the major components of the CCDT 4.1 project. The interviews were planned in two steps:

1. targeted interviews for the purpose of collecting background information that would contribute to the environmental scan, to inform the development of the Supply Survey and to collect initial information on demand issues; and
2. targeted interviews for the Demand component, with key users of allograft tissue in Canada, in particular those using bone, soft tissue, cardiovascular, ocular and skin.

Step 1. Interviews (Environmental Scan and Supply)
Through the initial planning phases and discussions with CCDT and CIHI representatives, a number of key individuals were identified as critical resources to the CCDT 4.1 project on Supply and Demand of Human Tissue in Canada.

Seven (7) interviews were conducted in December 2002 with representatives/experts in the following areas of interest:

1. Bone and soft tissue banking
2. Cardiac valve banking
3. Uses and applications of cardiac allograft tissue
4. Eye banking
5. National standards and regulation
6. Provincial network—Ontario
7. Provincial network—Quebec

Although the primary purpose of these interviews was to contribute to background information for tissue banking in Canada, valuable information on the topic of Supply was also collected.

Step 2. Interviews (Demand)
These interviews were planned with a focus on the key users of human allograft tissue in Canada, including, but not limited to surgeons in a variety of specialties. The criteria for planning these interviews included:

- representatives of surgical specialties that commonly use allograft tissue;
- users of tissue types included in project scope (bone and tendons, soft tissue, cardiovascular tissue, ocular tissue, skin);
- range of users from different sizes of facility (community based, large teaching hospitals, centres of excellence); and
- individuals who are leaders in their field with provincial and/or national perspectives on the issues affecting supply and demand of human allograft tissue.

Although the focus of these interviews was on demand issues, a number of important themes arose during discussion that related to the topic of Supply. For this reason, these interviews are included in the Supply Report. More detailed information arising from these interviews will be reported on in the Demand Report.

Sixteen (16) interviews were conducted from January 2003–March 2003 with representatives/experts in the following specialty areas:

- Surgical bone banking, community hospital
- Surgical bone banking, large teaching hospital
- Orthopaedic surgeon, sports medicine, large teaching hospital
- Orthopaedic surgeon, sports medicine, community hospital based
- Orthopaedic surgeon, joint replacement, provincial and national focus
- Orthopaedic surgeon, provincial focus

- Trauma surgery, musculoskeletal
- Neurosurgery, spine surgery
- Paediatric cardiac surgery
- Adult cardiac surgery
- Dentistry—Oral and maxillo-facial surgery
- Dentistry—Periodontal
- Ophthalmic surgery, corneal transplantation
- Eye banking
- Ocular tissue donation and retrieval
- Skin banking, large burn centre

Limitations

In many cases, information obtained through Key Informant Interviews with users and tissue banking representatives reflected their personal preferences, opinions, observations and/or local processes and practices. The information provided by key informants has not been endorsed by the CCDT or CIHI, nor does it necessarily represent the opinion of any particular health care organization, professional association or surgical specialty.

Themes and Key Messages on Supply from Key Informant Interviews

Access to Canadian Supply

There were a number of factors raised in interviews that highlighted reasons why users could not or did not access Canadian tissue:

- Tissue is produced by a limited numbers of centres in Canada that may charge cost recovery fees depending on the type of tissue (e.g. costs can range from $450 for 40 cc's of ground bone to $5000 for a large structural bone graft). Hospital budgets may not cover these costs or have line items to which these costs can be charged.
- Surgeons may be restricted in selecting and using these products due to administrative policies and budget restraints imposed on them.

Common Sources of Supply

Some Canadian users access tissue from a number of sources within Canada and internationally (primarily the United States). Some order tissue from both countries and others may order exclusively from the United States. Examples of this follow:

- Large structural bone grafts are produced at a limited number of Canadian centres but if a specific graft such as a hemi-mandible is required for oral and maxillo-facial surgery it is ordered from the U.S.
- Despite the fact that there are regional differences in the variety and volume of tissue products produced in Canada, it was stated that it was feasible to access tissue from other parts of Canada in a timely fashion.
- Common sources for commercial supply of demineralized bone products include but are not limited to—GenSci, Wright Medical Technologies, Regeneration Technologies and Osteotech.

- Users in the Dental Industry (periodontists and oral surgeons) access allograft tissue primarily from commercial sources.

Awareness and Knowledge of Canadian Tissue Supply

The interviews revealed a wide variation in the understanding and awareness of the allograft tissue supply in Canada:

- A number of interviewees stated that they were not aware of or had no knowledge about tissue processing in Canada or of how easily tissue could be obtained. This group included users of cardiovascular and bone products.
- In some cases, the interviewees were not immediately aware that certain products used in their practice contained a form of human allograft tissue (e.g. forms of demineralized bone).
- As there is no standardized approach to sharing information regarding tissue supply and uses in Canada, there may be instances where there is an over supply of tissue in one region and a user who is short of supply in another region. A burn centre reported that they had difficulty obtaining skin grafts while a tissue bank representative commented that they no longer recovered skin grafts because there were no requests for this tissue.
- It was noted in one interview that a significant effort would be required to educate physicians and other key stakeholders on the applications, benefits and sources of human allograft tissue.

Safety of Current Canadian Supply

During the interviews there were a number of comments related to safety issues:

- Interviewees who had practiced in the United States and used human tissue extensively felt that the benefits of its use far outweighed the risk. One user considered the risk of disease transmission to be “1 in a million”.
- Others expressed concern that Canada did not have standards in place or a means for verifying that tissue was being retrieved and processed safely.
- Surgeons expressed concerns about patient safety and liability issues related to using products with a risk of transmission of disease.

Impact of Tissue Supply on Surgical “Best Practices”

A number of interviewees commented on the impact of low supply of allograft tissue in Canada on their surgical practices and client outcomes. As decisions regarding use of graft types (e.g. autograft vs. allograft vs. synthetic) may be dependent on supply of tissue and resources to purchase grafts, clients may be negatively affected as a result. Examples cited include:

- Neurosurgeons and orthopaedic surgeons use allograft bone products in common procedures such as reconstructive spinal surgery and osteotomies. If allograft tissue is not available the surgeon is required to do an autograft from second site (commonly harvesting bone from the patient’s iliac crest). This may result in increased time for surgery/ anaesthesia, length of stay for the client, increased pain and restricted mobility and other surgical risks such as infection.
- There is growing interest in the use of bone morphogenic protein to enhance the outcome of joint replacement revisions. Currently this is not available in Canada and the cost to purchase from the U.S. is prohibitive ($5,000 U.S. for 2 cc’s).

- Allograft tendons are used for reconstructive ligament surgery for revisions of anterior cruciate ligament repairs, primary repairs of posterior cruciate ligaments and multiple ligament repairs. Supply of these tissues is an issue and as a result the surgeon may need to use an autograft.
- There is currently little supply of osteochondral grafts to repair articular surfaces. Use of these grafts in the early stages of degenerative joint disease may delay or rule out the need of a joint replacement.
- In one case a surgeon described a failed procedure for facial reconstruction using an autograft. The surgeon's opinion was that, if an allograft had been used initially, the outcome would have been successful and that length of stay (from complications) would have been reduced from several weeks to a few days.

Demineralized Bone Products

Demineralized bone products must be ordered from the U.S. as they are not produced in Canada (although there are a number of Canadian distributors for these products). From the interviews conducted, it was noted that:

- A wide range of users interviewed use this product including orthopaedic surgeons, oral and maxillo-facial surgeons, periodontists, neurosurgeons and trauma surgeons.
- This product is commonly ordered through operating rooms in hospitals in specific volumes and forms (e.g. putty, pellets).
- These products are commonly packaged in certain sizes (e.g. 5 cc's) that are often too large for a specific procedure. Once the package is opened it is not reusable and there is wastage and an impact on cost.
- It was clear that some users did not immediately recognize that these products contain human tissue.
- One user commented that purchase of these products is through distributors and a number of "middle men", resulting in high cost product and profit making for the manufacturers.
- In order to accurately quantify current supply of this product in Canada, every hospital, operating room and surgeon would have to be contacted for their purchasing data.

Surgical Bone Banks

Users of bone products in orthopaedic surgery access products from a number of supply sources. A common source is surgical bone (femoral heads) from living donors who undergo total hip replacement.

- This source of bone is considered an "unknown source of supply" as there is no standard approach to identify those hospitals that retrieve and use surgical bone.
- Commonly, this bone is used locally within the hospital where it is retrieved and is not available to other facilities or users.
- Both community based and large centres use this approach for bone supply.
- There is clearly a dependency of these facilities on this source of supply and a perception that this is a low cost, low risk source of allograft bone.
- There is currently no information available to identify all existing surgical bone banks in Canada.
- As standards and regulations become mandatory it is likely that many of these surgical bone programs will not have the resources to comply and may be forced to shut down.

Cardiovascular Tissue

Both paediatric and adult cardiac surgeons use heart valves. Their requirements differ based on the size of valves required and the procedure. Some centres have access to a supply of valves based on the hearts they retrieve and send for processing to Toronto. Other features of valve supply include:

- A range of sizes is required to meet the needs of paediatric and adult surgery.
- It is difficult to plan for the size you need as they are often used in emergency procedures.
- Not all users are aware of the Canadian sources of supply.
- Overall supply of human valves in Canada would increase with improved donation rates and from explanted hearts (hearts removed from transplant recipients). There may be issues with valves from explanted hearts vis a vis pathology affecting the heart that was explanted.
- Supply of valves can be negatively affected by delays in clearing quarantine. An example of this includes access to post-mortem results that may take up to a year.

Ocular Tissue

The following points were raised during interviews with specialists in this area:

- There appear to be regional differences in the supply of ocular tissue. In the Atlantic region access to corneal tissue is restricted whereas it is in good supply in central Canada.
- Barriers to corneal transplantation in central Canada are more related to OR time rather than to supply of tissue. As a result most of the corneal tissue users have significant wait lists (50–100).
- Supply of amniotic membrane is very limited in Canada. Users are required to order most of this product from the U.S.

General

In addition to these themes and key messages the following points were of general interest as they relate to supply:

- Supply continues to be a challenge. Current donor rates are not increasing significantly. Currently, many tissue donors are also organ donors who often tend to be the victims of traumatic injuries. The rate of deaths from these injuries is being reduced through the efforts of safety initiatives.
- An adequate supply of safe tissues on an ongoing basis requires constant efforts to recruit healthy donors and to procure and process tissues according to strict standards.
- There are a limited number of facilities that process human tissue in Canada.
- Not all tissue products are processed in Canada prompting users to look at international sources (e.g. demineralized bone).
- The allocation of tissues between regions requires recognized accreditation, which is too costly for many facilities to obtain.
- The absence of a national structure makes it difficult to establish national allocation algorithms and ensure that they are adhered to.
- The constraints on the health system have a real impact on demand for some allograft tissues. As constraints are lifted demand increases. At the same time donor availability may

increase or decrease. Should there be a good supply of donors during a time of few resources in the system large inventories of allograft tissues result.

- Some areas of the country may have access to an adequate supply of tissues that others do not (e.g. sufficient corneas in Ontario but not in Atlantic Canada).
- In order to ensure an adequate supply to allograft tissue to meet Canadian needs, an adequate selection of tissue type and volume of tissue grafts will be needed. Examples of this include the requirements for a range of cardiac valve sizes for paediatrics and adult surgery. Large structural bone grafts in a variety of sizes and forms are required to meet different age groups and skeletal build to match donor to a potential recipient.
- Coordination of efforts is important to ensure that as donor supply increases that there is adequate processing facilities and storage capacity and to avoid wastage.

Estimation of Canadian Tissue Supply from Unknown Sources

Methodology

There is currently no system for directly measuring the supply of allograft tissue in Canada. For the purposes of this report "allograft tissue supply" is defined as being comprised of two components:

- "Known Supply"—tissue produced by known tissue banks in Canada; and
- "Unknown Supply"—tissue produced by unknown tissue banks (surgical bone banks) that may exist at hospitals across Canada, and tissue products directly imported by health care organizations and users.

Allograft Tissue Supply =
Known Supply (Supply Survey) + Unknown Supply (Imports and Surgical Bone)
For the purposes of this report Known Supply was measured directly through the Supply Survey sent to known tissue and Eye Banks across Canada. Unknown Supply is much more difficult to quantify.

Through research, and Key Informant Interviews, the project team determined that there are several tissue types for which Canadian supply is augmented through importation and Surgical Bone Banks (Unknown Supply). Where a basis of estimation could be established, the project team attempted to measure the components of Unknown Supply. These estimates are subject to several assumptions and limitations listed in the following section. The table below provides an outline of the components of Unknown Supply that have been estimated. It was not considered feasible (or in some cases applicable) to estimate Unknown Supply for the remaining tissue types.

Table 20. Estimated Components of Unknown Supply

Estimation Method	Component of Unknown Supply	Source
#1	Cancellous Bone	Unknown Surgical Bone Banks
#2	Cancellous Bone	Imports required for total hip and knee joint replacement revisions.
#3*	Demineralized Bone (DMB) Products	Sales by commercial companies to Canadian clients
#4*	Demineralized Bone and Bovine/Synthetic Bone Products	Purchases by Canadian hospitals
#5	Cardiovascular Tissue	Imports

Note: Components of Unknown Supply are not necessarily mutually exclusive (i.e. Estimation Methods #3, #4 represent alternatives to estimating imports of products purchased from commercial sources by Canadian customers).

Assumptions/Limitations

The following general assumptions and limitations were made in relation to the estimates for Methods #1 to 5:

- Disease states do not vary dramatically across the various regions of Canada.
- Clinical practices do not vary dramatically.
- Similar hospital profiles would result in:
  - use of similar volumes of allograft tissue and related products;
  - similar ordering patterns and quantities; and
  - numbers of surgical bone banks across the country.
- Due to the competitive nature of the market, prices across manufacturers do not vary dramatically for a similar unit of measure.
- The marketing and sales efforts of commercial companies are similar across the country.
- Product preferences result in similar purchasing patterns.

In many cases the estimates of Unknown Supply are based on the extrapolation of data obtained from one organization or a small sample of organizations. The data used as a basis for extrapolation is subject to inaccuracies. For example, allograft tissue products are ordered/received by many individuals/departments within the same organization (e.g. multiple material management representatives located at various campuses of one health care organization, OR staff, surgeons offices). It is difficult, if not impossible, to identify and capture the data associated with these various procurement points in a comprehensive and exhaustive manner.

In addition, the information used to estimate quantities and costs associated with importation of allograft tissue products are not necessarily based on data from the same fiscal period (e.g. sales revenue and pricing information).

Estimates: Methods #1 to #5

The following section details the calculations for Methods #1 to 5 estimates. These estimates have been incorporated in the Discussion and Summary sections of this report.

Method #1—Cancellous Bone from Unknown Surgical Bone Banks

Results of the Supply Survey and interviews with key informants indicated that surgical bone is a common and important source of allograft bone for revisions of total hip and total knee replacements (as well as other orthopaedic and neurosurgical procedures such as osteotomies and spinal fusions).

Assumptions

- Hospitals that perform total hip and knee joint replacements:
  - are users of cancellous bone allograft tissue,
  - would benefit from surgical bone banks, and
  - may have surgical bone banks.
- Surgical bone banks exist in both community and large teaching hospitals.
- Hospitals of similar size will retrieve approximately the same number of femoral heads.
- Each femoral head will produce approximately 50 cc's of cancellous bone.

Limitations

- The sample of hospitals used to establish the average number of femoral heads retrieved by community and teaching hospital surgical bone banks is small (n=7).

Estimate

Estimation of surgical bone was undertaken using the following steps:

- The Supply Survey included surgical bone bank respondents from both community and large teaching hospitals. Using the data collected from these sites an average annual number of femoral heads was calculated:
  - 40 femoral heads from community hospital surgical bone banks; and
  - 125 femoral heads from large teaching hospital surgical bone banks.
- The hospitals in Canada that performed hip and knee replacements in 2000 were identified using the Hospital Morbidity Data Base (HMDB), a hospital separation database managed by CIHI.
- The bed count for each of these hospitals was determined using the CIHI MIS Database (1995–2000).
- Hospitals with < 500 beds were grouped as "Small" type hospitals (community hospitals) and those with greater than 500 beds were grouped as "Large" hospitals:
  - The number of "Small" hospitals performing hip and knee replacements is estimated to be 134.
  - The number of "Large" hospitals performing hip and knee replacements is estimated to be 39.

Table 21. Small and Large Hospitals by Province

Province	# Small Hospitals	# Large Hospitals
B.C.	24	7
Alta.	6	4
Sask.	9	
Man.	5	2
Ont.	44	11
Que.	31	11
N.B.	4	2
P.E.I.	1	
N.S.	4	2
N.L.	5	
Nun.	1	
Total	**134**	**39**

It is unlikely that all hospitals performing hip and knee replacements have surgical bone banks; however, as it is difficult to know what how many hospitals have surgical bone banks. It was decided that Method #1 would be estimated across 2 ranges as follows:

- Method #1A—Assuming that 50% of "Small" and "Large" hospitals have a surgical bone bank; and
- Method #1B—Assuming that 25% of "Small" and "Large" hospitals have a surgical bone bank.

The tables below outline the calculation of the Method #1 estimates.

Table 22. Method #1A—Estimate of Cancellous Bone from Unknown Surgical Bone Banks (50%) Extrapolation Rate

Grouping	# of Hospitals	50% of Peer Hospitals	Avg. # Femoral Heads	# Unknown Cancellous Bone Grafts
Small Hospitals	134	67	40	2,680
Large Hospital	39	19	125	2,375
Total	**273**	**86**		**5,055**

Table 23. Method #1B—Estimate of Cancellous Bone from Unknown Surgical Bone Banks (25%) Extrapolation Rate

Grouping	# of Hospitals	25% of Peer Hospitals	Avg. # Femoral Heads	# Unknown Cancellous Bone Grafts
Small Hospitals	134	34	40	1,360
Large Hospitals	39	10	125	1,250
Total	**273**	**43.25**		**2,610**

Method #2—Unknown Supply of Cancellous Bone for Total Hip and Total Knee Replacement Revisions

Information collected through the Environmental Scan and Key Informant Interviews highlighted the role of allograft cancellous bone in joint replacement procedures. A representative of the Canadian Joint Replacement Registry (CJRR), stated that virtually all revisions of total hip and knee replacements required the use of allograft cancellous bone.

The CJRR is a national registry that collects information on total hip and total knee replacement surgeries performed in Canada. It was developed jointly between the Canadian Institute for Health Information (CIHI) and Canadian orthopaedic surgeons under the auspices of the Canadian Orthopaedic Association and the Canadian Orthopaedic Foundation.

Assumptions

- Supply of cancellous bone from known tissue banks in Canada was similar in 2001 and 2002.
- Estimated supply of surgical bone from Canadian sources was similar in 2001 and 2002.
- All revisions of joint replacements required allograft cancellous bone.
- Each joint replacement revision requires on average, one graft or 50 cc's of cancellous bone.

Estimate

Approximately 43,000 joint replacements were conducted in Canada in 2000–2001. Roughly one half of these are hip joint and the other half are knee joint replacements. CJRR data indicates that approximately 11% of hip replacements are revised and 8% of knee replacements are revised *(Source: CJRR 2002 Supplementary Report).*

Based on this data it is estimated that 3,700 total hip replacement revisions and 1,540 knee replacement revisions were performed in 2000–2001. If one graft, or 50 cc's of cancellous bone is used for each procedure, the total used in 2000–2001 would be as follows:

revisions = 3,700 hip revisions + 1,540 knee revisions = 5,240 procedures
grafts required = 5,240 grafts or 262,000 cc's (5240 x 50 cc's)

Table 24. Method #2—Estimate Cancellous Bone Imports for Total Hip and Total Knee Replacement Revisions

Total # Cancel. Bone Grafts Required	Total Known Supply from Canadian Tissue Banks # Grafts	Additional Requirement # Grafts	Additional Supply—Surgical Bone Banks— # Grafts		Estimated Additional Imports Cancellous Bone Grafts
5,240	2,044	3,206	Method #1A	5,055	N/A
5,240	2,044	3,206	Method #1B	2,558	648

After application of Method #1B estimate for Unknown supply of cancellous bone from unknown Surgical Bone Banks, an additional 648 grafts (or 32,400 cc's) would have been imported to meet the minimum requirement for total hip and knee joint replacement revisions in 2000–2001. The CJRR reports that there has been a 33.5% increase in joint replacements over the recent 7 year period. Although it also notes that the recent trend is a decrease in total hip replacements, there is an increase in knee joint replacements (Source: CJRR 2002 Supplementary Report). This would suggest that the number of these procedures is likely to remain steady or increase over time and that the requirement for cancellous bone for total hip and knee joint replacement revisions will remain constant or increase over time.

Method #3—Commercial Sales of Demineralized Bone Products to Canadian Clients

Web sites of the major manufacturers of demineralized bone products were reviewed to determine if information might be obtained in relation to quantity of product sold to Canadian sources. In addition, an attempt was made to contact a sample of these companies to inquire as to whether or not this information might be available. In some cases no response was received; however, in a few cases some information was provided. The nature of these responses is outlined below:

Organization	Response
The American Red Cross	Indicated that they rarely export tissue to Canada. When they do the information is considered confidential.
Allosource	Response was as follows, “As we are not a publicly held company, I am not at liberty to offer any such information as might be found in an annual report. Regarding Canadian customers, I would estimate that less than 1% of our products are typically distributed in Canada. Our highest priority is to return our products to the same regions from which we obtained the donated tissues.”
GenSci	Reported $3,067,332 of sales to Canada in their 2001 annual report but indicated that they do not release these figures segmented by product within country. A GenSci representative later confirmed that these sales would have been related to the DynaGraft product as the other product lines were not available in Canada during the 2001 fiscal year. A 2003 Canadian price list was provided.

Key Informant Interviews revealed that users frequently purchase demineralized bone products manufactured from the following companies:

- GenSci
- Wright Medical Technologies
- Regeneration Technologies
- Osteotech

Estimate

This estimate incorporated the following steps:

- Determine Canadian sales from a commercial company(s).
- Estimate average cost per cc of a demineralized bone product from the sample company(s) (e.g. cost per cc of DMB putty).
- Determine the average package size in cc’s.
- Estimate volume of product sold to Canada.
- Extrapolate across a range to estimate the total volume of purchases by Canadian clients.

The following information contributed to the calculation of the Method 2 estimate:

- GenSci recorded sales of $ 3,067,322 to customers located in Canada during 2001. A GenSci representative confirmed that these sales would have been related to DynaGraft as the other product lines were not available in Canada during the 2001 fiscal year. *(Source: GenSciInc. Annual Report, 2001).*
- A recent price List for DynaGraft Putty and Gel reveals the average cost to be approximately $203.00 per cc. (Note: Average cost per cc determined using GenSci OCF Inc. Canadian Price list—January 2003).
- Total sales of $3,067,322 divided by an average price of $203.00 per cc would suggest that Canadian clients purchased approximately 15,110 cc's of GenSci's demineralized bone products.
- At average product size of 2.5 cc's this would equal 6,044 packages.

Notes:

1. The assumption has been made that all GenSci sales to clients located in Canada consisted of DynaGraft Gel and Putty. In reality, it is likely that some sales were associated with the DynaGraft Matrix product that is sold dimensionally rather than by the cc. As the split across product types is not available, the Matrix product could not be factored into the estimate; however, the price is not materially different from the Putty or Gel formations.
2. It is likely that a portion of the demineralized bone products being purchased by Canadian sources is associated with importation by the Dental Industry (periodontists and oral surgeons).

The estimate was calculated over two ranges as follows:

- Method #3A—Assuming that equal quantities are purchased by Canadian clients from 4 commercial companies.
- Method #3B—Assuming that equal quantities are purchased by Canadian clients from 2 commercial companies.

The table below details the calculation of the Method #3 estimates.

Table 25. Methods #3A and 3B—Estimate of Canadian Sales of DMB Products

	Estimated # of cc's of DMB Products Purchased From GenSci	# of Companies Used For Extrapolation	Estimated Unknown # of cc's of DMB	Estimated Cost at $203 per cc	Estimated # of DMB Packages at 2.5 cc's
Method #3A	15,110	4	60,440	$12,269,320	24,176
Method #3B	15,110	2	30,220	$6,134,660	12,088

Method #4—Purchases of DMB and Bovine/Synthetic Products by Canadian Hospitals

Interviews with key users of allograft tissue and hospital personnel revealed that tissue products are routinely purchased from commercial providers (mostly U.S. based companies) and/or their Canadian distributors. Discussions with key informants suggested that the majority of the products imported from the commercial sources are demineralized bone products and bovine/synthetic bone substitutes.

Note: It was determined that it would be meaningful to attempt to gain an understanding of the importation of related bone products (e.g. synthetic/bovine) as users indicated that these products are sometimes utilized as cheaper alternatives to demineralized bone products. It is anticipated that should a Canadian model result in access to reasonably priced demineralized bone products, users

may choose to purchase less of the alternative product. It is important to note however, that there are instances when synthetic products are the preferred choice.

The method to estimate purchases of Demineralized and Bovine/Synthetic Bone Products by Canadian Hospitals is based on annual volumes, quantities and sizes of these products that 2 sample acute care hospitals purchased over a recent 12-month period:

- Sample Hospital #1—Community Hospital (~ 200 beds, 5 orthopaedic surgeons)
- Sample Hospital #2—Large teaching hospital (~ 800 beds, ~20 orthopaedic and neurosurgeons)

The number of peer hospitals for Sample Hospitals #1 and 2 is deemed to be the number of "Small" and "Large" hospitals as determined under Method #1 above:

- # of Small Hospitals = 134
- # of Large Hospitals = 39

Limitations
As this estimate is based on hospital data it does not include purchases made by the Dental Industry (periodontists and private practice oral surgeons).

Estimate
This estimate incorporated the following steps:

- Obtain purchase data over a recent 12-month period from Sample Hospital #1.
- Obtain purchase data over recent 12-month period from Sample Hospital #2.
- Determine the number of peer hospitals to Sample Hospital #1 (Small hospitals from Method #1 calculation).
- Determine the number of peer hospitals to Sample Hospital #2 (Large hospitals from Method #1 calculation).
- Extrapolate purchases of Sample Hospitals #1 and #2 using a range based on number of peer hospitals.

The following table outlines the annual purchases of demineralized bone and bone substitute products by Sample Hospital #1 (Small type hospital).

Table 26. Sample Hospital #1—Annual Purchases extrapolated to Small Hospitals

Product	Quantity	Total # cc's	Number of Grafts*	Extrapolated to 134 Small Hospitals
Demineralized Bone Products (Dynagraft)	8	20	8.0	1,072
Osteoset (bone substitute)	3	9	3.6	482
Total grafts				**1,554**
Total graft excl. bone substitutes				**1,072**

*__Note__: For demineralized and bone substitute products a graft has been calculated at 2.5 cc's.
The following table outlines the annual purchases of demineralized bone, bone substitutes, and other bone tissues imported by Sample Hospital #2 (Large type hospital).

Table 27. Sample Hospital #2—Annual Purchases Extrapolated to Large Hospitals

Product	Quantity	Total # cc's	Number of Grafts*	Extrapolated to 39 Large Hospitals
Demineralized Bone Products (Dynagraft)	35	239	95.6	3,728
Osteoset (bone substitute)	26 (various sizes)	920	368	14,352
Mandible (freeze dried)	1		1	39
Fem. Cort. Struts	47		47	1,833
Fem. Head w/cartilage	1		1	39
Total grafts				**19,991**
Total grafts excl. bone substitutes				**5,639**

*__Note__: For demineralized and bone substitute products a graft has been calculated at 2.5 cc's.

Sample Hospital #2 spent approximately $275,000 on allograft tissue and bone substitute products in 2002. It should be noted that this figure includes purchases of products from some Canadian tissue banks (not included in the above tables). Assuming a similar purchasing pattern by the 39 large type hospitals across the country, approximately $10,725,000 would have been expended by these hospitals on allograft tissues and bone substitute products.

To account for some variation in bed size between Sample Hospitals #1 and 2 and their peer hospitals, this estimate is extrapolated over two ranges as follows:

- Method #4A—Assuming that equal quantities of products are purchased by 100% of peer hospitals.
- Method #4B—Assuming that equal quantities of products are purchased by 75% of peer hospitals.

Table 28. Method #4A—Estimate of Purchases (100% of Peer Hospitals)

Grouping	# of Hospitals	# Unknown Grafts Purchased by Canadian Hospitals
Small Hospitals	134	1,072
Large Hospitals	39	5,639

Table 29. Method #4B—Estimate of Purchases (75% of Peer Hospitals)

Grouping	# of Hospitals	75% of Peer Hospitals	# Unknown Grafts Purchased by Canadian Hospitals
Small Hospitals	134	100.50	804
Large Hospitals	39	29.25	4,229

Method #5—Cardiovascular Tissue Imports from International Sources

In order to estimate Unknown Supply of cardiovascular tissue (valves and conduits), two methods were used to estimate current use of valves and conduits for adult and paediatric cardiac surgery:

1. Adult valves—data from demand surveys on current use of allograft valves and conduits was extrapolated across the number of surgeons in the survey sample (29). An estimate of 476 valves was derived.
2. Paediatric valves—based on information from a key informant interview, it was estimated that the number of pump procedures in 4 of 5 major centres in Canada (Vancouver, Edmonton, Toronto, Ottawa, Halifax) is 1,080. It was also estimated that 25% of these procedures would use allograft valves, or 270 valves.
3. Conduits for paediatric surgery—data from paediatric demand surveys on current use of conduits were extrapolated across paediatric respondents (9). An estimate of 86 conduits was derived.

Table 30. Method #5—Estimate of Imports of Cardiovascular Tissue

	Valves	Conduits	Total Grafts
Estimated Total Current Requirement for Grafts	746	86	832
Known Supply of Cardiovascular Tissue (Supply Survey)	(210)	(39)	(249)
Total Estimated Cardiovascular Tissue Imports	536	47	583

Discussion

The following section focuses on key aspects of the Canadian supply of human allograft tissue. The results of the various methods used in this report (Supply Survey, Estimates and Key Informant Interviews) are integrated to present an overall picture for each tissue type.

Note: All tissue types include data on Known Supply based on the Supply Survey results. Where there were appropriate methods and it was feasible to determine Unknown Supply for certain tissue types, this information is included (i.e. for bone, cardiovascular).

Tissue Specific Supply

Supply of Allograft Bone—Known and Unknown

The results of the Supply Survey showed that, of all grafts produced by known tissue banks in Canada (excluding ocular tissue), 55% of grafts are bone. There are no tissue banks in Canada producing demineralized bone products (DMB) but it is clear from Key Informant Interviews and other investigations that DMB is commonly purchased from the U.S. and used in Canada by a variety of specialists (orthopaedic surgeons, neurosurgeons, and the dental industry). As well, it is clear that other types of bone grafts (small and large structural bone) are imported to supplement supply. Finally, it is understood that there are a number of "unknown" Surgical Bone Banks (SBB) that produce bone grafts.

Table 31. Known and Unknown Components of Allograft Bone Supply.

	Tissue Product	#	% of Total Grafts (excl ocular)
Known Supply (Supply Survey)	Cancellous Ground Bone	541	7%
	Cancellous Bone	1,503	21%
	Small Structural Grafts	423	6%
	Large Structural Grafts	1,534	21%
	Total Known Supply—Bone	**4,001**	**55%**
Unknown Supply	Demineralized Bone Products	?	
	Surgical Bone Grafts	?	
	Small and Large Structural Grafts	?	
	Total Unknown Supply—Bone	**?**	

One of the objectives of this project was to investigate the feasibility of determining Unknown Supply. The following section provides the results of the estimation methods used to calculate Unknown Supply of DMB and cancellous bone grafts from SBB's. It was not considered feasible to estimate the Unknown Supply of structural grafts. Details of the methodology used to derive this estimate may be found in the "Estimation of Canadian Tissue Supply from Unknown Sources" section of this report.

Table 32. Estimated Supply of Bone Allograft Tissue Products in Canada: Methods #1 and 3 (Higher Range)

Source	Cancellous Ground Bone	Cancellous Bone	Small Structural	Large Structural	Demin. Bone Products*
Total Comprehensive Tissue Banks	538	576	315	595	
Total Surgical Bone Banks		281			
Total Musculoskeletal Tissue Banks		626	108	939	
Total Tissue Specific Banks		20			
Sub-Total Known Supply	**541**	**1,503**	**423**	**1,534**	**0**
Unknown Supply—Method #1A—Unknown Surgical Bone—50% extrapolation rate		5,055			
Unknown Supply—Method #3A—Sales of Demineralized Bone Products—4 company extrapolation					24,175
Total Estimated Supply Bone	**541**	**6,558**	**423**	**1,534**	**24,175**

***Note**: For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Table 33. Estimated Supply of Bone Allograft Tissue Products in Canada: Methods #1, 2 and 3 (Lower Range)

Source	Cancellous Ground Bone	Cancellous Bone	Small Structural	Large Structural	Demin. Bone Products*
Total Comprehensive Tissue Banks	538	576	315	595	
Total Surgical Bone Banks		281			
Total Musculoskeletal Tissue Banks		626	108	939	
Total Tissue Specific Banks		20			
Sub-Total Known Supply	**541**	**1,503**	**423**	**1,534**	**0**
Unknown Supply—Method #1B—Unknown Surgical Bone—25% extrapolation rate		2,558			
Unknown Supply—Method #2B—Cancellous Bone Imports for Total Hip and Knee Joint Revisions		648			
Unknown Supply—Method #3B—Sales of Demineralized Bone Products—2 company extrapolation					12,088
Total Estimated Supply Bone	**541**	**4,709**	**423**	**1,534**	**12,088**

***Note**: For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Table 34. Estimated Supply of Bone Allograft Tissue Products in Canada: Methods #1 and 4 (Higher Range)

Source	Cancellous Ground Bone	Cancellous Bone	Small Structural	Large Structural	Demin. Bone Products*
Total Comprehensive Tissue Banks	538	576	315	595	
Total Surgical Bone Banks		281			
Total Musculoskeletal Tissue Banks		626	108	939	
Total Tissue Specific Banks		20			
Sub-Total Known Supply	**541**	**1,503**	**423**	**1,534**	**0**
Unknown Supply—Method #1A—Unknown Surgical Bone—25% extrapolation rate		5,055			
Unknown Supply—Method #4A –Purchases by Canadian Hospitals—100% extrapolation rate			1,872	39	4,800
Total Estimated Supply Bone	**541**	**6,558**	**2,295**	**1,573**	**4,800**

*__Notes__: 1) For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Table 35. Estimated Supply of Bone Allograft Tissue Products in Canada: Methods #1, 2, and 4 (Lower Range)

Source	Cancellous Ground Bone	Cancellous Bone	Small Structural	Large Structural	Demin. Bone Products*
Total Comprehensive Tissue Banks	538	576	315	595	
Total Surgical Bone Banks		281			
Total Musculoskeletal Tissue Banks		626	108	939	
Total Tissue Specific Banks		20			
Sub-Total Known Supply	**541**	**1,503**	**423**	**1,534**	**0**
Unknown Supply—Method #1B—Unknown Surgical Bone—25% extrapolation rate		2,558			
Unknown Supply—Method #2B—Cancellous Bone Imports for Total Hip and Knee Joint Revisions		648			
Unknown Supply—Method #4A—Purchases by Canadian Hospitals—75% extrapolation rate			1404	29	3600
Total Estimated Supply Bone	**541**	**4,709**	**1827**	**1,563**	**3,600**

*__Notes__: 1) For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Supply of Tendons and Soft Tissue

Canadian tissue banks reported processing a variety of tendon types and soft tissue (fascia, meniscus, pericardium). The following table details the volume of tendons and soft tissue produced by known tissue banks.

Table 36. Known Supply of Tendons and Soft Tissue

Source	Tendons	Soft tissue
Total for Comprehensive Banks	**393**	**340**
Total for Musculoskeletal Tissue Banks	**73**	**36**
Total Tissue Specific Banks	**-**	**40**
Total Supply of Tendons and Soft Tissue	**466**	**416**

A range of tendon types were produced by Canadian tissue banks and reported in the Supply Survey. Five (5) types of tendons were reported with the most common (~60%) being the achilles tendon and the whole patellar tendon. The following figure illustrates the break down of tendon types.

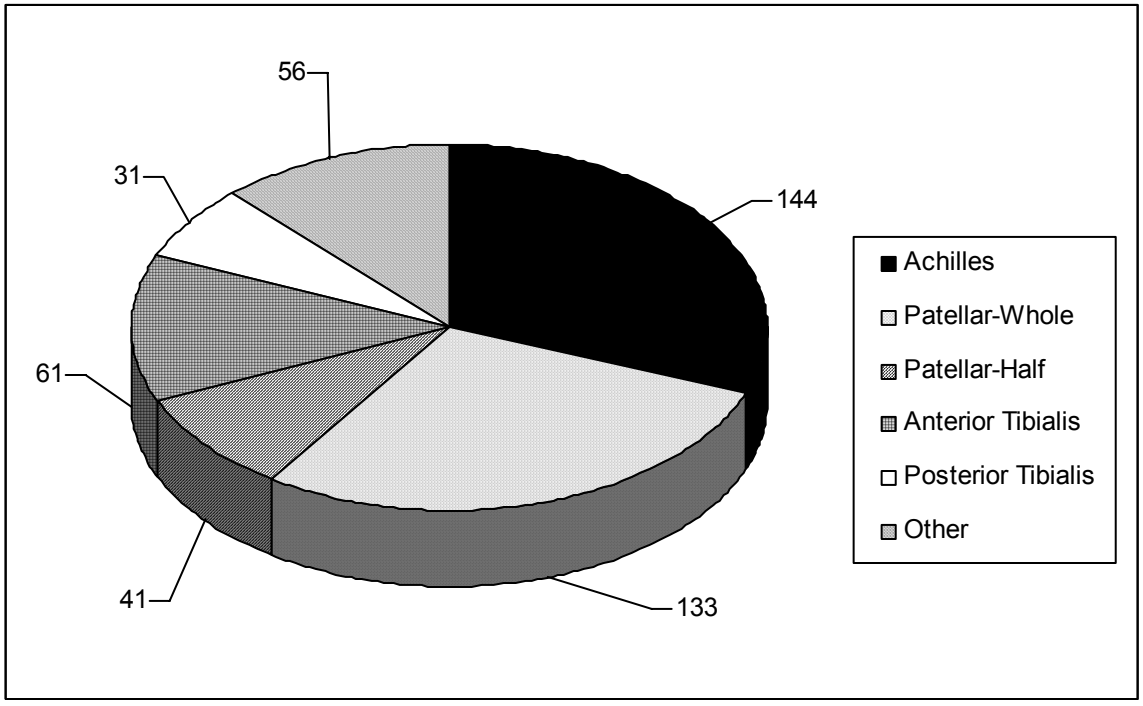


Figure 7. Volume of Tendon Types Produced by Canadian Tissue Banks

The “other” tendon types represented 12% of the total reported and included:

- Peroneus longus
- Quadriceps
- Flexor hallucis longus
- Extensor hallucis
- Fibularis longus

Through interviews with tissue bank representatives and key users it was apparent that the patellar tendon is a commonly requested tendon type. The patellar tendons (whole and half) make up the largest tendon grouping or 37% of the total.

Of the survey respondent banks, only Comprehensive Tissue Banks and Musculoskeletal Tissue Banks produced tendons. The majority of tendons (84%) were produced by the 4 CTB's. For the purposes of this report processed soft tissues included:

- Fascia lata
- Meniscus
- Pericardium

A total of 416 soft tissue grafts were produced of which fascia comprised the largest component (85%). Only 9 or 2% of this total was meniscus. According to users, meniscal transplants are becoming more common. If more than 9 transplants were done in Canada in the past year, it is likely that there is a quantity of allograft menisci being obtained from international sources.

The majority of fascia lata is produced by two Comprehensive Tissue Banks (>82%). Approximately 50% of the menisci are produced 1 CTB and the other 50% by 2 Musculoskeletal Tissue Banks. Pericardium is produced at two centres that both process heart valves.

Supply of Musculoskeletal Tissue (bone, tendons, soft tissue)

Several survey banks processed groups of tissue types that are commonly referred to as "musculoskeletal". The following tissue types are included in this grouping:

- Cancellous ground bone—packages;
- Cancellous bone—femoral condyles hemi and whole, femoral head, humerus head, tibia proximal, other;
- Small structural grafts—Uni-cortical and bi-cortical dowels, tri-cortical wedge, femoral rings, other;
- Large structural grafts—Acetabulum, hemi-pelvis, femur with and without head, proximal femur with and without head, distal femur with condyle, distal femur with flair, femoral shaft and strut, fibula whole and segment, proximal humerus with rotator cuff, proximal humerus with head, humerus shaft, tibia whole, tibial shaft and strut, distal and proximal tibia, other;
- Tendons—Achilles, patellar whole and half, tibialis anterior and posterior, other; and
- Soft tissue—Fascia lata, meniscus, pericardium.

The results of the Supply Survey for musculoskeletal tissue revealed that a total of 4,883 grafts were produced by 4 bank types (CTB, SBB, MSB and TSB). Of this total the CTB's and MSB's produced the most significant portions.

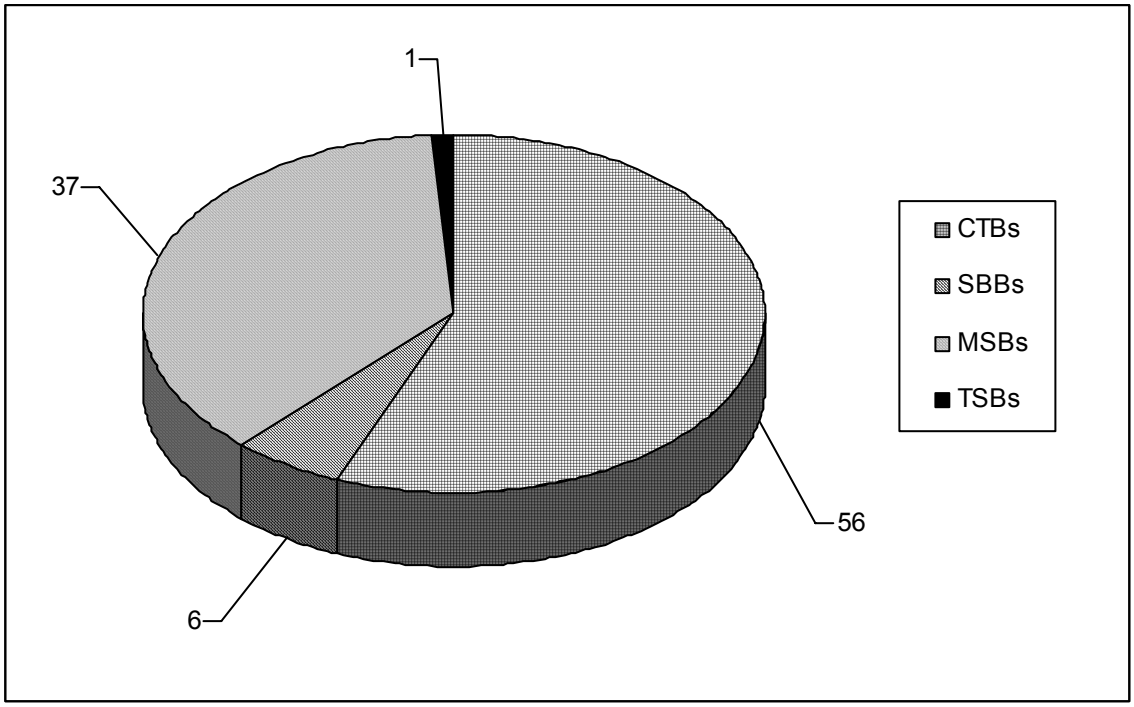
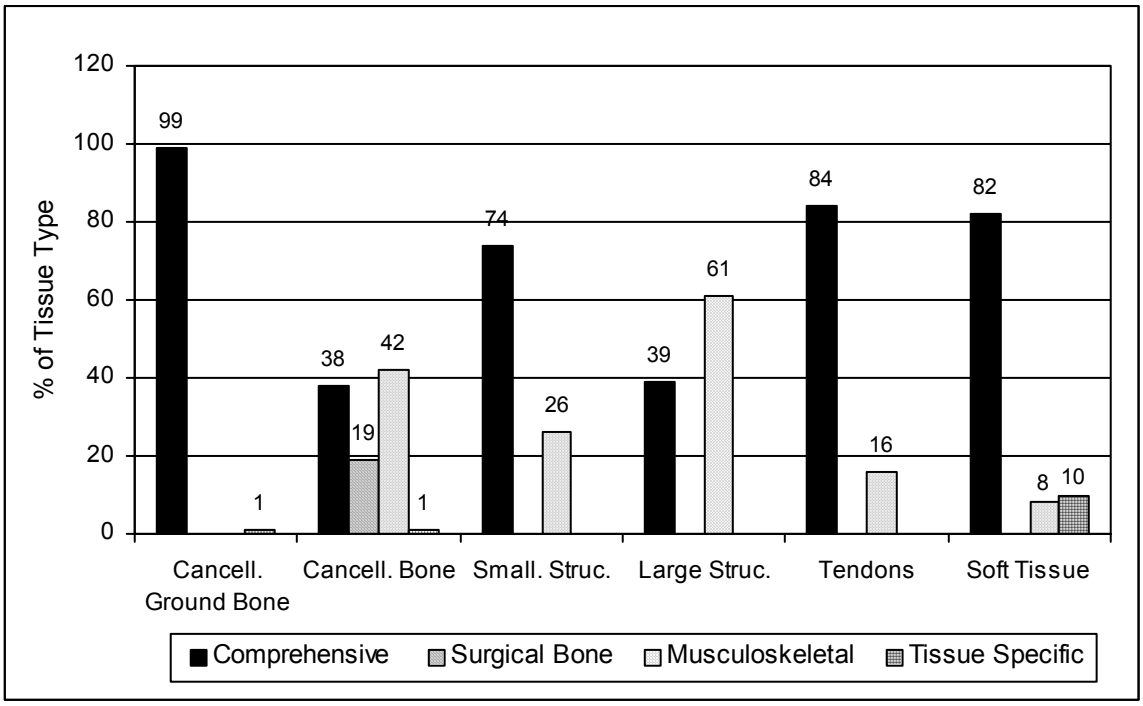


Figure 8. Percentage of Musculoskeletal Tissues Processed by Bank Type

In the following figure, the relative contribution by different bank types to the supply of musculoskeletal tissue is highlighted. CTB's contribute a major proportion of all musculoskeletal tissue types, ranging from 99% of packaged ground bone to 38% of cancellous bone. One (1) of the CTB's produces 86% of the ground bone packages. CTB's also produce 82%–84% of all tendons and soft tissue. The MSB's also contribute to the full range of musculoskeletal products (except cancellous ground bone packages) with significant proportions in the cancellous and large structural bone categories (42% and 61% respectively). The other bank type contributing to musculoskeletal tissue is the Surgical Bone Bank. Known Supply from SBB is 19% of cancellous bone. The total supply from SBB's is likely higher as not all SBB's were included in the survey sample.

Figure 9. Percentage of Musculoskeletal Tissues Processed by Tissue and Bank Type



Although the CTB's contribute significantly to musculoskeletal tissue it is clear that MSB's also play a significant role. In considering models for tissue banking in the future it may be informative to compare these two bank types more closely.

The following table includes a simple comparison using FTE's as a proxy for resource and numbers of grafts produced. In the first comparison, MSB's appear more efficient with a ratio of 154 grafts: 1 FTE; however, this ratio only reflects the musculoskeletal graft production. CTB's also produce cardiovascular and skin grafts.

When these numbers are incorporated, their ratio increases to 268 grafts: 1 FTE.

Table 37. Comparison of Graft Production to Resources by Bank Type

Bank Type	# MS Grafts Produced	# FTE's	Grafts : FTE's
CTB	2,757	20.5	135 : 1
MSB	1,782	11.8	154 : 1

Bank Type	# All Grafts Produced	# FTE's	Grafts : FTE's
CTB	5,511	20.5	268 : 1
MSB	1,802	11.8	153 : 1

Supply of Cardiovascular Tissue—Known and Unknown

Cardiovascular allograft tissue for transplantation was produced by 3 tissue banks. It was noted that the supply of tissue is affected by quarantine times that may be lengthy due to post-mortem reports returned up to a year later. In addition, it was reported that approximately 40% of retrieved cardiac tissues are typically discarded following testing procedures and quality control measures.

Table 38. Known Supply of Cardiovascular Tissue

Source	Valves	Conduits	Total Grafts
Total for Comprehensive Banks	**73**	**24**	**97**
Total for Tissue Specific Banks	**137***	**15**	**152**
Total Supply of Cardiovascular Tissue	**210**	**39**	**249**

*** based on estimate provided**

A source of supply of allograft heart valves in other countries is explanted hearts (hearts removed from a heart transplant recipient) (Schutt, 1997). Key Informant Interviews to date have indicated that this is not a common source of allograft valves in Canada and that the majority of retrieved valves come from cadaveric donors. Reasons for this are not clear although some concern regarding the pathology of the explanted heart has been cited. Further information on this topic is being collected through the Demand survey.

The following table summarizes the estimated total supply of cardiovascular allograft tissue. Details of the methodology used to derive this estimate may be found in the "Estimation of Canadian Tissue Supply from Unknown Sources, Method #5" section of this report.

Table 39. Estimation of Unknown Supply of Cardiovascular Tissue

	Valves	Conduits	Total Grafts
Known Supply of Cardiovascular Tissue (Supply Survey)	(210)	(39)	(249)
Estimated Total Current Requirement/Usage of Grafts for Adults	476		476
Estimated Total Current Requirement/Usage for Grafts for Paediatrics	270	86	356
Total Estimated Current Supply	**746**	**86**	**832**
Estimate of Unknown Supply of Cardiovascular Tissue in Canada (Imports)	**536**	**47**	**583**

This estimation exercise indicates that the Canadian supply of cardiovascular allograft tissue is insufficient for current needs and that it is likely that more than double the Canadian supply is being imported from other sources.

Supply of Skin Grafts

The results of the Supply Survey indicate that 99% of skin grafts are being produced by 3 of the Comprehensive Tissue Banks.

Table 40. Known Supply of Skin Grafts

Source	Skin
Total for Comprehensive Banks	**2,189**
Total for Tissue Specific Banks	**21**
Total Supply of Skin Grafts	**2,210**

Data received from 1 one of the busiest burn centres in Canada indicated they used 248 skin grafts in one year. Preliminary data from other Canadian burn centres indicates much lower use (20–30 grafts/year). Extrapolating this information across all Canadian centres (15), would indicate that less than 1,000 skin grafts are used per year, and that there would be a surplus of skin allograft tissue in Canada. Despite this, one of the Canadian burn centres reported that they import skin grafts from the U.S..

Supply of Ocular Tissue

The Supply Survey indicates that stand-alone EB's produce 83% of Canada's supply of ocular tissue. The other significant portion is produced by Comprehensive Tissue Banks (14%). Only two banks are producing amniotic membrane and the majority (68%) is produced at one CTB. Information gathered through interviews indicated that this tissue was not always accessible and the need for it would increase in the future.

The following table details the source of ocular tissue grafts by bank type:

Table 41. Known Supply of Ocular Tissue

Source	Corneas	Sclera (whole, ½, and ¼ globe)	Amniotic Membrane	Total Ocular
Total for Comprehensive Banks	**167**	**211**	**90**	**468**
Total for Musculoskeletal Banks	**20**	**-**	**-**	**20**
Total for Eye Banks	**2,355**	**412**	**43**	**2,810**
Total for Tissue Specific Banks	**89**	**-**	**-**	**89**
Total Supply of Ocular Tissue	**2,631**	**623**	**133**	**3,387**

Although several banks indicated that they commonly are not able to meet demand for corneas, review of the HMDB for numbers of procedures using ocular grafts, indicated that grafts used in 2000 were less than the total supply reported in the Supply Survey. This would indicate that there are currently enough corneas available given the number of transplant procedures being performed. Key informants did indicate that OR time poses a significant constraint for corneal transplants and that there may not be corneas available when OR time is available or vice versa.

Other features relating to supply of ocular tissue include:

- Supply Survey results indicate that Eye Banks recovered tissue from over 3,600 cadaveric donors or 63% of all donors reported by survey respondents. Although some of these

donors may not have either consented to, or been eligible to donate other tissues, the success of Eye Banks in recruiting donors presents a potential opportunity for increasing the overall supply of all tissue types in Canada.

- Based on statistics reported by EBAA (2001) and Supply Survey results for 2002 for the same 7 banks, supply of corneal grafts increased by 6%.
- Importation of corneal grafts from the U.S. to Canada was insignificant. Thirteen (13) corneas were imported in 2001 (*Source:* EBAA 2001 Statistical Report).

The remaining portion of the Discussion is focused on: characteristics of Canadian tissue banks, safety of the Canadian supply of allograft tissue and Surgical Bone Banks.

Characteristics of Tissue Banks

During the first phase of the project, the Environmental Scan, it was observed that the tissue domain as it exists today in Canada is fragmented, unregulated, undocumented, lacks national coordination and is underdeveloped when compared to the situation the U.S.

The responses to the Supply Survey and Key Informant Interviews reinforced this observation as illustrated by the following:

- Although 50% of the known tissue banks who responded to the survey are located in Ontario, the most comprehensive banks are not located in central Canada.
- The majority of Canadian tissue is processed in the west (39%), with 36% of tissue being processed in the central portion of the country and 25% processed in the Atlantic region.
- Of the tissues produced in the central region (the most populous area of the country) 50% is ocular tissue.
- There does not appear to be a lack of supply of corneas for transplantation in Ontario (users indicated that OR time is their most significant constraint) while there appears to be a shortage of corneas in the Atlantic region.
- Several users were surprised to learn that CTB's existed within Canada.
- Forty three (43) percent of tissue banks reported only one partnership or affiliation.
- There are no formal mechanisms for consistent information sharing. One user indicated a requirement to import skin due to unavailability within Canada while a tissue banking representative indicated that skin was no longer being procured due to perceived lack of demand.
- The ratio of tissues retrieved to cadaveric donors is approximately 3:1. This likely reflects a lack of formal coordination of tissue procurement efforts.
- Survey data indicates that a significant amount of unprocessed cardiovascular tissue (22%) was exported to the U.S. despite the apparent shortage of cardiovascular tissue (as determined in estimation exercise) and although facilities exist to process this tissue in Canada.
- Only 7 of 28 tissue banks indicated that they are involved in research and development activities.

Safety of the Allograft Tissue Supply

Tissues banking representatives and key users of allograft tissue have expressed concerns about the safety of the Allograft Tissue Supply in Canada.

Observations made during the Environmental Scan phase revealed the following:

- A lack of Canadian standards has resulted in differences in processes and practices among Canadian tissue banks.
- Staff at some health care facilities are uneasy about the use of "informal" surgical bone banks.
- There is no program in place to certify tissue bank technologists in Canada. Currently individuals learn "on the job" and write a certification exam in the U.S. Not all technologists have the opportunity to train at a comprehensive tissue centre.
- The Centre for Disease Control in the U.S. clearly views the risks associated with tissue donation and transplantation as being similar to those associated with blood products and have recommended the same guidelines for screening tissue donors as those used for blood.

Key Informant Interviews highlight the following in relation to safety issues:

- The lack of mandatory Canadian standards is of great concern and there is frustration at the length of time it is taking to implement them.
- There is a high degree of concern that the government does not fully recognize the seriousness of the situation.
- Several interviewees referenced the blood scandal of recent years and the potential for the same situation to occur in relation to allograft tissue.
- Users clearly see benefit to patients in relation to the use of allograft tissue but feel "at risk" in terms of patient safety and potential liability when using allograft. This perceived risk appears to stem from the lack of a formal tissue banking model/ framework, mandatory standards, and education/information concerning tissue procurement, processing, and distribution in Canada.
- Surgeons, who had practiced in the U.S., where they used allograft tissue extensively, were the most comfortable with its use and believed the risks to be extremely low. They did however recognize that the tissue domain is much less developed in Canada.
- Surgeons commented that they are not always confident that their patients truly understand the implications of an allograft transplant and that there should be an independent credible source of information that patients can be pointed to when weighing the pros and cons of alternatives (e.g. the choice between autograft and allograft).
- There was need expressed for a physician education program to provide users with more detailed information about the processes that are in place to ensure safety in relation to the tissue supply in Canada.

The concerns expressed by users are reflected by the information collected in the Supply Survey.

Staff Certification
Respondents reported a total of 58.9 FTE's dedicated to tissue banking activities. These FTE's are represented by 52 full time and 143 part time staff. Of the staff involved in tissue banking, 34 are AATB certified and 17 are EBAA certified. Cer

The table below provides an overview of the certification status by bank type. The Comprehensive and Tissue Specific banks have the highest percentage of certified staff to total full and part time staff members. It should be noted that Surgical Bone Banks reported no certified staff. In addition, many Surgical Bone banks were unable to provide any staffing data.

Table 42. Certification as Percentage of Full and Part Time Staff

Bank Type	# Full and Part Time Staff	# AATB Certified	# EBBA Certified	% of Total Staff Certified
Total for all Types of Tissue Banks	**195**	**34**	**17**	**26%**

Note: Readers should note that the nature of the tasks performed by the various individuals contributing time to tissue banking activities, and whether these tasks would normally be associated with certification, is not known.

Tissue Bank Accreditation
Only Eye Banks have a current accreditation rate of over 50%. Five (5) out of 8, or 63% of Eye Banks are EBAA accredited. Comprehensive Tissue banks are next with 2 of 4, or 50% holding AATB accreditation.

Eleven (11) percent of respondents indicated that they are currently in compliance with the draft Canadian standards. The time indicated to comply ranges from 1 month to 24 months.

Information Systems
Most respondents (75%) reported some level of automation in terms of information systems however the large majority of these systems are stand-alone and in-house developed. There is no national system to facilitate consistency in terms of data gathering, information sharing, research and/or consistent application of standards, algorithms and/ or best practices. All of these functions are critical to a safe supply of allograft tissues.

Review of literature relevant to allograft tissue safety in the U.S. indicates that tissue transplants have had a remarkably good safety record. While incidents of disease transmission have occurred they are few and far between. The table below provides a summary of some recent relevant literature.

Table 43. Literature Relevant to the Safety of Allograft Tissue

Document	Author/Source	Summary/Relevance to Supply
Benefits of Musculoskeletal Allograft Tissue Outweigh Risks	American Academy of Orthopaedic Surgeons (AAOS)—February 6, 2003	This new release addresses the concerns about the safety of allograft tissue expressed by many users. • Main message "Patients need not be afraid of receiving allograft tissue transplants was the message during a media briefing held today at the American Academy of Orthopaedic Surgeons' 70th Annual Meeting in New Orleans, La.". • Document indicated that the risks from allograft are extremely low but emphasizes that tissues must come from banks following best practices such as those with AATB accreditation. • Over 800,000 grafts are performed per year in the United States with few complications. • Advantages of allografts cited include: – Eliminates need for second surgery site. – Eliminates need to sacrifice normal structure in one location for another. – Reduces complications from having another procedure (e.g. blood loss, pain, recovery time). • Indicated that users have a responsibility to know where their hospital or practice acquires allografts.
Musculoskeletal Allograft Tissue Safety	American Academy of Orthopaedic Surgeons—69th Annual Meeting, February 13–17, 2002, Dallas Texas. Michael, J. Joyce, M.D., A. Seth Greenwald, D. Phil. (Oxon), Jeanne Mowe, Jeanie Kennedy, Christine S. Heim, B.Sc., Randy N. Rosier, M.D., Ph.D.	Discusses responsibility of surgeons in relation to use of allograft tissue. • Musculoskeletal allograft usage has increased significantly in reconstructive orthopaedic procedures (approximately 350,000 grafts in 1990 to approximately 800,000 grafts in 2000). • Surgeon knowledge of tissue banking practices in important. Surgeons also must inform patients of risks and benefits. • Provides overview of episodes of Documented Disease Transmission: – Over 4,000,000 allografts safely transplanted over past decade in U.S. – Reported disease transmission: ▪ 1953—Tuberculosis—One case (4 recipients) ▪ 1988—Misc. Infections—Three cases ▪ 2001—Misc. Infections—Five cases under investigation

Document	Author/Source	Summary/Relevance to Supply
		▪ 1954—Hep. B One case ▪ 1992—Hep. C One case ▪ 1995—Hep. C Two cases ▪ 1983—HIV One case (Pre-HIV antibody testing) ▪ 1992—HIV Three cases (tissue retrieved in 1985) • Message to surgeons: – Disease transmission is very rare – No reports of disease transmission using demineralized bone products – Inherent safety of graft is based upon Good Tissue Practices – Need for centralized reporting of adverse episodes by surgeons with subsequent investigation and documentation – Outcome studies to improve safety and efficacy – Surgeons need to know the tissue bank – Surgeon/patient interaction regarding risk/benefit is required
Allograft Deemed Safe for Spinal Fusion	American Academy of Orthopaedic Surgeons—Academy News—February 15, 1997	Discusses the use of allograft in patients with idiopathic adolescent scoliosis undergoing posterior spinal fusion and instrumentation. • Complications of iliac harvesting include – Donor site wound problems. – Nerve, arterial or ureteral injury. – Pelvic stress factures or pelvic injury Instability. – Peritoneal perforation or iliac hernia. – Abductor limp. • Without complications the harvest leaves an additional scar and the possibility of a cosmetic deformity. Also adds to post surgical pain, OR time and blood loss. • Allograft carries some risk of disease transmission. “The risk, Dr. Kalen said has most recently been estimated at 1:500,000 for unprocessed bone and virtually nil for processed bone”. • Allograft cost was $800. At one of the study’s two institutions the surgical charge alone for iliac harvest was $1,208 (excluding the cost of OR charge and anaesthesia charges for the increased surgical time). • Studies re: efficacy of allograft: – Dodd, et al reviewed 40 patients—half

Document	Author/Source	Summary/Relevance to Supply
		fused with autograft and half with allograft. At six months no differences in radiographic assessment of bone graft mass or maintenance of corrections. – Belgian report in 1991 reviewed 99 cases of allograft bone in idiopathic scoliosis at one year—found no difference in correction compared to 83 patients receiving autografts.

Surgical Bone Banks

Surgical Bone Banks are typically located in health care organizations where procedures are performed that consistently require allograft bone (e.g. hip and knee joint replacement revisions). These banks obtain their tissue from living donors and are typically staffed by individuals whose primary function within the organization is most likely other than tissue banking.

Seven (7) SBB's responded to the Supply Survey. All were located in one province. It is understood that there are SSBs in other regions of Canada. Collectively these banks retrieved 455 pieces of surgical bone or 29% of the total number of pieces of surgical bone retrieved by all respondents. They processed 281 cancellous bone grafts or 19% of the total cancellous bone grafts processed.

These banks are typically established as a response to local demand. As their users (mainly orthopaedic and neurosurgeons) typically perform procedures that require ongoing supply of allograft bone, it is likely that unknown SBB's comprise a significant portion of the Unknown Supply of allograft bone in Canada.

Key Informant Interviews provided additional information with regard to Surgical Bone Banks as follows:

- Hospital staff have expressed uneasiness about the use of these "informal" tissue banks.
- Some surgeons consider SBB's to be a source of safe allograft tissue due to the typical profile of donors. There is a perception that they are unlikely to be carriers of serious viruses such as Hepatitis C and HIV.
- Surgeons are highly dependent on what they see as an inexpensive source of ongoing supply and would be significantly impacted should this source of tissue not be available.
- SBB's are perceived to be inexpensive to operate.
- Key functions are often allocated across several individuals/departments.

Reponses to the Supply Survey reflected a number of characteristics of SBB's that may be of concern:

- There are very few FTE's dedicated to these banks given the volume of tissues they are producing.
- Many SBB's were unable to provide information concerning staffing levels.
- Currently, no SBB's possess AATB accreditation and none indicated plans to obtain this accreditation in the future.

- There were no AATB certified staff reported by the SBB's.

Given the limited resources of the SSB's it is unlikely that many will be in a position to comply with Canadian standards once they become mandatory. This is of concern as users are dependent on the tissues they provide. Should this source of allograft bone become unavailable without identification of, and access to, an affordable alternative, the result could be problematic for Canadian patients.

Summary

Canadian Tissue Supply

The results of this study, *Supply of Human Allograft Tissue in Canada,* have provided a snapshot of the current Canadian supply of allograft tissue grafts. As measured directly using the Supply Survey, 10,729 grafts comprised of various tissue types, were produced by "known" tissue banks in Canada.

Using estimation methods for the Unknown Supply of various tissue types (bone, cardiovascular), the following ranges of Canadian tissue supply were derived:

1. When incorporating the method based on purchases of bone products from commercial companies (Method #3), additional tissue supply in Canada is estimated to be in the range of 15,877 to 29,814 grafts. Combining the Known and Unknown Supply provides an estimate of total supply in the range of 26,606 to 40,543 grafts (see Table 48 on page 74).
2. When incorporating the method based on purchases of bone products by Canadian hospitals (Method #4), additional tissue supply in Canada is estimated to be in the range of 8,822 to 12,349 grafts. Combining the Known and Unknown Supply provides an estimate of total supply in the range of 19,551 to 23,078 grafts (see Table 49 on page 75).

Note: As this estimate is based on hospital data it does not include purchases made by the Dental Industry (periodontists and private practice oral surgeons).

It should be noted that although it was not considered feasible to estimate the unknown supply of some tissues (small and large structural bones, tendons, soft tissue, ocular and skin), Key Informant Interviews would suggest that there is currently some importation of these tissue types from U.S. sources by Canadian health care organizations. The project team believes that the level of this activity is fairly limited. Key informants frequently cited cost and other constraints, which impact their ability to import tissues.

Importation of Tissue—Demineralized Bone Products

It is clear from this study that a significant portion of the Unknown Supply is Demineralized Bone Product imported into Canada.

Interviews with key users of allograft tissue and hospital personnel revealed that tissue products are routinely purchased from commercial providers (mostly U.S. based companies) and/or their Canadian distributors. Discussions with key informants suggested that the majority of the products imported from the commercial sources are demineralized bone products and bovine/synthetic bone substitutes.

These products are not currently produced in Canada and they are a product preference of many Canadian users including orthopaedic surgeons, neurosurgeons and the Dental Industry. The Dental Industry, comprising periodontists and oral and maxillo-facial surgeons, have been identified through this study as common users of these products.

The following Tables 44 and 45, provide an overview of the total estimated Canadian Tissue supply by combining Known Supply with Unknown or Estimated Supply using estimation methods detailed in the *Estimation of Canadian Tissue Supply from Unknown Sources* section of this report.

Table 44. Total Estimated Supply—Methods #1, 2, 3 and 5

Source	Cancel. Ground Bone	Cancel. Bone	Small Struc-tural	Large Struc-tural	Demin. Bone*	Tendons	Soft Tissue	Cardiac	Skin	Ocular
Compressive Tissue Banks	538	576	315	595		393	340	97	2,189	468
Surgical Bone Banks		281								
Musculoskeletal Tissue Banks	3	626	108	939		73	36			20
Eye Banks										2,810
Tissue Specific Banks		20					40	152	21	89
Total Known Supply	**541**	**1,503**	**423**	**1,534**		**466**	**416**	**249**	**2,210**	**3,387**
Unknown Surgical Bone—Method #1		2,558–5,055								
Unknown—Cancel. Bone Method #2		648—n/a								
Unknown DMB Products—Method #3					12,088–24,176					
Unknown C.V.—Method #5								583		
Total Estimated Unknown Supply		**3,206–5,055**			**12,088–24,176**			**583**		
Total Estimated Canadian Supply	**541**	**4,709–6,558**	**423**	**1,534**	**12,088–24,176**	**466**	**416**	**832**	**2,210**	**3,387**

***Notes**: 1) For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Table 45. Total Estimated Supply—Methods #1, 2, 4 and 5

Source	Cancel. Ground Bone	Cancel. Bone	Small Struc-tural	Large Struc-tural	Demin. Bone*	Tendons	Soft Tissue	Cardiac	Skin	Ocular
Compressive Tissue Banks	538	576	315	595		393	340	97	2,189	468
Surgical Bone Banks		281								
Musculoskeletal Tissue Banks	3	626	108	939		73	36			20
Eye Banks										2,810
Tissue Specific Banks		20					40	152	21	89
Total Known Supply	**541**	**1,503**	**423**	**1534**		**466**	**416**	**249**	**2,210**	**3,387**
Unknown Surgical Bone—Method #1		2,558–5,055								
Unknown—Cancel. Bone Method #2		648–n/a								
Purchases by Canadian Hospitals—Method # 4			1,404–1,872	29–39	3,600–4,800					
Unknown C.V.—Method #5								583		
Total Estimated Unknown Supply		**3,206–5,055**	**1,404–1,872**	**29–39**	**3,600–4,800**			**583**		
Total Estimated Canadian Supply	**541**	**4,709–6,558**	**1,827–2,295**	**1,563–1,573**	**3,600–4,800**	**466**	**416**	**832**	**2,210**	**3,387**

***Notes:** 1) For Demineralized Bone Products one graft has been calculated at a rate of 2.5 cc's.

Current Tissue Banking System in Canada

The results of the Supply Survey, Key Informant Interviews and results of the Environmental Scan reveal that the tissue domain as it exists today in Canada is fragmented, unregulated, undocumented, lacks national coordination and is underdeveloped.

This was evidenced in responses to the Supply Survey and Key Informant Interviews as follows:

- There are regional disparities across Canada in the type and comprehensiveness of tissue services provided.
- There appears to be a general lack of knowledge and awareness of various stakeholders regarding availability and access to Canadian allograft tissue.
- Tissue activities are generally locally managed, funded and monitored with little or no coordination between services and only a minor amount of activity in tissue related research and development agencies.
- Information sharing and data management standards are lacking.
- Potential for tissue donation will not be realized until there are improved processes in place to coordinate tissue procurement activities across agencies and programs.
- There is no mechanism of coordinating supply with demand on a national basis.

Benefits of Comprehensive Tissue Banks in Canada

Of the range of tissue bank types included in this study, the 4 Comprehensive Tissue Banks in Canada produce a significant portion of Canada's tissue supply with the exception of ocular tissue which is well developed by the stand-alone Eye Banks across Canada.

This comprehensive model of tissue banking appears to be very efficient, achieving high volumes of production and maximization of resources. At the same time, CTB's provide services that meet internationally accepted standards for tissue banking through staff certification and accreditation of banks. Although CTB's are not centrally located in Canada they manage transportation of tissue in a safe and timely fashion across Canada.

Surgical Bone Banks

Surgical Bone Banks are typically located in health care organizations where procedures are performed that consistently require allograft bone (e.g. hip and knee joint replacement revisions). These banks obtain their tissue from living donors and are typically staffed by individuals whose primary function within the organization is most likely other than tissue banking.

These banks are typically established as a response to local demand. As their users (mainly orthopaedic and neurosurgeons) typically perform procedures that require ongoing supply of allograft bone, it is likely that unknown SBB's comprise a significant portion of the Unknown Supply of allograft bone in Canada.

SSB's do not have certified Tissue Banking Specialists on staff and are not AATB accredited with no plans to obtain accreditation in the future. It is unlikely that these tissue banks will have the resources to comply with Canadian tissue banking standards once they are mandatory. At

the same time, users are highly dependent on these banks as a source of what they perceive to be convenient and inexpensive cancellous bone.

At the same time, the individuals who manage and administer these surgical bone banks are dedicated individuals who often contribute personal time to ensure ongoing supply to their users and patients. Both the Surgical Bone Bank staff and their users represent potential supporters/resources/clients for a future Canadian Tissue Banking Model.

Safety

The results of the Supply Survey and Key Informant Interviews highlight a number of concerns related to the safety of the Canadian tissue Supply.

There is currently a heightened awareness on the part of the public and key stakeholders regarding the safety issues for tissue transplantation. The recent focus in the press on an Ear Bank in British Columbia that was closed is a case in point. Tissue bank representatives, users and others have stated their frustration with the time it is taking to implement national standards for the tissue domain.

Potential users of tissue products express concern regarding safety and the potential liability/risk involved. There is also some lack of awareness and acknowledgement that a properly managed system of tissue banking would result in extremely low risks for disease transmission.

The results of the Supply Survey substantiate the concerns for the current safety of Canadian tissue as levels of staff certification and bank accreditation are inconsistent across bank types and alarmingly low for some bank types

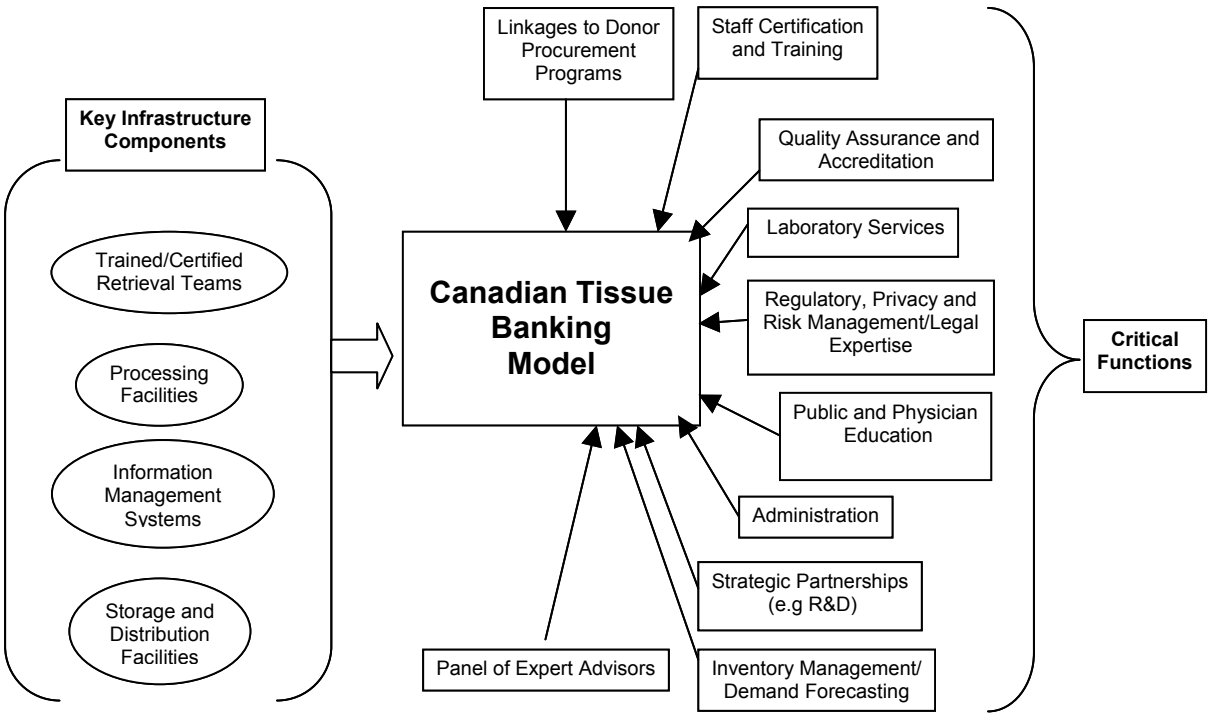
Considerations for a Canadian Tissue Banking Model

The Supply Survey and Key Informant Interviews provided information and data that could contribute to the CCDT's recommendations for a Tissue Banking Model for Canada. This section provides an overview of some of the considerations that have been highlighted by this study.

Key Components of a Tissue Banking Model

Figure 10 below depicts the components that will be critical to establishing a safe, accessible supply of allograft tissue that will benefit all Canadians. These components have been divided into two categories: infrastructure components and critical functions.

Figure 10. Critical Components for a Safe, Accessible, Allograft Tissue Supply



Infrastructure Components

A Canadian Tissue Banking Model will require the following key infrastructure components:

- trained and certified tissue banking specialists,
- processing facilities,
- storage and distribution facilities, and
- information management systems.

Key findings and observations of this study relevant to the above are as follows:

- There are many individuals who are currently involved in critical tissue banking activities who are not certified as Tissue Banking Specialists. A model that employs certified specialists will be key to ensuring the safety of the supply, addressing the safety concerns of users, building confidence in relation to tissues services, and evolving the tissue domain in Canada.
- The greater efficiency of the Comprehensive Tissue Banks was noted in this report. This more robust model allows for the optimization of processing, storage and distribution facilities as well as provides opportunities to minimize overhead through economies of scale. Other advantages include: optimization of resources for tissue retrieval, opportunities to cross train staff, increased ability to consolidate and achieve consistencies with regard to data gathering and management.

It was noted that geography is not necessarily a significant factor in relation to access to tissue. Key Informant Interviews revealed that many users where quite accustomed to receiving tissues from a considerable distance and some commented that with the use of modern shipping processes they could receive product very quickly and efficiently.

- A comprehensive information management system(s) that facilitates information recording/tracking/reporting, performance measurement, and outcomes will be a critical component of a Canadian Tissue Banking Model. The information management model must facilitate the recording and management of:
  - user requests,
  - donor tracking,
  - tissue production,
  - inventory tracking,
  - tissue tracking,
  - audit and QA reports,
  - recording of adverse outcomes,
  - application of distribution algorithms,
  - measurement of performance vs. benchmarks and objectives, and
  - planning functions.

Although 75% of known tissue banks reported some level of automation in relation to information management, the majority of these systems are in-house developed and stand-alone. A comprehensive tissue-banking model will require integrated systems to support critical functions and meaningful reporting.

It may be possible to incorporate some existing databases/registries into the overall information management model. Not only might this be more efficient, it could contribute to the overall

quality and usefulness of the data. Partnership and/or outsourcing opportunities should also be explored in relation to a proposed information management infrastructure. This could reduce the requirement for capital investment and in-house expertise, which is costly to recruit and maintain.

Critical Functions

The following critical functions will be required to support a Canadian Tissue Banking Model:

- Linkages to Donor Procurement Programs;
- Staff Training and Certification;
- Quality Assurance and Accreditation;
- Laboratory Services;
- Regulatory, Privacy, Risk Management and Legal Expertise;
- Public and Physician Education;
- Media/Public Relations;
- Administration (e.g. Finance, HR, Support Staff);
- Strategic Partnerships;
- Inventory Management/Demand Forecasting; and
- Panel of Expert Advisors.

Key findings and observations of this study relevant to the above are as follows:

- This study highlighted the fact that although the Canadian Tissue and Eye Banks interacted with 4,141 cadaveric donors over the most recent 12 month period an average of only 3 tissues was retrieved from each donor. Although this study did not attempt to understand the various consent processes and the suitability of these donors, these numbers do highlight the fact that there are most likely missed opportunities through poor linkages with Donor Procurement Programs and lack of coordination of Tissue Retrieval Teams. In addition, the data would indicate that Eye Banks interact with the majority of cadaveric donors. A more comprehensive model would likely contribute to the maximization of the potential for a wide range of tissues to be retrieved from the current donor base.

- It will be critical for a future Canadian Tissue Banking Model to address safety concerns both from a user and a public perspective. This will contribute to an increased level of confidence, allowing the model to evolve and resulting in further benefit to Canadians. The functions that will contribute to this objective include, Staff Training and ultimately a process to certify Tissue Banking Specialists in Canada, Quality Assurance and Accreditation, Public and Physician Education, and Media/Public Relations.
  - One of the most critical functions to address safety issues is staffing practices that provide adequate training and require certification. In addition, Canadian tissue banks should be accredited and allocate adequate resources to ongoing QA activities and preparation for the renewal of relevant accreditations.
  - During interviews users indicated that they require a better understanding of tissue banking (process and procedures) in order to confidently recommend allograft tissue to their patients. In addition, they require a source of information (e.g. Web Site) to point patients to so that they better understand what receiving an allograft transplant means.

  - A public and physician education program would serve two purposes; to educate the physician community concerning tissue banking standards, testing and the rigorous QA process that carried out by a certified tissue bank, and to provide the public with more information on tissue donation, tissue banking and the facts concerning the use of an allograft tissue when it is recommended as part of a course of treatment.
  - It was also noted through Key Informant Interviews, that all users and hospital personnel do not necessarily recognize demineralized bone products as an allograft tissue. Although these products are used frequently, it is not clear that recipients consent to and/or are aware that they are in receiving a transplanted tissue when these products are used.

- Recent media exposure in relation to tissue banking has often been focused around negative stories. This may have the effect of alarming both users and the public and ultimately affecting donation rates. Literature reviewed as part of this study indicates that in actual fact tissue transplantation has an incredibly high safety record. It will be critical to employ the use of effective media and public relation strategies/tools to ensure that the facts concerning tissue donation and transplantation are disseminated appropriately.

- The development of a Demand Forecasting function and model will be key to optimizing production and inventory management decisions. In many ways Tissue Banking is a manufacturing process. The provision of an adequate supply of tissue will require the establishment of inventory targets for certain types/sizes of tissue products (e.g. heart valves, large structural grafts). To achieve adequate supply/selection, more donors may be required and more tissue processed and placed in inventory that would otherwise be the case. A surplus of some tissues/products could result. The value associated with these surplus tissues (costs associated with efforts to procure and process) may not be realized until sometime in the future, if at all. This “unrealized value” could put a strain on the system unless consideration is given to a means of unlocking this value—perhaps through providing surplus tissue on a cost recovery basis to other countries that do not have access.
  - An adequate demand forecasting model will need to incorporate many elements: requirements of users, new disease states, changes to existing disease states, trends (e.g. clinical practice, demographics, technology).
  - Changes to constraints on the health care system, etc. Proper management of inventory levels will be key to effective allocation of resources and to ensuring that the highest level of service is provided for the lowest possible cost.

- The obvious comparisons between tissue and blood are difficult to ignore. While both are highly beneficial to Canadians in terms of providing optimal health care, they carry similar risks. The blood system is currently highly regulated and it would appear as though the tissue domain is heading in that direction.
  - The shift to a more regulated environment will require a significant change in the mindset of many of those involved in the transplantation and handling of tissues. Many of the individuals involved in this area have a medical background and may not be familiar with the standards, practices, and degree of diligence involved in dealing with a heavily regulated product.
  - A Canadian model will require Regulatory, Privacy, Risk Management and Legal expertise in order to address the challenges that accompany operating in such an

environment. Other functions that will be required will be standard administrative functions (e.g. Finance, H.R.) as well as services that many tissue banks currently obtain through their home hospitals (e.g. Laboratory Services, Materials Management etc.). There are organizations that currently operate in similar, highly regulated environments (e.g. The Canadian Blood Services). There may be opportunities to partner with these organizations in a manner that would result in cost savings and/or increased efficiencies.

- It would be important for a Canadian Tissue Banking Model to incorporate partnerships with Canadian research programs such as tissue engineering programs. Synergies may exist that will result in mutual benefit and assist to evolve tissue banking in Canada. In addition a panel of experts should be recruited to provide expertise and advice on issues such as product development, future demand, clinical tends and best practices in relation to allograft tissue use.

Other Considerations

This study highlighted the following issues that the CCDT Tissue Committee will want to consider in relation to the establishment of a Canadian Tissue Banking Model:

- The Surgical Bone Banks that exist within Canada do not operate in a manner that will allow them to transition easily to a regulated environment. At the same time, users are highly dependant on these banks as a source of what perceive to be convenient and inexpensive cancellous bone. Sudden unavailability of this source of allograft bone will impact both Canadian patients and users. Consideration will have to be given to transition with regard to an alternative source of supply.

- Consideration should be given to the addition of synthetic products and/or specialized services that might allow for a more robust tissue model ultimately providing more benefit to Canadian users and patients. There are many users that use allograft tissue products in combination with synthetic products (e.g. often demineralized bone products are used in combination with synthetic products that provide structure into which new bone can grow. There are other trends such as kits, which include a prosthesis, such as a cage, in combination with allograft bone filler. Additional, services could include allograft matching. The Musculoskeletal Transplant Foundation (www.mtf.org) provides graft matching services for large structural and osteochondral allografts to ensure best possible contour conformity and sizing.

  – It is possible that revenues from these complimentary products might be used to offset the cost of retrieving, processing and distributing allograft tissues. In additional a greater selection of products and services will allow for “one-stop shopping” discouraging importation.

- Linkages with the Dental Industry could be very beneficial to a Canadian Tissue Banking Model. The Dental Industry (periodontists and oral surgeons) are significant users of allograft bone products. In addition, they posses considerable expertise regarding the successful application of these products. They could contribute significantly to a Canadian Tissue Banking Model both from an advisory perspective and as potential clients.

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