

CANADIAN COUNCIL FOR DONATION AND TRANSPLANTATION



DEMAND FOR HUMAN  
ALLOGRAFT TISSUE IN CANADA  
FINAL REPORT  
MAY 2003

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Canadian Institute  
for Health Information  
Institut canadien  
d'information sur la santé

# **Demand for Human Allograft Tissue in Canada**

**Final Report  
May 2003**

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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 document represents the CCDT Project 4.1 deliverable of “Demand for Human Allograft Tissue in Canada—Final Report”. The Demand study has focused on a range of key users of allograft tissue in Canada (primarily surgical specialists), their product preferences, and predicted use of tissue in the future.

The purpose of this study is:

- to estimate the Current Demand for human allograft tissue (bone, tendons, soft tissue, cardiovascular, ocular and skin) in Canada;
- to estimate predicted demand for allograft tissue in Canada;
- to investigate common procedures using allograft tissue, factors affecting demand; and
- to consider demand in context with Known Supply.

The findings of the Environmental Scan and interviews with key informants pointed to 3 methods for studying demand. These included:

1. Structured interviews with key/high volume users of allograft tissue.
2. Demand Surveys for select User Groups and Tissue Types: structured survey instruments for 5 surgical specialties: (corneal transplant surgeons, orthopaedic surgeons, neurosurgeons, burn specialists/plastic surgeons and cardiac surgeons).
3. Methods for estimating demand of allograft tissue in Canada using existing databases and survey results.

This report provides the results of these methods as well as discussion and key observations based on these results.

Surveys were conducted with known users of allograft tissue, primarily surgical specialists:

- Orthopaedic surgeons
- Neurosurgeons
- Cardiac surgeons
- Corneal transplant surgeons
- Canadian Burn Units/plastic surgeons

Using CIHI sources, the number of potential users nationally and by province in each User Group was determined. Extrapolating respondent demand across 3 ranges results in the following totals of annual demand for allograft tissue:

- Low range—34,442 grafts
- Medium range—48,616 grafts
- High range—62,098 grafts

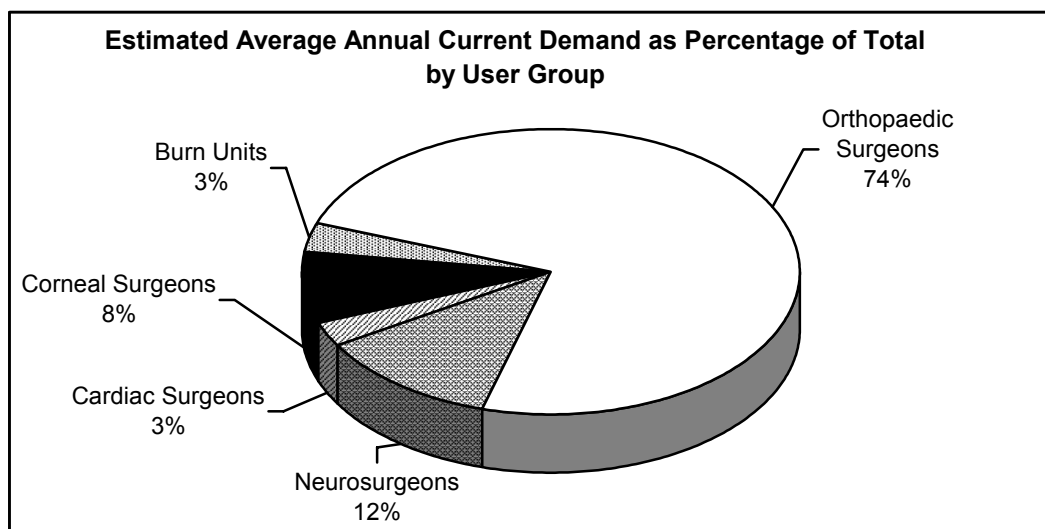
Predicted increases in allograft tissue use over the next 1–2 years across User Groups ranges from a low of 3% for cardiovascular tissue to a high of 36% for soft tissue (fascia lata) used by neurosurgeons. When predicted increases are applied to the extrapolated respondent demand, predicted annual usage of allograft tissue increases as follows:

- Low range—42,589 grafts
- Medium range—60,435 grafts
- High range—72,210 grafts

A summary of the annual Current Demand (across the 3 estimation ranges) by User Group/tissue type is presented in the table below:

Tissue Product	Range of Demand for Orthopaedic Surgeons	Range of Demand for Neurosurgeons	Range of Demand for Cardiac Surgeons	Range of Demand for Burn Units	Range of Demand for Corneal Surgeons
Surgical/Cancellous Bone	7,720–15,441				
Cancellous Bone 50cc packages	2,246–4,493	756–1,133			
Small Structural Grafts	2,024–4,048	1,700–2,550			
Large Structural Grafts	3,319–6,639				
Demin. Bone Products	7,339–14,679	1,313–1,969			
Tendons	1,128–2,255				
Soft Tissues		803–1,204			
Cardio. Tissues			1,089–1,643		
Skin Grafts				1,614	
Ocular Tissues					3,391–4,430
<b>Total</b>	<b>23,776–47,555</b>	<b>4,572–6,856</b>	<b>1,089–1,643</b>	<b>1,614</b>	<b>3,391–4,430</b>

To provide an understanding of the estimated Current Demand associated with each User Group in relation to total Current Demand, the following figure reflects the percentage by User Group based on average demand over the 3 estimation ranges.



When comparing estimated Current Demand versus the Known Supply of Canadian tissue, the predicted shortfall/surplus across the 3 ranges is as follows:

- Low range—annual shortfall of 23,713 tissues or 69% of total extrapolated demand
- Medium range—annual shortfall of 37,887 tissues or 78% of total extrapolated demand
- High range—annual shortfall of 51,369 tissues or 83% of total extrapolated demand

When regional comparisons are made between Known Supply and extrapolated demand at different ranges, the shortfall for various tissue types by region are highlighted. The following table illustrates these differences and it should be noted that the two regions that have Comprehensive Tissue Banks (Atlantic and western Canada) have surpluses for certain tissue types at both lower and higher extrapolation ranges.

Tissue Product	Atlantic		Central		West	
	Low Range	High Range	Low Range	High Range	Low Range	High Range
Cancellous/Surgical Bone	(431)	(1,005)	(4,230)	(9,321)	(1,556)	(3,612)
Cancellous Ground Bone	259		(1,953)	(3,670)	(767)	(1,486)
Small Structural Grafts	14	(184)	(2,302)	(4,166)	(1,013)	(1,825)
Large Structural Grafts	(33)	(279)	(1,263)	(3,453)	(489)	(1,373)
Demineralized Bone Products	(619)	(1,199)	(5,656)	(10,909)	(2,377)	(4,540)
Tendons	(6)	(90)	(673)	(1,415)	17	(284)
Soft Tissues	136	114	(429)	(678)	(94)	(224)
Cardiovascular Tissues	(41)	(79)	(534)	(885)	(265)	(430)
Skin Grafts	848	848	(684)	(684)	432	432
Ocular Tissues	0	(85)	(475)	(1,137)	471	179

**Note:** Numbers in parentheses represent shortfalls.

Of 198 respondents, 57% reported accessing 100% of their tissue from Canadian tissue banks, 15% from United States tissue banks and 19% from a variety of sources. Eight percent (8%) reported accessing 100% of their tissue from "other sources"; the majority of these responses were local surgical bone banks. The most relevant factor related to purchasing tissue outside of Canada was the lack of available tissue in Canada.

The Demand study has also provided important information about user preferences for the characteristics of a preferred supplier of allograft tissue. Users indicate a strong preference to obtain their tissue from an accredited Canadian tissue bank. There was also strong support for a not-for-profit model that provides adequate provider screening for quality standards, recipient tracking and adverse outcome monitoring.

A section of the surveys focused on the trends and technologies that could increase or decrease the use of allograft tissue in the future. Highlights of the responses include the following:

- An aging population, prevalence of obesity and conditions such as osteoarthritis and osteoporosis were cited as factors that will increase demand for allograft tissue.
- A significant use of bone tissue is required for revisions of total hip and knee procedures.
- Osteochondral grafts, if used earlier in the course of degenerative joint disease, may avoid joint replacements later in life.
- The use of autografts, such as iliac crest harvesting for bone is still common practice; however, there appears to be less tolerance for 2<sup>nd</sup> site surgeries with related morbidity.
- Development of biologics such as rh BMP-2 (bone morphogenetic protein) are noted as having a significant potential/contribution in a number of orthopaedic and neurosurgical applications.
- Highly specialized bone grafts, such as machined dowels, rings and struts are being used in spine surgery. Other advancements such as the “cage” for reconstruction of the spine are used in conjunction with allograft bone fillers.
- Development of artificial tissues such as the artificial disc and the artificial cornea could reduce demand for these tissues.

The supply and demand studies have provided a number of opportunities to gain an in-depth understanding of the range of procedures for which human allograft tissue is used, the details of which are documented in this report. In addition, Key Informant Interviews provided invaluable information also detailed within this document.

It is important to consider the concept of Future Demand in relation to allograft tissue. Future Demand may be thought of as the amount of allograft tissue that will be required to meet the needs of all Canadians all of the time. Future Demand is driven by health conditions and is not dependent on the current constraints limiting the use of allograft tissue within Canada.

$$\text{Future Demand} = \text{Current Demand} + \text{Unrealized Demand}$$

Factors that will influence Future Demand for allograft tissue include the following:

- new health conditions (disease, pathology and types of injury);
- new/emerging technologies;
- increases and decreases in health conditions;
- unidentified treatments for known health conditions; and
- changes in clinical standards and practices.



Future Demand incorporates 2 components:

- Current Demand—the allograft tissue required to meet the needs of Canadians whose course of treatment incorporates allograft tissue transplantation.
- Unrealized Demand—the allograft tissue that would be required to meet the needs of those persons who are not yet receiving treatment and may or may not receive treatment using allograft tissue in the future. This component of demand can represent “pent up” demand or demand that has not yet been identified. Unrealized Demand is impacted by a series of factors, which, if unleashed, could result in changes to the level of Future Demand.

The demand project has identified several factors that are currently influencing or constraining the level of Current Demand for allograft tissue in Canada. Significant “unleashing” of these factors will result in an increased requirement for allograft tissue in Canada. To ensure that the tissue banking system is prepared to respond to these changes, demand forecasting will be a critical management activity within a Canadian Tissue Banking Model. The factors identified in this study as likely to impact demand will provide a foundation, or starting point, for the development of this function.

The Demand study provided many opportunities to observe the gaps in relation to data concerning allograft tissue use. The development of a Canadian Tissue Banking Model will provide an excellent opportunity to address these gaps, which include:

- user demand;
- inventory tracking;
- data concerning current use of allograft tissue (graft use—procedure, type of graft);
- donor/recipient tracking; and
- outcomes reporting.

Addressing these gaps in data will provide opportunities to:

- apply equitable allocation algorithms;
- perform research concerning the use of allograft tissue; and
- forecast short and long-term demand.

Through estimating Current Demand, and compiling additional qualitative information, the Demand study represents a key step in addressing the paucity of information concerning the demand for allograft tissue in Canada. In addition, the study provides a foundation on which more detailed studies may be based as the CCDT makes recommendations for a Tissue Banking model of services for Canada.

## 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 December 2002 *Environmental Scan* highlighted a number of important points regarding the topic of Demand. The brief summary on the following page will provide the reader with a flavour for the themes and issues that have been borne out in the results of the *Demand for Human Allograft Tissue in Canada* study.

***Excerpt from Environmental Scan: Supply and Demand of Human Tissue in Canada, CIHI December 2003***

The demand for human allograft tissue is growing both in Canada and around the world. There are many factors contributing to this growth in demand including the following:

- new life saving and life enhancing procedures;
- an aging population;
- an ongoing increase in the indications for use of allograft tissue by surgeons; and
- new products produced by the bio-engineering/bio-technology industries that incorporate human tissue or are used in conjunction with human tissue, thus increasing demand.

Some examples of references to the increase in demand for human tissue, as identified through this environmental scan, include the following:

- Projections indicate that in 10 years 50% of all orthopaedic procedures will involve tissue grafts. (*Source: Tissue Donation—Hackett, July 2001*).
- The demand for human corneas for Penetrating Keratoplasty (PK) has escalated significantly and is expected to continue:
  - 1979—7,900 transplanted;
  - 1984—24,000 transplanted; and
  - 1990—40,000 transplanted.

(*Source: Corneal Surgery-Theory, Technique and Tissue—Mosby, 1993*)

- Comparative United States Transplantation Statistics:

Tissue Type	1984	1990
Corneas	23,500	40,631
Bone	1,000	350,000
Skin	1,000	5,500

(*Source: Corneal Surgery-Theory, Technique and Tissue—Mosby, 1993*)

- United States sales of bone grafts and bone substitutes were over \$500M in 2001 as compared to approximately \$150M in 1997. (*Source: Bone-Graft Substitutes: Facts, Fictions & Applications—American Academy of Orthopaedic Surgeons—February, 2002*).

Clinical experts have estimated that in order to meet the future demands for tissue the donation rate would have to increase by 2.5 times the current rate. Current projections indicate that in 10 years 50% of all orthopaedic procedures will involve tissue grafts.

## Introduction and Purpose

The Demand study 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. This report provides the methods, results, and findings as they relate to the study of *Demand for Human Allograft Tissue in Canada*.

The purpose of this study is:

- to estimate the Current Demand for human allograft tissue (bone, tendons, soft tissue, cardiovascular, ocular and skin) in Canada;
- to predict demand for allograft tissue in Canada;
- to investigate common procedures using allograft tissue, factors affecting demand; and
- to consider demand in context with Known Supply.

The findings of the Environmental Scan and interviews with key informants pointed to 3 methods for studying Demand. These included:

1. Structured interviews with key/high volume users of allograft tissue.
2. Demand Surveys for select User Groups and Tissue Types: structured survey instruments for 5 surgical specialties: (corneal transplant surgeons, orthopaedic surgeons, neurosurgeons, burn specialists/plastic surgeons and cardiac surgeons).
3. Methods for estimating demand of allograft tissue in Canada using existing databases and survey results.

The purpose of this report is to provide the results of these methods, and to provide discussion and observations based on these results.

# Demand Surveys

## Overview of Methodology

The project team recommended a number of strategies to collect data in relation to the demand for human allograft tissue. The primary strategy was the use of structured surveys for target User Groups of allograft tissue.

Through input from CCDT representatives, the outcome of the Environmental Scan and Step 1 Interviews, high volume User Groups were identified as follows:

- orthopaedic surgeons;
- neurosurgeons;
- ophthalmologists, specifically corneal transplant surgeons;
- plastic surgeons, specifically those at Canadian Burn Units; and
- cardiac surgeons—adult and paediatric surgery.

The survey design and content was developed to include consistency across User Groups while at the same time building in unique and customized content where appropriate. The surveys were reviewed by representatives of the various User Groups prior to finalization. In general, all surveys included questions addressing:

- estimated use of allograft tissue over a monthly or yearly period;
- predicted increase or decrease in demand for tissue in the future;
- sources and access to allograft tissue;
- characteristics affecting selection of tissue supplier; and
- trends and emerging technologies affecting demand.

A number of surveys included questions asking for common types of surgical procedures that require allograft tissue. Other surveys were customized based on information gleaned from interviews and recommendations of key informants. For example, the Ocular survey included a question on age of respondent. This was considered important as a number of corneal transplant surgeons are preparing for retirement. There may be a lack of corneal transplant surgeons in the future which will affect demand for corneal and other ocular tissue. Copies of the 5 surveys are included in Appendix A.

Two approaches for establishing survey samples were used:

1. Survey what is believed to be the “universe” of surgeons.
2. Survey a representative sub-set of the user group, those known to be, or highly likely to be users of allograft tissue.

Orthopaedic surgeons are considered to be a high-volume user group, with the potential to significantly increase their use of allograft tissue in the future (particularly if they have improved access to safe, affordable allograft tissue products). For this reason, the project team elected to survey the full “universe” of Canadian surgeons using CIHI sources to identify the list.

The second approach was used for the Ocular, Cardiac, Neurosurgical and Skin surveys. A representative sample of each user group was identified based on criteria recommended by key informants.

The methods for these two approaches are explained in more detail as follows:

1. Demand for Human Bone and Soft Tissue Allograft Products: **Orthopaedic Surgeons.**

A mailing list was created using the *2002 Canadian Medical Directory* listing of orthopaedic surgeons. This source lists 1,156 surgeons.

The list was then modified by a cross-check with the list of the orthopaedic surgeons participating in the Canadian Joint Replacement Register (CJRR). Participants in the CJRR are surgeons who do total hip and/or knee replacements and practice outside of Ontario (see Table 1). There were 14 CJRR participating surgeons who were not listed in the *2002 Canadian Medical Directory*. In addition, 5 CJRR participating surgeons were listed in different provinces from the *2002 Canadian Medical Directory*. For these 19 cases, the CJRR mailing addresses were used.

The list was further refined by deleting 147 orthopaedic surgeons where, in the *2002 Canadian Medical Directory*:

- no mailing address was provided;
- it was identified that the surgeon was semi-retired/retired or had graduated earlier than 1963;
- it was identified that the surgeon was a consultant (workers’ compensation, legal), or an academic with no hospital affiliation; and
- it was identified that the surgeon was a new graduate with no hospital or clinic affiliation.

**Table 1. CJRR Participant Surgeons (Number)**

Province/ Territory	CJRR Participating Surgeons (N)
Alta.	36
B.C.	55
Man.	19
N.B.	25
N.L.	11
N.S.	23
N.W.T.	1
Ont.	0
P.E.I.	3
Que.	78
Sask.	18
<b>Total</b>	<b>269</b>

These deletions did not alter the provincial distribution of surgeons. That is, these exclusions affected each province in proportionately equal ways. The resulting survey mailer consisted of 1,028 surgeons (see Table 2 below for details).

**Table 2. Survey Frame: Orthopaedic Surgeon Tissue Demand Survey**

Province/ Territory	2002 Canadian Medical Directory (N)	Modified by CJRR Participating Surgeons <sup>a</sup>	Modified List (%)	Deleted (N)	Total Mailer (N)	Total Mailer Distribution (%)
Alta.	105	106	9.0%	19	87	8.5%
B.C.	162	163	13.9%	16	147	14.3%
Man.	35	39	3.3%	3	36	3.5%
N.B.	28	31	2.6%	1	30	2.9%
N.L.	13	15	1.3%	0	15	1.5%
N.S.	32	33	2.8%	1	32	3.1%
N.W.T.	1	1	0.1%	0	1	0.1%
Ont.	439	439	37.4%	61	378	36.7%
P.E.I.	3	4	0.3%	0	4	0.4%
Que.	312	314	26.7%	44	270	26.3%
Sask.	26	30	2.6%	2	28	2.7%
<b>Total</b>	<b>1,156</b>	<b>1,175</b>	<b>100.0%</b>	<b>147</b>	<b>1,208</b>	<b>100.0%</b>

<sup>a</sup> There were 14 CJRR participating surgeons who were not listed in the 2002 Canadian Medical Directory. In addition, 5 CJRR participating surgeons were listed in different provinces from the 2002 Canadian Medical Directory. For these 19 cases, the CJRR mailing list was used.

## 2. Demand Surveys for Ocular, Cardiovascular, Musculoskeletal and Skin Allograft Tissue: Corneal Surgeons, Cardiac Surgeons, Neurosurgeons, and Canadian Burn Units.

The method used to identify the survey sample for each of these groups was developed primarily with input from key informants. In addition, key contacts in surgical specialties were identified using CIHI Advisory Group lists and tissue bank contact lists. The approach for each survey differed to some extent and is noted below.

### Ocular Tissue

The most significant user group of ocular tissue is the corneal transplant surgeon group. The Eye Bank Association of American (EBAA) reports that over 90% of ocular procedures using allograft tissue in 2001 involved corneal grafts for transplantation (*Source: EBAA 2001 Eye Banking Statistical Report*). It was recommended that the Canadian sample for this survey include corneal transplant surgeons who perform a minimum of 20–30 corneal transplants per year. Thirty-seven (37) contacts who met this criteria were identified in 7 provinces. This represented approximately 40% of the corneal surgeons who billed for this procedure in 2000–2001.

### Cardiovascular Tissue

At the time of planning the surveys it appeared that the most significant users of cardiovascular tissue were the cardiac surgeons (paediatric and adult surgery). The vascular surgeon group was also considered but through key informants and other sources, the indication was that use of allograft tissue in vascular surgery was limited. For this reason a separate survey was not executed for vascular surgeons.

In order to focus on cardiac surgery, Key Informant Interviews were conducted at leading adult and paediatric centres in Canada. As the procedures and the patterns of allograft tissue use appeared to differ between the adult and the paediatric populations, it was recommended that both groups of surgeons be represented in the survey sample.

Contacts were identified using CIHI advisory group lists for CORR (Canadian Organ Retrieval Registry), and from tissue banks distributing allograft tissue for cardiac surgery. Paediatric cardiac surgery takes place at 5 major centres in Canada: Vancouver, Edmonton, Toronto, Ottawa and Montréal. The project team insured that the survey sample included representatives from each of these centres. Thirty-eight (38) contacts were identified in 5 provinces. Of these, 9 contacts were paediatric surgeons.



## Musculoskeletal Tissue for Neurosurgery

The primary sources for contacts for this survey were tissue banks distributing allograft tissue to neurosurgeons. In addition, CIHI contacts for neurosurgery were added to the list. Thirty-four (34) contacts were identified in 5 provinces. Neurosurgery is a growth area in terms of demand for allograft tissue. A sub-group of neurosurgeons specializes in spine surgery and therefore uses a variety of bone products. Neurosurgeons that specialize in cranial surgery and related procedures are likely to use a greater proportion of soft tissue, i.e. fascia lata. Key informants advised that the largest User Group of neurosurgeons specializes in spinal surgery and makes up approximately 50% to 75% of the total group. The survey sample focused on this group. It should be noted that while this group represents a growth area, the total group (FTE equivalent basis for 2000–2001) totals 170, which is approximately 17% of the size of the orthopaedic surgeon group.

## Skin

The most common use for allograft skin is for treatment of burn patients. Specialists using allograft skin for burn care are plastic surgeons that specialize in burn treatment. There are approximately 15 active burn units in Canada (*Source: American Burn Association Web site—Listing of Canadian Sites*). A survey was sent to the director of each of these burn units.

## Assumptions

The analysis presented in this report is based on the following assumptions:

- health conditions do not vary dramatically across the country;
- clinical practice within a specialty does not vary dramatically across the country; and
- within the various User Groups, data provided by survey respondents will be reasonably representative of the User Group as a whole.

## Limitations

There are several limitations associated with the analysis presented in this report as follows:

- The project was scheduled over an aggressive timeline. As such, it was not possible to perform a complete census of demand across all possible users of allograft tissue in Canada.
- The study was focused on the following User Groups as identified during the planning phase of the project:
  - Orthopaedic surgeons
  - Neurosurgeons
  - Cardiac surgeons
  - Corneal transplant surgeons
  - Plastic surgeons/burn units

- Users in the vascular, urology and dental domains were not surveyed directly. In addition, a range of possible uses by plastic surgery, in areas other than burn care, was not incorporated into the survey process.
- The survey of orthopaedic surgeons was conducted using the “universe” of users. The remaining 4 surveys, directed towards neurosurgeons, cardiac surgeons, corneal transplant surgeons, and Canadian Burn Units, were conducted using a sample of targeted users of allograft tissue. Users were identified in a manner so as to provide sufficient information on which data could be extrapolated. It is understood that these survey samples did not include all users of in-scope allograft tissues within these User Groups.
- Project stakeholders and key users pilot tested the surveys prior to finalization. Enhancements were made to the final design and content of each survey; however, all respondents may not have interpreted each question consistently.
- In some cases survey respondents did not complete some questions/sections. In certain cases this was consistent within a given User Group.
- Many of the questions asked the users to provide data regarding allograft usage or an **estimate** of usage.
- Readers of this report are cautioned that the projections for Canadian demand of allograft tissues contained within this report may be influenced by respondent bias. Respondents may be biased toward frequent users of allograft products and non-respondents may be biased toward those who are less frequent users of allograft tissue. The projections have been calculated across several ranges in an attempt to offset the impact of this potential bias.
- The analysis, extrapolation, and estimation methods provided in this report incorporate the use of existing national databases that may be subject to some inaccuracies.
- In some cases the analysis, extrapolation and estimation methods relies on historical data.

## Response Rates

### 1. Demand for Human Bone & Soft Tissue Allograft Products: **Orthopaedic Surgeons.**

Overall, the response rate was 19.6%, varying from a high of 40.0% in Newfoundland and Labrador to no responses from Prince Edward Island and Northwest Territories. The distribution of the response rates relative to the distribution of the total mailer suggests that Quebec was underrepresented among the surgeons who responded to the survey.

Survey response rate was calculated by deleting the surveys where:

- the survey was returned with an incorrect address (n = 36);
- the respondent indicated the survey was not applicable to his/her practice (n = 2; one respondent had moved out of country and another indicated that he had retired); and
- the survey was not returned by February 25, 2003 (n = 788).

The details of the response rate are provided below in Table 3.

**Table 3. Response Rate: Orthopaedic Survey**

Province/ Territory	Total Mailer (N)	Survey Returned (N)	Response Rate (%)	Response Distribution (%)	Total Mailer Distribution (%)
Alta.	87	22	25.3%	10.9%	8.5%
B.C.	147	30	20.4%	14.9%	14.3%
Man.	36	9	25.0%	4.5%	3.5%
N.B.	30	8	26.7%	4.0%	2.9%
N.L.	15	6	40.0%	2.9%	1.5%
N.S.	32	6	18.8%	2.9%	3.1%
N.W.T.	*	*	0.0%	0.0%	0.1%
Ont.	378	81	21.4%	40.1%	36.7%
P.E.I.	*	*	0.0%	0.0%	0.4%
Que.	270	33	12.2%	16.3%	26.3%
Sask.	28	7	25.0%	3.5%	2.7%
<b>Total</b>	<b>1,208</b>	<b>202</b>	<b>19.6%</b>	<b>100.0%</b>	<b>100.0%</b>

\* Number in table suppressed due to cell size < 5

## 2. Demand for Ocular, Cardiac, Musculoskeletal for Neurosurgery, Skin Allograft Tissue: Corneal Surgeons, Cardiac Surgeons, Neurosurgeons, and Canadian Burn Units.

The response rates for these surveys varied from a low of 32% for the neurosurgery survey to high of 41% for the ocular survey.

Survey response rate was calculated by deleting the surveys where:

- the respondent indicated the survey was not applicable to his/her practice; and
- the survey was not returned by April 11<sup>th</sup>, 2003.

**Table 4. Response Rate: Ocular, Cardiac, Neurosurgery, Burn Units**

Province/ Territory	Ocular Mailed (N)	Ocular Returned (N)	Cardiac Mailed (N)	Cardiac Returned (N)	Neuro Mailed (N)	Neuro Returned (N)	Skin Mailed (N)	Skin Returned (N)
Alta.	*		6	*	10	*	*	
B.C.	7	*	4	*	*	*	*	*
Man.	*	*					*	
N.B.					*	*		
N.L.								
N.S.	*		*		*	*	*	
N.W.T.								
Ont.	17	9	16	8	17	*	6	*
P.E.I.								
Que.	*	*	7	*				
Sask.	*	*					*	
<b>Total</b>	<b>37</b>	<b>15</b>	<b>38</b>	<b>14</b>	<b>34</b>	<b>11</b>	<b>15</b>	<b>5</b>
Response rate		41% **		37%		32% **		33%

**Notes:**

\* Number in table suppressed due to cell size < 5

\*\* Two ocular and 2 neurosurgery surveys were received after the cut-off date. Comments from these surveys have been incorporated into the qualitative report summaries. Due to the late receipt of surveys, data was not included in the quantitative demand results and estimations.

## Results: Survey Respondent Demand

The survey respondents were requested to provide a variety of statistics in relation to their current and predicted use of allograft tissue. The results are presented in the sections that follow.

### Results by Tissue Type and User Group

The sections below provide an overview of demand based on data reported in the Demand Surveys. The information has been organized by tissue type and user group and reflects data as reported by respondents. The data reflected in this section **has not been extrapolated**.

In addition to the statistics reported in the tables, additional data was reported according to specific questions asked in the surveys (in some cases these questions differed based on recommendations from key informants). Examples of these questions included:

- age of respondent;
- tissue specifics such as size, type and preference for cardiac valve replacement;
- use of explanted hearts for valves;
- number of patients requiring allograft skin over past 5 years; and
- general comments reported were reviewed and summarized.

### Musculoskeletal Tissue (Bone, Tendons, Soft Tissue)

The following tables provide an overview of the demand for bone, tendons and soft tissue as reported by orthopaedic surgeon and neurosurgeon respondents.

**Table 5. Demand for Bone Products—As per Survey Responses**

Users	Surgical/ Cancel. Bone per Year	Cancellous Packages (50 cc's) per Year	Small Structural Grafts per Year	Large Structural Grafts per Year	Packages of Demineralized Bone Products per Year
Orthopaedic Surgeons (n = 202)	3,040	885	797	1,307	2,890
Neurosurgeons (n = 9)		80	180		139
<b>Total</b>	<b>3,040</b>	<b>965</b>	<b>977</b>	<b>1,307</b>	<b>3,029</b>

**Table 6. Demand for Tendons and Soft Tissue—As per Survey Responses**

Users	Tendons per Year	Pieces of Fascia Lata per Year
Orthopaedic Surgeons (n = 202)	444	0
Neurosurgeons (n = 9)	0	85
<b>Total</b>	<b>444</b>	<b>85</b>

The following table presents data for all of the musculoskeletal tissues by orthopaedic and neurosurgeons.

**Table 7. Demand for Musculoskeletal Tissue—As per Survey Responses**

Users	Surgical/Cancel. Bone per Year	Cancellous Packages (50 cc's) per Year	Small Structural Grafts per Year	Large Structural Grafts per Year	Demineralized Bone Products per Year	Tendons per Year	Fascia Lata per Year
Orthopaedic Surgeons (n = 202)	3,040	885	797	1,307	2,890	444	
Neurosurgeons (n = 9)		80	180		139		85
<b>Total</b>	<b>3,040</b>	<b>965</b>	<b>977</b>	<b>1,307</b>	<b>3,029</b>	<b>444</b>	<b>85</b>

#### *Neurosurgical Respondents: Additional Results*

In addition to the statistics reported for use of bone and fascia by neurosurgeons, the respondents provided input on access issues and general comments as follows:

#### **Access to Tissue**

Only 1 respondent indicated that an alternative to allograft tissue was required due to lack of availability. For 20% of procedures requiring allograft fascia an alternative was used. Several respondents who are geographically near a comprehensive tissue bank reported no issues of access to cancellous or structural bone. Demineralized bone (DMB) is accessed through commercial companies based in the United States. Price was also a factor affecting access.

#### **General Comments**

The following comments, related to the demand for allograft tissue in neurosurgery were reported in the survey responses:

- 1 respondent indicated preference for use of autograft fascia;
- autografts and/or bovine dowels are used as alternatives to allograft bone;
- allografts for neurosurgery must be sized for appropriate procedures and these are commonly available through commercial companies; and
- 1 respondent noted that recipient tracking/adverse outcome monitoring was a "waste of time".

## Cardiovascular Tissue

The following table presents the data reported by 13 cardiac surgeons and 1 vascular surgeon by tissue type.

**Table 8. Demand for Cardiovascular Tissue—As per Survey Responses**

Users	Aortic Valves per Year	Pulmonary Valves per Year	Conduits per Year	Pieces of Pericardium per Year	Saphenous Veins per Year
Cardiac Surgeons (n = 13) Vascular Surgeon (n = 1)	105	79	111	6	2

### *Cardiac Respondents: Additional Results*

The responses to the Demand survey for cardiovascular tissue included 5 paediatric surgeons (38%) from 3 of 5 centres in Canada that perform paediatric procedures. The responses from those performing surgery on adults represented 7 centres in 4 provinces (B.C., Alta., Ont., Que.). One survey was completed by a vascular surgeon, providing some additional information on the use of conduits for vascular surgery.

The following sections present additional results from the cardiac survey specific to this specialty area, including:

- Demand for Size and Type of Valve for Replacement;
- Access to Allograft Tissue;
- Use of Explanted Hearts for Valves;
- Age Range of Survey Respondents;
- Vascular Surgery; and
- General Comments.

### **Demand for Size and Type of Valve for Replacement**

Access to a variety of valve sizes is an important factor in the use of allograft valves for both paediatric and adult cardiac surgery. The survey asked respondents to indicate the size of allograft valve most commonly used in their practice and to indicate which size was the most difficult to obtain. Information on grouping or standard sizes of valves was obtained from surgeons and tissue banks processing heart valves. The following table provides a listing of the valve sizes and the number of respondents reporting that size.

Data for both adult and paediatric surgery are included under “All surgeons” and “Paediatric” only is split out.

**Table 9. Sizes of Cardiac Valves Used by Cardiac Respondents**

Valve Size	Number of Respondents Indicating Common Use		Number of Respondents Indicating Difficulty Obtaining Size of Graft	
	All Surgeons n = 13	Paediatric n = 5	All Surgeons n = 13	Paediatric n = 5
Small < 14mm	3	3	5	5
Medium 15mm—20mm	6	4	1	1
Large 21mm—24mm	10	3	2	0
Extra Large > 25mm	4	2	3	0

Cardiac surgeons who were interviewed for this study indicated that the most common valves that are replaced using allograft tissue are aortic and pulmonary valves. In addition, they indicated that there are different types of valves (mechanical, xenograft, and allograft) that can be selected for replacement. Different criteria are used for selection of valve type and these range from social-cultural characteristics of the patient, patient health status, evidence on durability of valve type and experience/preference of the surgeon. In addition, there may be differences between the selection of valve type in paediatric versus adult surgery.

The table below provides data on different types of valves that respondents, on average, indicated they use for aortic and pulmonary valve replacement.

**Table 10. Percentage of Use of Valve Types by Cardiac Respondents**

Valve Type	Aortic Valve Percentage of Respondents	Pulmonary Valve Percentage of Respondents
Mechanical	30% (range 5%—100%)	0%
Xenograft	50% (range 0—80%)	50% (range 0—100%)
Allograft	20%*	50% (range 0—100%)

**\*Note:** 4 respondents indicated that the percentage provided (ranging from 25% to 50%) referred to those valves moved from the pulmonary position to the aortic position (as in Ross procedure). Therefore the data provided actually referred to “autograft” not allograft.



### **Access to Allograft Tissue**

The respondents were asked to indicate what percentage of time they had to use an alternative type of valve when they would have preferred allograft (due to lack of supply).

Eight (8) respondents indicated that they had access issues. The percentage of time that they reported having to use an alternative because allograft tissue was not readily available ranged from 5%–99% of the time. The most common issue related to access was the inability to obtain specific sizes of valves. In one instance the respondent noted that, due to chronic lack of supply, they have shifted to using a substitute, the Contegra™ Pulmonary Valved Conduit by Medtronic which is derived from bovine jugular vein. Two other respondents noted that there is no clear evidence that allograft valves have better outcomes than other types.

### **Use of Explanted Hearts for Valves**

A source of supply of allograft heart valves in Canada and other countries is explanted hearts (hearts removed from a heart transplant recipient). Interviews 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. A question in the survey was included to address this topic. Respondents were asked if this was a common practice at their centre, and if not, the reasons why.

Over 50% of respondents indicated that they did not use explanted hearts for valves. The most common reasons cited for this included:

- consent issues;
- safety, risk of contamination;
- cost and liability; and
- previous use of Cryolife to process—no longer due to safety issues.

Administrative reasons were also cited. Two respondents from centres that do not use these valves stated a preference to do so and that there should be no barriers to do so.

### **Age Range of Survey Respondents**

Based on interviews with these surgeons, it was noted that a surgeon's use of allograft tissue could be related to their past experience and preferences for using different types of valves for replacement procedures. It was also noted that the level of technical precision and expertise required to transplant allograft valves is very high. There are limited opportunities to gain this level of expertise. This combined with alternatives for allograft that appear to perform as well, may result in lower rates of use by the next generation of cardiac surgeons.

Based on this information the project team was interested in the age ranges of respondents to gain some understanding of what stage of their careers they are in. Over 55% of both groups (those performing paediatric and those performing adult surgeries) are in the 41–50 year range, or mid-career. It is likely that these groups will be doing surgery for at least 15–25 more years and that their demand for allograft tissue in the near future at least will be similar to that reported in the surveys.

**Vascular Surgery**

One (1) vascular surgeon responded to the Demand survey sent out to the cardiac group. Although the survey was not targeted towards vascular surgeons, some of the questions were relevant to vascular surgery and the information provided some insight into the use of allograft conduits in this domain. Preliminary investigations had indicated that the use of allograft tissue in vascular surgery was limited and for this reason a separate survey was not executed. However, there may be a trend toward allograft use by some of these specialists as indicated in the information provided below, received from the vascular surgeon.

- Uses 1–2 aortic allografts (conduits)/year for replacing infected aortic grafts.
- Uses 1–2 saphenous vein allografts for lower extremity bypass when no other conduit available.
- Uses alternatives 75% of the time when allograft preferred.
- Would use more allograft tissue if available at a reasonable cost.
- Estimates an increase in demand of 200%–300% over next 1–2 years.

**General Comments**

The following comments related to demand for allograft tissue in cardiac surgery were included in the survey responses:

- use of allograft tissue will probably be phased out when tissue engineering becomes practical;
- no clear indication that there will be an increase in the demand for allografts in cardiac surgery;
- there is little evidence that allograft valves have better durability/outcomes compared to alternatives such as xenograft for pulmonary position;
- aortic valve allografts in various sizes are required for emergency replacement procedures (for acute endocarditis); and
- Contegra™ Pulmonary Valved Conduit (bovine jugular vein, valved conduit) is being used as an alternative to allograft to correct congenital defects in the right side of the heart.

## Ocular Tissue

The following table presents the data reported by 13 corneal surgeons by tissue type.

**Table 11. Demand for Ocular Tissue—As per Survey Responses**

Users	Corneas per Year	Sclera per Year	Pieces Amniotic Membrane per Year
Corneal Surgeons (n = 13)	653	44	14

### *Corneal Surgeons: Additional Results*

In addition to the statistics reported for use of corneas, sclera and amniotic membrane, the respondents provided input on wait lists, age ranges and general comments.

### Wait Lists

Survey respondents were asked if they currently had wait lists for procedures requiring allograft tissue. Of the 13 respondents reporting wait list data, an average number was 53 patients (range 0–180). Based on key informant interviews, the common factor affecting numbers on wait lists is access to OR time.

### Age Range of Survey Respondents

Another factor identified in interviews that could potentially affect the demand for allograft tissue for ocular procedures is the age of corneal transplant surgeons. These specialists are concerned that the overall numbers of surgeons performing these procedures are going down and that many are approaching retirement. Although this survey did not include all corneal transplant surgeons, the trend noted in age groups shows that over 50% are over 51 years.

### General Comments

Survey respondents highlighted the following points that were also noted in key informant interviews, the supply component of the study and the Environmental Scan:

- Canadian standards are needed now.
- Increased resources (OR time, tissue availability) are needed to meet increased demand for corneal transplantation in an aging population.
- Increased demand for amniotic membrane which is currently not available or affordable.
- One respondent noted that cases cancelled routinely because of lack of tissue (B.C.). Despite legislation requiring identification of possible donors, hospitals have not implemented this due to lack of resources and resistance to setting up harvesting teams.
- Another respondent commented that the quality of care Canadians receive is sub-standard due to the issues of accessibility and wait times which was considered unacceptable and unnecessary.
- Perception that the United States system is much more reliable and user-friendly.

## Skin

The following table presents the data reported by 5 Canadian burn units.

**Table 12. Demand for Skin Grafts—As per Survey Response**

Users	Average Skin Grafts per Year
Canadian Burn Units (n = 5 )	343

The following sections present additional results from the survey of burn units, including numbers of burn patients requiring allograft tissue and access to allograft tissue.

### Number of Burn Patients Over 5 Year Period

It was evident from Key Informant Interviews that there is a trend for decreasing numbers of burn patients requiring allograft skin (due to improved safety, fewer serious burns). The survey data for a children's burn centre reflects this trend, as does the data from 3 adult centres to a lesser degree.

**Table 13. Burn Patients Requiring Allograft Skin 1996–2000**

Year	Number of Burn Patients Requiring Allograft Skin				
	1996	1997	1998	1999	2000
Children (n = 1 centre) and Adults (n = 3 centres)	38	60	30	30	22

### Access to Allograft Skin

Respondents were asked by what percentage their usage of allograft skin would go up if a safe, reliable supply was available. Three (3) centres indicated that their use would go up between 5% and 40%. The 40% increase was noted by one of the busiest burn centres in Canada.

Respondents were also asked how often they had to use an alternative to allograft tissue because it was not available. Two (2) centres reported 10% and 40% of the time.

Other comments received regarding access include:

- identified need for developing provincial graft procurement teams;
- retrieval of tissue is uncoordinated and often focused on only one tissue, e.g. ocular, bone. This is inefficient and results in less product; and
- skin procurement could be profitable as the dermis is needed by certain companies to develop certain templates.

# Extrapolation of Demand Survey Results

## Introduction

To adjust for the fact that the survey response was less than 100% of surveys mailed, and that the survey sample did not in all cases, reflect the entire “universe” of users, the results of the survey were extrapolated to provide estimates of what the results might have reflected if a greater proportion of users had responded. In all cases it was assumed that data provided by those who responded to the surveys would be representative of the User Group.

## User Groups

For the purpose of this project the User Group is considered to be the number of users in a particular surgical specialty who are most likely to be users of human allograft tissue in Canada.

The User Groups have been defined as follows:

- **Orthopaedic Surgeons:** This survey was forwarded to a list of 1,028 believed to represent all practicing orthopaedic surgeons in Canada. Two surveys were returned indicating that the survey was not applicable. These were eliminated from the total leaving the user group for orthopaedic surgeons in Canada defined as 1,026 surgeons.
- **Neurosurgeons:** The report based on the National Physician Database (NPDB) (*Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI*) has been used to define the user group for Neurosurgeons. This database provides information on the demographic characteristics of physicians and their level of activity within Canada. Physician counts are provided on an FTE basis which incorporates the impact of those who work part-time, are semi-retired etc. For the purposes of this report, the User Group has been defined as the number of FTE neurosurgeons in Canada in 2000–2001 recorded in the National Physician Database which is 170.
- **Cardiac Surgeons:** The report based on the National Physician Database (NPDB) (*Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI*) states that there are 211 FTE cardiovascular and thoracic surgeons billing for procedures in Canada. Only a portion of this group is cardiac surgeons. Using the provincial billing codes for Aortic Valve Replacement and Pulmonary Valve Replacement (common cardiac procedures using allograft tissue), it was determined that there were 94 cardiac surgeons billing for these procedures across Canada in 2000–2001. In order to allocate a percentage of these surgeons to provinces, the Hospital Morbidity Database (HMDB) for 2000 was used to determine the number of procedures done by province. The procedure numbers were then turned into percentages by province which were used to allocate the number of cardiac surgeons.

- **Corneal Surgeons:** The report based on the National Physician Database (NPDB) (*Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI*) states that there are 1,094 FTE ophthalmologists billing for procedures in Canada. Only a portion of this group uses ocular tissue for corneal transplantation. Using the provincial billing codes for Penetrating Keratoplasty (the most common procedure using allograft corneal tissue), it was determined that there were 95 corneal transplant surgeons that billed for corneal transplantations across Canada in 2000–2001. In order to allocate a percentage of these surgeons to provinces, the NPDB report was used to determine the percentage by province for all ophthalmologists.
- **Burn Units.** The User Group was defined as the Canadian Burn Units listed in the American Burn Association directory (Saskatoon was excluded as this unit indicated that anyone requiring allograft would be sent to Edmonton). One additional unit was allocated to Quebec (not listed in ABA). Key informant interviews suggested that any allograft used in Quebec would be used in Montréal. This resulted in a total User Group of 16 Burn Units.

The table below provides a summary of the number of users in each User Group. These numbers will be used as a basis for extrapolation of survey data and predicted demand.

**Table 14. Summary of User Group Numbers for Extrapolation Purposes**

User Group	Number Used for Extrapolation Purposes
Orthopaedic surgeons	1,026
Neurosurgeons	170
Cardiac surgeons	94
Corneal surgeons	95
Burn units	16

## Methodology

Key Informant Interviews, and information gathered during the Environmental Scan Phase of the project, suggested that hospital procedures/budgets, physician preferences, access to allograft tissue (or perceived access), concerns about safety/liability etc. influence allograft usage. As a result, where other options exist, certain users may not be as likely to use allograft tissue as others. To allow for these variations some of the survey data has been extrapolated across a series of ranges. This will provide a picture of what demand might look like at various levels of usage.

The methods of extrapolation across the various User Groups are described below:

- Orthopaedic surgeons (n = 1,026)

Orthopaedic surgeons have a variety of options available to them for many of the procedures they perform. These include synthetic and bovine bone substitutes as well as autografts. Interviews indicated that usage within this group might vary significantly. As a result, the data received from the Orthopaedic surgeon group has been extrapolated across 3 ranges as follows:

- assuming a 50% User Group response rate (n = 513)
- assuming a 75% User Group response rate (n = 769.5)
- assuming a 100% User Group response rate (n = 1,026)

- Neurosurgeons (n = 170)

The Environmental Scan and interview data identified neurosurgery as a growth area in terms of demand for allograft tissue. For many procedures allograft is required the majority (over 50%) of the time. It is also understood that a portion of neurosurgeons specialize in spine surgery and use a variety of bone products. Neurosurgeons that specialize in cranial surgery and related procedures likely use a greater proportion of soft tissue, i.e. fascia lata. It is also understood that there is a proportion of neurosurgeons that use very little allograft tissue. In addition, it is likely that the largest user group of neurosurgeons (specializing in spinal surgery) is approximately 50% to 75% of the total group. As there appears to be a range of uses of different types of tissue across the “universe” of neurosurgeons, the data for this group has been extrapolated across 2 ranges.

- assuming a 50% User group response rate (n = 85)
- assuming a 75% User group response rate (n = 128)

- Corneal Surgeons (n = 95)

Key Informant Interviews suggested that currently, the “average volume” of transplant procedures for corneal transplant surgeons in Canada is approximately 30 per year. This is fairly consistent with the number of surgeons represented in this User Group (95) and the Known Supply of corneas. The respondent data indicated use of ~ 50 corneas per user per year (reported use of 653 corneas by 13 surgeons over the past year). It is possible that the survey response is somewhat biased toward higher volume users. It is also understood that although corneal transplant surgeons are constrained by the challenge of coordinating resources (i.e. OR time) with tissue availability, should additional tissue supply become available, there might be some opportunity to shift non-transplant cases to colleagues, resulting in opportunities to perform additional transplantation procedures. Interestingly, the NPDB report (*Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI*) suggests that in Ontario the FTE Ophthalmologists count is greater than the actual Ophthalmologist count, suggesting that this group of practitioners may be prepared to work on more than a “full-time” basis. This is of note because currently Ontario has 42% of the Known Supply of corneas.

The above factors resulted in a decision to extrapolate the demand for this User Group across 2 ranges, a higher range which reflects a potential to transplant more tissue than is currently available, and a lower range which is more reflective of the typical volume of procedures performed by these specialists. These ranges are as follows:

- assuming a 65% User group response rate (n = 62)
- assuming a 85% User group response rate (n = 81)

- Cardiac surgeons (n = 94)

Information gained from Key Informant Interviews indicated that the use of allograft tissue in cardiac surgery is likely stable and possibly decreasing, particularly for adult surgery. The reasons stated for this included:

- Emerging evidence showing that allograft valves may not be as durable as once thought.
- Chronic issues with access to sizes of valves, particularly the very small (< 12mm) and the very large (> 26mm). This has led to clinicians selecting substitutes/alternatives such as the Contegra™ graft.
- High level of technical skill and expertise required for allograft transplantation may not be obtained by newer generations of physicians.



Although there are procedures where an allograft valve is the only choice (e.g. emergency valve replacement for acute endocarditis), there appear to be a number of emerging technologies and advancements that are changing practice patterns in the selection of allograft tissue. For these reasons extrapolation rates are less than 100%:

- assuming a 50% User group response rate (n = 48)
- assuming a 75% User group response rate (n = 71)

- Burn Units

Interview data suggests that skin grafts are used primarily for serious, third degree burns. There is some use of skin grafts for other applications, such as wound care; however, this use is quite limited in nature. Autograft is always preferable to allograft tissue when treating burn patients although in severe cases it is generally not possible to obtain skin autografts. When allograft is required but not available, alternatives are limited and costly. This would suggest that extrapolating across a series of ranges would not be appropriate. As a result, the demand for allograft skin grafts has been extrapolated across the total user group (defined as 16 burn units).

The data were extrapolated to non-respondent Burn Units based on their similarity to respondent Units (e.g. paediatric units were extrapolated on the basis of paediatric responses, adult unit were extrapolated based on the responses of comparable adult unit respondents).

## Extrapolation by Tissue Type and User Group

The following table presents demand data extrapolated for musculoskeletal tissue and by User Group (orthopaedic and neurosurgeons).

**Table 15. Demand for Musculoskeletal Tissues—Survey Responses Extrapolated**

User Group	Surgical/ Cancel. Bone per Year	Cancellous Packages (50 cc's) per Year	Small Structural Grafts per Year	Large Structural Grafts per Year	Demineralized Bone Products per Year	Tendons per Year	Soft Tissues per Year
<b>50% Extrapolation Rate Across User Group</b>							
Orthopaedic Surgeons—50% extrapolation (n = 513 )	7,720	2,246	2,024	3,319	7,339	1,128	
Neurosurgeons—50% (n = 85)		756	1,700		1,313		803
<b>Total at 50% Extrapolation</b>	<b>7,720</b>	<b>3,002</b>	<b>3,724</b>	<b>3,319</b>	<b>8,652</b>	<b>1,128</b>	<b>803</b>
<b>75% Extrapolation Rate Across User Groups</b>							
Orthopaedic Surgeons—75% extrapolation (n = 769.5 )	11,581	3,370	3,036	4,979	11,009	1,691	
Neurosurgeons—75% extrapolation (n = 128)		1,133	2,550		1,969		1,204
<b>Total at 75% Extrapolation</b>	<b>11,581</b>	<b>4,503</b>	<b>5,586</b>	<b>4,979</b>	<b>12,978</b>	<b>1,691</b>	<b>1,204</b>
<b>100% Extrapolation Rate Across Orthopaedic User Group</b>							
Orthopaedic Surgeons—100% extrapolation (n = 1026 )	15,441	4,493	4,048	6,639	14,679	2,255	
<b>Total at 100% Extrapolation</b>	<b>15,441</b>	<b>4,493</b>	<b>4,048</b>	<b>6,639</b>	<b>14,679</b>	<b>2,255</b>	

The following table presents demand data extrapolated for cardiovascular tissue and by User Group (cardiac surgeons).

**Table 16. Demand for Cardiovascular Tissues—Survey Responses Extrapolated**

Users	Aortic Valves per Year	Pulmonary Valves per Year	Conduits per Year	Pieces of Pericardium per Year
<b>50% Extrapolation Rate Across User Group</b>				
Cardiac Surgeons—50% extrapolation (n = 48)	380	286	401	22
<b>75% Extrapolation Rate Across User Group</b>				
Cardiac Surgeons—75% extrapolation (n = 71)	573	431	606	33

The following table presents demand data extrapolated for ocular tissue by User Group (ophthalmic surgeons).

**Table 17. Demand for Ocular Tissues—Survey Responses Extrapolated**

Users	Corneas per Year	Sclera per Year	Pieces Amniotic Membrane per Year
<b>65% Extrapolation Rate Across User Group</b>			
Corneal Surgeons—65% extrapolation (n = 62)	3,114	210	67
<b>85% Extrapolation Rate Across User Group</b>			
Corneal Surgeons—85% extrapolation (n = 81)	4,069	274	87

The following table presents demand data extrapolated for allograft skin by User Group (burn units).

**Table 18. Demand for Skin Grafts—Survey Response Extrapolated to 16 Burn Units**

User Group	Skin Grafts per Year
<b>100% Extrapolation Rate Across User Group</b>	
Canadian Burn Units (n = 16)	1,614

## Extrapolated Demand by Province and Tissue Type

The tables provided in this section provide an overview of the extrapolated demand organized by province. In all cases, with the exception of allograft skin, the ratio used is based on the allocation across provinces of the full time equivalent physicians who comprise the applicable User Groups. The source for this ratio is the National Physician Database. (Source: *Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI*). The allocation of allograft skin by province has been based on the physical location of the Burn Units.

### Methodology for Extrapolation by Province

It was possible to extrapolate demand data provincially using a variety of methods. The following table outlines the percentage allocation by province. Information sources used to determine these calculations are listed below the table.

**Table 19. Ratios Used for Extrapolation of Demand by Province**

Province	Orthopaedic Surgeons % Allocation by Province <sup>a</sup>	Neurosurgeons % Allocation by Province <sup>b</sup>	Cardiac Surgeons % Allocation by Province <sup>c</sup>	Corneal Surgeons % Allocation by Province <sup>d</sup>	Burn Units % Allocation by Province <sup>e</sup>
N.L.	2	3	0	1	0
P.E.I.	0	0	0	0	0
N.S.	3	1	6	4	13
N.B.	3	2	1	3	0
Que.	27	24	25	25	6
Ont.	39	38	38	39	37
Man.	3	3	1	3	13
Sask.	3	3	4	3	6
Alta.	8	10	10	8	19
B.C.	12	16	15	14	6
<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>

#### Source for Allocation:

<sup>a</sup> National Physician Database (NPDB), Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI).

<sup>b</sup> National Physician Database (NPDB), Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI).

<sup>c</sup> Hospital Morbidity Database (HMDB, 2000, CIHI).

<sup>d</sup> National Physician Database (NPDB), Full-time Equivalent Physicians Report, Canada, 1999/2000 and 2000/2001, CIHI).

<sup>e</sup> American Burn Association website: Listing of Canadian Burn Units + Quebec

### Extrapolated Demand for Tissue by Province and User Group

Table 20 presents the extrapolated demand for musculoskeletal tissue at 3 different ranges for orthopaedic surgeons—50%, 75% and 100%.

**Table 20. Extrapolated Demand for Musculoskeletal Tissues by Province for Orthopaedic Surgeons**

	<b>Surgical/ Cancel. Bone per Year</b>	<b>Cancellous Packages (50 cc's) per Year</b>	<b>Small Structural Grafts per Year</b>	<b>Large Structural Grafts per Year</b>	<b>Demineralized Bone Products per Year</b>	<b>Tendons per Year</b>
<b>Orthopaedic Surgeons 50% Extrapolation Rate (n = 513)</b>						
N.L.	120	35	31	52	114	18
P.E.I.	32	9	8	14	30	5
N.S.	202	59	53	87	192	29
N.B.	222	64	58	95	211	32
Que.	2,095	610	549	901	1,991	306
Ont.	2,994	870	786	1,286	2,846	438
Man.	264	77	69	113	251	39
Sask.	239	70	63	103	228	35
Alta.	625	182	164	269	594	91
B.C.	927	270	243	399	882	135
<b>Total at 50% Extrapolation</b>	<b>7,720</b>	<b>2,246</b>	<b>2,024</b>	<b>3,319</b>	<b>7,339</b>	<b>1,128</b>

**Table 20. Extrapolated Demand for Musculoskeletal Tissues by Province for Orthopaedic Surgeons (cont'd)**

	<b>Surgical/ Cancel. Bone per Year</b>	<b>Cancellous Packages (50 cc's) per Year</b>	<b>Small Structural Grafts per Year</b>	<b>Large Structural Grafts per Year</b>	<b>Demineralized Bone Products per Year</b>	<b>Tendons per Year</b>
<b>Orthopaedic Surgeons 75% Extrapolation Rate (n = 769.5)</b>						
N.L.	180	52	47	77	171	26
P.E.I.	47	14	12	20	45	7
N.S.	303	88	79	130	288	44
N.B.	332	97	87	143	316	49
Que.	3,143	915	824	1,352	2,988	459
Ont.	4,493	1,307	1,178	1,932	4,270	656
Man.	395	115	104	170	376	58
Sask.	359	104	94	154	341	52
Alta.	938	273	246	403	892	137
B.C.	1,391	405	365	598	1,322	203
<b>Total at 75% Extrapolation</b>	<b>11,581</b>	<b>3,370</b>	<b>3,036</b>	<b>4,979</b>	<b>11,009</b>	<b>1,691</b>

**Table 20. Extrapolated Demand for Musculoskeletal Tissues by Province for Orthopaedic Surgeons (cont'd)**

	<b>Surgical/ Cancel. Bone per Year</b>	<b>Cancellous Packages (50 cc's) per Year</b>	<b>Small Structural Grafts per Year</b>	<b>Large Structural Grafts per Year</b>	<b>Demineralized Bone Products per Year</b>	<b>Tendons per Year</b>
<b>Orthopaedic Surgeons 100% Extrapolation Rate (n = 1,026)</b>						
N.L.	240	70	63	103	228	35
P.E.I.	63	18	17	27	60	9
N.S.	404	117	106	173	384	59
N.B.	443	129	116	191	421	65
Que.	4,191	1219	1,099	1,802	3,984	612
Ont.	5,989	1744	1,569	2,575	5,694	874
Man.	527	153	138	227	501	77
Sask.	479	139	126	206	455	70
Alta.	1,250	364	328	538	1,189	183
B.C.	1,855	540	486	797	1,763	271
<b>Total at 100% Extrapolation</b>	<b>15,441</b>	<b>4,493</b>	<b>4,048</b>	<b>6,639</b>	<b>14,679</b>	<b>2,255</b>

Table 21 presents the extrapolated demand for musculoskeletal tissue at 2 different ranges for neurosurgeons—50% and 75%.

**Table 21. Extrapolated Demand for Musculoskeletal Tissues by Province for Neurosurgeons**

	<b>Cancellous Packages (50 cc's) per Year</b>	<b>Small Structural Grafts per Year</b>	<b>Demineralized Bone Products per Year</b>	<b>Tendons per Year</b>	<b>Soft Tissues per Year</b>
<b>Neurosurgeons 50% Extrapolation Rate (n = 85)</b>					
N.L.	21	47	37	0	22
P.E.I.	0	0	0	0	0
N.S.	4	9	7	0	4
N.B.	16	36	28	0	17
Que.	183	413	318	0	195
Ont.	290	650	501	0	308
Man.	22	49	38	0	23
Sask.	26	59	45	0	28
Alta.	77	174	135	0	82
B.C.	117	263	204	0	124
<b>Total at 50% Extrapolation</b>	<b>756</b>	<b>1,700</b>	<b>1,313</b>	<b>0</b>	<b>803</b>



**Table 21. Extrapolated Demand for Musculoskeletal Tissues by Province for Neurosurgeons (cont'd)**

	<b>Cancellous Packages (50 cc's) per Year</b>	<b>Small Structural Grafts per Year</b>	<b>Demineralized Bone Products per Year</b>	<b>Tendons per Year</b>	<b>Soft Tissues per Year</b>
<b>Neurosurgeons 75% Extrapolation Rate (n = 128)</b>					
N.L.	32	71	55	0	34
P.E.I.	0	0	0	0	0
N.S.	6	13	10	0	6
N.B.	24	54	41	0	25
Que.	275	619	478	0	292
Ont.	432	975	753	0	460
Man.	33	73	57	0	35
Sask.	39	88	68	0	42
Alta.	116	262	202	0	123
B.C.	176	395	305	0	187
<b>Total at 75% Extrapolation</b>	<b>1,133</b>	<b>2,550</b>	<b>1,969</b>	<b>0</b>	<b>1,204</b>

Table 22 presents the extrapolated demand for cardiovascular tissue in 2 different ranges—50% and 75%.

**Table 22. Extrapolated Demand for Cardiovascular Tissue by Province for Cardiac Surgeons**

Users	Aortic Valves per Year	Pulmonary Valves per Year	Conduits per Year	Pieces of Pericardium per Year	Total per Year
<b>Cardiac Surgeons at 50% Extrapolation Rate (n = 47)</b>					
N.L.	0	0	0	0	0
P.E.I.	0	0	0	0	0
N.S.	23	17	24	1	65
N.B.	4	3	4	0	11
Que.	95	71	100	6	272
Ont.	144	109	153	9	415
Man.	4	3	4	0	11
Sask.	15	11	16	1	43
Alta.	38	29	40	2	109
B.C.	57	43	60	3	163
<b>Total at 50% Extrapolation</b>	<b>380</b>	<b>286</b>	<b>401</b>	<b>22</b>	<b>1,089</b>
<b>Cardiac Surgeons at 75% Extrapolation Rate (n = 71)</b>					
N.L.	0	0	0	0	0
P.E.I.	0	0	0	0	0
N.S.	34	26	36	2	98
N.B.	6	4	6	0	16
Que.	143	108	152	9	412
Ont.	218	164	230	13	625
Man.	6	4	6	0	16
Sask.	23	17	24	1	65
Alta.	57	43	61	3	164
B.C.	86	65	91	5	247
<b>Total at 75% Extrapolation</b>	<b>573</b>	<b>431</b>	<b>606</b>	<b>33</b>	<b>1,643</b>

Table 23 presents the extrapolated demand for ocular tissue at ranges of 65% and 85% rates of extrapolation.

**Table 23. Extrapolated Demand for Ocular Tissue by Province for Corneal Surgeons**

	Corneas per Year	Sclera per Year	Amniotic Membrane per Year	Total
<b>Corneal Surgeons—65% Extrapolation Rate (n = 62)</b>				
N.L.	33	2	1	36
P.E.I.	9	1	0	10
N.S.	136	9	3	148
N.B.	79	6	2	87
Que.	769	52	16	837
Ont.	1,220	82	27	1,329
Man.	78	5	2	85
Sask.	94	6	2	102
Alta.	255	17	5	277
B.C.	441	30	9	480
<b>Total at 65% Extrapolation</b>	<b>3,114</b>	<b>210</b>	<b>67</b>	<b>3,391</b>
<b>Corneal Surgeons—85% Extrapolation Rate (n = 81)</b>				
N.L.	43	3	1	47
P.E.I.	12	1	0	13
N.S.	178	12	4	194
N.B.	103	7	2	112
Que.	1,004	68	22	1,094
Ont.	1,593	107	34	1,734
Man.	103	7	2	112
Sask.	123	8	3	134
Alta.	334	22	7	363
B.C.	576	39	12	627
<b>Total at 85% Extrapolation</b>	<b>4,069</b>	<b>274</b>	<b>87</b>	<b>4,430</b>

Table 24 presents the extrapolated demand for allograft skin at a rate of 100% extrapolation.

**Table 24. Extrapolated Demand for Allograft Skin by Province for Burn Units**

<b>Number of Skin Grafts per Year</b>	
<b>Burn Units -100% Extrapolation Rate (n = 16)</b>	
N.L.	0
P.E.I.	0
N.S.	202
N.B.	0
Que.	101
Ont.	605
Man.	202
Sask.	101
Alta.	303
B.C.	101
<b>Total at 100% Extrapolation</b>	<b>1,614</b>

## Summary of Extrapolated Data

This section provides a summary of the extrapolated data across 3 ranges:

- Low Range:
  - Orthopaedic surgeons demand extrapolated to 50% of User Group
  - Neurosurgeon demand extrapolated to 50% of User Group
  - Burn Units extrapolated to 100% of User Group
  - Corneal surgeon demand extrapolated to 65% of User Group
  - Cardiac surgeon demand extrapolated to 50% of User Group
- Medium Range:
  - Orthopaedic surgeons demand extrapolated to 75% of User Group
  - Neurosurgeons demand extrapolated to 75% of User Group
  - Burn Units extrapolated to 100% of User Group
  - Corneal surgeon demand extrapolated to 65% of User Group
  - Cardiac surgeon demand extrapolated to 50% of User Group

- High Range:
  - Orthopaedic surgeons demand extrapolated to 100% of User Group
  - Neurosurgeons demand extrapolated to 75% of User Group
  - Burn Units extrapolated to 100% of User Group
  - Corneal surgeon demand extrapolated to 85% of User Group
  - Cardiac surgeon demand extrapolated to 75% of User Group

When selecting the extrapolation rate for the various User Groups to be used to calculate the Medium Range, the project team considered all of the information compiled to date. In each case, the rate selected is the rate believed to be most likely to represent Current Demand for that User Group.

The following Tables 25 to 28 summarize the extrapolated data across the ranges and by province within each range.

Table 25. Summary of Extrapolated Data Across Ranges by User Group

Users	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
Orthopaedic Surgeons—50% of User Group	7,720	2,246	2,024	3,319	7,339	1,128					23,776
Neurosurgeons—50% of User Group		756	1,700		1,313		803				4,572
Burn Units—100% of User Group									1,614		1,614
Corneal Surgeons—65% of User Group										3,391	3,391
Cardiac Surgeons—50% of User Group								1,089			1,089
<b>Total Extrapolated Demand—Low Range</b>	<b>7,720</b>	<b>3,002</b>	<b>3,724</b>	<b>3,319</b>	<b>8,652</b>	<b>1,128</b>	<b>803</b>	<b>1,089</b>	<b>1,614</b>	<b>3,391</b>	<b>34,442</b>
Orthopaedic Surgeons—75% of User Group	11,581	3,370	3,036	4,979	11,009	1,691					35,666
Neurosurgeons—75% of User Group		1,133	2,550		1,969		1,204				6,856
Burn Units —100% of User Group									1,614		1,614
Corneal Surgeons—65% of User Group										3,391	3,391
Cardiac Surgeons—50% of User Group								1,089			1,089
<b>Total Extrapolated Demand—Medium Range</b>	<b>11,581</b>	<b>4,503</b>	<b>5,586</b>	<b>4,979</b>	<b>12,978</b>	<b>1,691</b>	<b>1,204</b>	<b>1,089</b>	<b>1,614</b>	<b>3,391</b>	<b>48,616</b>

Table 25. Summary of Extrapolated Data Across Ranges by User Group (cont'd)

Users	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
Orthopaedic Surgeons—100% of User Group	15,441	4,493	4,048	6,639	14,679	2,255					47,555
Neurosurgeons—75% of User Group		1,133	2,550		1,969		1,204				6,856
Burn Units—100% of User Group									1,614		1,614
Corneal Surgeons—85% of User Group										4,430	4,430
Cardiac Surgeons—75% of User Group								1,643			1,643
<b>Total Extrapolated Demand—High Range</b>	<b>15,441</b>	<b>5,626</b>	<b>6,598</b>	<b>6,639</b>	<b>16,648</b>	<b>2,255</b>	<b>1,204</b>	<b>1,643</b>	<b>1,614</b>	<b>4,430</b>	<b>62,098</b>

Table 26. Summary of Extrapolated Data by Province—Low Range

Province	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
N.L.	120	56	78	52	151	18	22	0	0	36	533
P.E.I.	32	9	8	14	30	5	0	0	0	10	108
N.S.	202	63	62	87	199	29	4	65	202	148	1,061
N.B.	222	80	94	95	239	32	17	11	0	87	877
Que.	2,095	793	962	901	2,309	306	195	272	101	837	8,771
Ont.	2,994	1,160	1,436	1,286	3,347	438	308	414	604	1,329	13,316
Man.	264	99	118	113	289	39	23	11	202	85	1,243
Sask.	239	96	122	103	273	35	28	44	101	102	1,143
Alta.	625	259	338	269	729	91	82	109	303	277	3,082
B.C.	927	387	506	399	1086	135	124	163	101	480	4,308
<b>Total</b>	<b>7,720</b>	<b>3,002</b>	<b>3,724</b>	<b>3,319</b>	<b>8,652</b>	<b>1,128</b>	<b>803</b>	<b>1,089</b>	<b>1,614</b>	<b>3,391</b>	<b>34,442</b>



Table 27. Summary of Extrapolated Data by Province—Medium Range

Province	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
N.L.	180	84	118	77	226	26	34	0	0	36	781
P.E.I.	47	14	12	20	45	7	0	0	0	10	155
N.S.	303	94	92	130	298	44	6	65	202	148	1,382
N.B.	332	121	141	143	357	49	25	11	0	87	1,266
Que.	3,143	1,190	1,443	1,352	3,466	459	292	273	101	837	12,556
Ont.	4,493	1,739	2,153	1,932	5,023	656	460	414	604	1,329	18,803
Man.	395	148	177	170	433	58	35	11	202	85	1,714
Sask.	359	143	182	154	409	52	42	43	101	102	1,587
Alta.	938	389	508	403	1094	137	123	109	303	277	4,281
B.C.	1,391	581	760	598	1627	203	187	163	101	480	6,091
<b>Total</b>	<b>11,581</b>	<b>4,503</b>	<b>5,586</b>	<b>4,979</b>	<b>12,978</b>	<b>1,691</b>	<b>1,204</b>	<b>1,089</b>	<b>1,614</b>	<b>3,391</b>	<b>48,616</b>

Table 28. Summary of Extrapolated Data by Province—High Range

Province	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
N.L.	240	102	134	103	283	35	34	0	0	47	978
P.E.I.	63	18	17	27	60	9	0	0	0	13	207
N.S.	404	123	119	173	394	59	6	98	202	194	1,772
N.B.	443	153	170	191	462	65	25	16	0	112	1,637
Que.	4,191	1494	1,718	1,802	4,462	612	292	412	101	1,094	16,178
Ont.	5,989	2176	2,544	2,575	6,447	874	460	625	604	1,734	24,028
Man.	527	186	211	227	558	77	35	16	202	112	2,151
Sask.	479	178	214	206	523	70	42	65	101	134	2,012
Alta.	1,250	480	590	538	1,391	183	123	164	303	363	5,385
B.C.	1,855	716	881	797	2,068	271	187	247	101	627	7,750
<b>Total</b>	<b>15,441</b>	<b>5,626</b>	<b>6,598</b>	<b>6,639</b>	<b>16,648</b>	<b>2,255</b>	<b>1,204</b>	<b>1,643</b>	<b>1,614</b>	<b>4,430</b>	<b>62,098</b>

## Predicted Demand

Survey respondents were asked if they believed that their use of allograft tissue would increase, decrease or stay the same over the next 1 to 2 years, and by what percentage. Results by User Group are reported in the following tables:

**Table 29. Orthopaedic Surgeons—Predicted Increase in Demand**

Tissue	N	Number of Reporting Increase	Number of Reporting Decrease	Number of Reporting Stay the Same	Percentage Increase
Range of bone types (surgical, cancellous, small and large structural and demineralized) and tendons	184	160	30	213	26%

**Table 30. Neurosurgeons—Predicted Increase in Demand**

Tissue	N	Number of Reporting Increase	Number of Reporting Decrease	Number of Reporting Stay the Same	Percentage Increase
Cancellous bone	7	4	0	3	17%
Demineralized bone	8	5	0	3	23%
Small structural bone grafts	6	4	0	2	26%
Fascia lata	7	6	0	1	36%

**Table 31. Cardiac Surgeons—Predicted Increase in Demand**

Tissue	N	Number of Reporting Increase	Number of Reporting Decrease	Number of Reporting Stay the Same	Percentage Increase
Cardiovascular tissue (valves, conduits, pericardium)	13	4	2	7	3%

**Table 32. Corneal Surgeons—Predicted Increase in Demand**

Tissue	N	Number of Reporting Increase	Number of Reporting Decrease	Number of Reporting Stay the Same	Percentage Increase
Corneas	11	8	0	3	19%
Sclera	10	3	0	7	6%
Amniotic Membrane	8	5	0	3	28%

**Table 33. Canadian Burn Units—Predicted Increase in Demand**

Tissue	N	Number of Reporting Increase	Number of Reporting Decrease	Number of Reporting Stay the Same	Percentage Increase
Skin	5	2	0	3	10%

The following table summarizes the average increase in the use of allograft tissue predicted by the various respondent User Groups over the next 1–2 year period.

**Table 34. Summary—Predicted Percentage Increase in Use of Allograft Tissue (next 1–2 years)**

	Bone	Small Structural Grafts	Dem. Bone Products	Tendons	Fascia Lata	Cardio-vascular Tissue	Skin	Ocular Tissue
Orthopaedic Surgeons	26% <sup>a</sup>		26%	26%				
Neuro-surgeons	17% <sup>b</sup>	26%	23%		36%			
Cardiac Surgeons						3%		
Burn Units							10%	
Corneal Surgeons								18% <sup>c</sup>

**Notes:**

<sup>a</sup> Bone includes surgical bone, cancellous and large structural bone.

<sup>b</sup> Bone includes cancellous bone.

<sup>c</sup> Represents average predicted increase across all Ocular Tissues (corneas, sclera, and amniotic membrane).

The table on the following page provides a summary of the extrapolated demand adjusted for predicted increases in use of allograft tissue over the next 1–2 year period.

Table 35. Summary of Extrapolated Demand Adjusted for Predicted Increase per Year in Use of Allograft Tissue

Extrapolated Demand Ranges	Surgical Bone	Cancellous (50 cc packages)	Small Structural Bone	Large Structural Bone	Demineralized Bone	Tendons	Soft Tissue	Cardio-vascular	Skin	Ocular <sup>b</sup>	Total per Year
	Bone	(50 cc packages)	Structural Bone	Structural Bone	Bone		Tissue	vascular			Year
Low Range	7,720	3,002	3,724	3,319	8,652	1,128	803	1,089	1,614	3,391	34,442
Predicted Increase 1-2 year (%) <sup>a</sup>	26%	26% (O) 17% (N)	26%	26%	26% (O) 23% (N)	26%	36%	3%	10%	18%	
Predicted 1-2 year increase	2007	584(O) 129(N)	968	863	1,908 (O) 302 (N)	293	289	33	161	610	8,147
<b>Total Predicted Demand—Low Range</b>	<b>9,727</b>	<b>3,715</b>	<b>4,692</b>	<b>4,182</b>	<b>10,862</b>	<b>1,421</b>	<b>1,092</b>	<b>1,122</b>	<b>1,775</b>	<b>4,001</b>	<b>42,589</b>
Medium Range	11,581	4,503	5,586	4,979	12,978	1,691	1,204	1,089	1,614	3,391	48,616
Predicted Increase 1-2 year (%)	26%	26% (O) 17% (N)	26%	26%	26% (O) 23% (N)	26%	36%	3%	10%	18%	
Predicted 1-2 year increase	3,011	876(O) 193(N)	1,452	1,295	2,862 (O) 453 (N)	440	433	33	161	610	11,819
<b>Total Predicted Demand—Medium Range</b>	<b>14,592</b>	<b>5,572</b>	<b>7,038</b>	<b>6,274</b>	<b>16,293</b>	<b>2,131</b>	<b>1,637</b>	<b>1,122</b>	<b>1,775</b>	<b>4,001</b>	<b>60,435</b>
High Range	15,441	5,626	6,598	6,639	16,648	2,255	1,204	1,643	1,614	4,430	62,098
Predicted Increase 1-2 year (%)	26%	26% (O) 17% (N)	26%	26%	26% (O) 23% (N)	26%	36%	3%	10%	18%	
Predicted 1-2 year increase	4,015	1,168 (O) 193 (N)	1,715	1,726	3,816 (O) 453(N)	586	433	49	161	797	15,112
<b>Total Predicted Demand—High Range</b>	<b>19,456</b>	<b>6,987</b>	<b>8,313</b>	<b>8,365</b>	<b>20,917</b>	<b>2,841</b>	<b>1,637</b>	<b>1,692</b>	<b>1,775</b>	<b>5,227</b>	<b>77,210</b>

## Notes:

<sup>a</sup> Percentage predicted increase followed by (O) refers to Orthopaedic Surgeon respondent group, (N) refers to Neurosurgeons respondent group.<sup>b</sup> Percentage predicted increase averaged across all ocular tissue types (corneas, sclera, amniotic membrane)

## Sources and Access to Allograft Tissue

Survey respondents were asked about the sources of their allograft tissue. Their responses are outlined in the table below.

**Table 36. Source of Allograft Tissue by User Group**

	Ortho. Surg.	Ortho. %	Neuro. Surg.	Neuro. %	Cardiac Surg.	Cardiac %	Corneal Surg.	Corneal Surg. %	Burn Units	Burn Unit %
Number of Responses 100% Canadian TB	86	53%	6	75%	6	50%	12	92%	3	75%
Number of Responses 100% American TB	27	17%			2	17%	0		0	
Number of Responses 100% "Other"	16	10%			0		0		0	
Number of Responses 100% "Unknown"	3	2%			0		0		0	
Number of Responses Consisting of a Variety of Sources	29	18%	2	25%	4	33%	1	8%	1	25%
<b>Total Number of Responses</b>	<b>161</b>	<b>100%</b>	<b>8</b>	<b>100%</b>	<b>12</b>	<b>100%</b>	<b>13</b>	<b>100%</b>	<b>4</b>	<b>100%</b>

The respondents were asked about the percentage of procedures they currently perform where they their preference would be to use an allograft tissue but where an alternative is utilized because allograft tissue is not readily available. Their responses are outlined in the table below:

**Table 37. Percentage of Procedures User Groups Use Alternative When Allograft Tissue Preferred**

User Group	Number of Responses for User Group	Average Percentage Procedures an Alternative is Used
Orthopaedic Surgeons	165	19%
Neurosurgeons	5	4%
Cardiac Surgeons	13	30%
Burn Units	5	10%
Corneal Surgeons	n/a	n/a

Respondents who purchase allograft from sources other than Canadian Tissue Banks were asked to rank specific factors (1 representing most important and 4 representing least important) in terms of relevance to their decision to purchase outside of Canada. The factors were as follows:

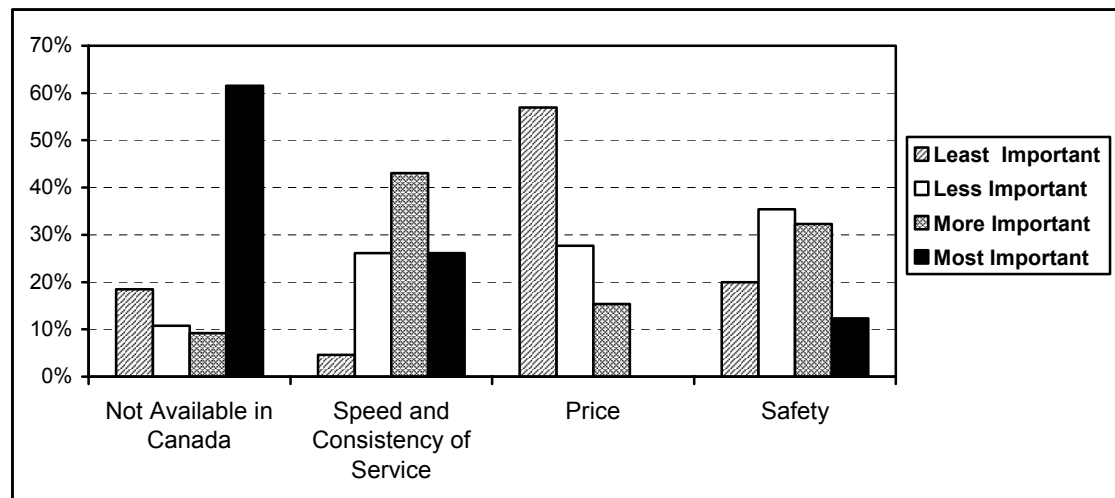
- not available in Canada;
- speed and consistency of service;
- price; and
- safety.

The responses across all User Groups are illustrated in the following table and figure:

**Table 38. Number of Responses Re: Factors for Purchases Outside of Canada**

	Not Available in Canada	Speed and Consistency of Service	Price	Safety
Least important	12	3	37	13
Less important	7	17	18	23
More important	6	28	10	21
Most important	40	17	0	8
<b>Total</b>	<b>65</b>	<b>65</b>	<b>65</b>	<b>65</b>

**Note:** As this question required respondents to rank factors on a scale of 1-4, all incomplete answers were excluded from the results presented above. Several respondents chose not to complete this question, including the majority of corneal surgeons.



**Figure 1. Percentage of Responses Re: Factors Relevant to Purchases Outside of Canada**

## Characteristics Affecting Selection of Supplier

Respondents were asked rate (1 through 7) how strongly factors relating to quality and service would impact their selection of a supplier for allograft tissues. A rating of **1** indicated the factor was not important while a rating of **7** indicated that the factor was very important in terms of selection of a supplier. The factors that were rated appear in the table below:

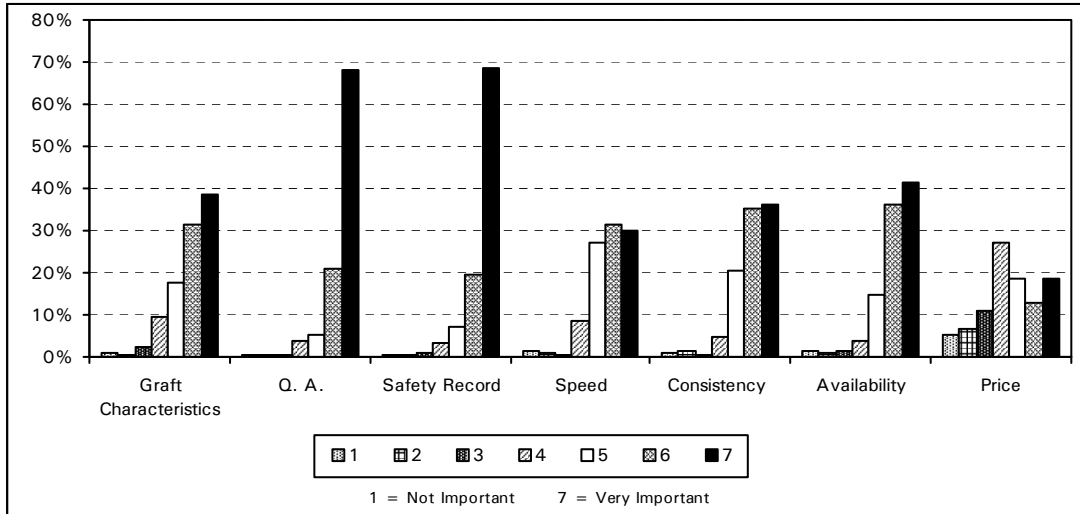
**Table 39. Quality and Service Factors Influencing Selection**

<b>Quality Factors</b>
Graft Characteristics (Ease of application, meets technical expectation)
Quality Assurance Program (Tissue Bank has accreditation status or demonstrated quality programs)
Demonstrated Safety Record (Tissue Bank has a record of taking action to minimize the risk of disease transmission)
<b>Service Factors</b>
Speed of service delivery (Tissue is distributed/received within acceptable timelines)
Consistency of service (Service is provided dependably and reliably each time)
Availability of tissue (Sufficient tissue is always available to meet needs)
Price (Price is lower than competitors)

**Table 40. Numbers of Responses Re: Characteristics Influencing Selection of Supplier**

<b>Rating</b>	<b>Graft Characteristics</b>	<b>QA</b>	<b>Safety</b>	<b>Speed</b>	<b>Consistency</b>	<b>Availability</b>	<b>Price</b>
1	2	1	1	3	2	3	12
2	1	1	1	2	3	2	15
3	5	1	2	1	1	3	24
4	21	9	7	19	11	9	60
5	39	12	16	61	46	33	41
6	70	47	44	70	79	81	29
7	86	153	154	67	81	93	41
<b>Total</b>	<b>224</b>	<b>224</b>	<b>225</b>	<b>223</b>	<b>223</b>	<b>224</b>	<b>222</b>

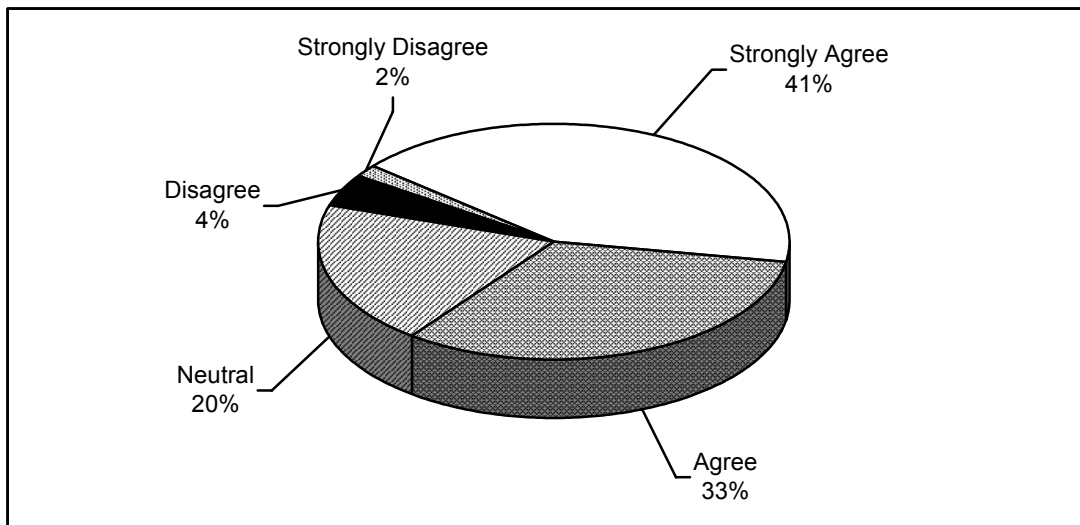




**Figure 2. Percentage of Responses Re: Characteristics Influencing Selection of Supplier**

Respondents were asked to indicate their degree of agreement/disagreement with a series of six statements related to the characteristics of preferred tissue banks.

1. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, I would give preference to the not-for-profit Tissue Bank (n = 233).



**Figure 3. Preference for Not-for-profit Tissue Bank**

- 2. Given a choice between a Canadian and an American tissue bank with comparable quality products I would give preference to the Canadian tissue bank (n = 232).

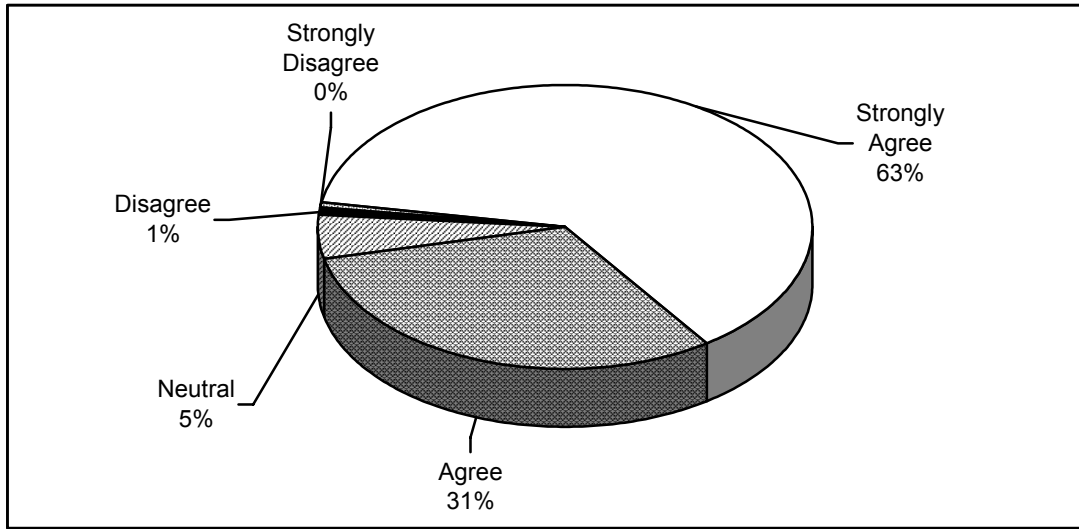


Figure 4. Preference for a Canadian Tissue Bank

- 3. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited tissue bank (n = 224).

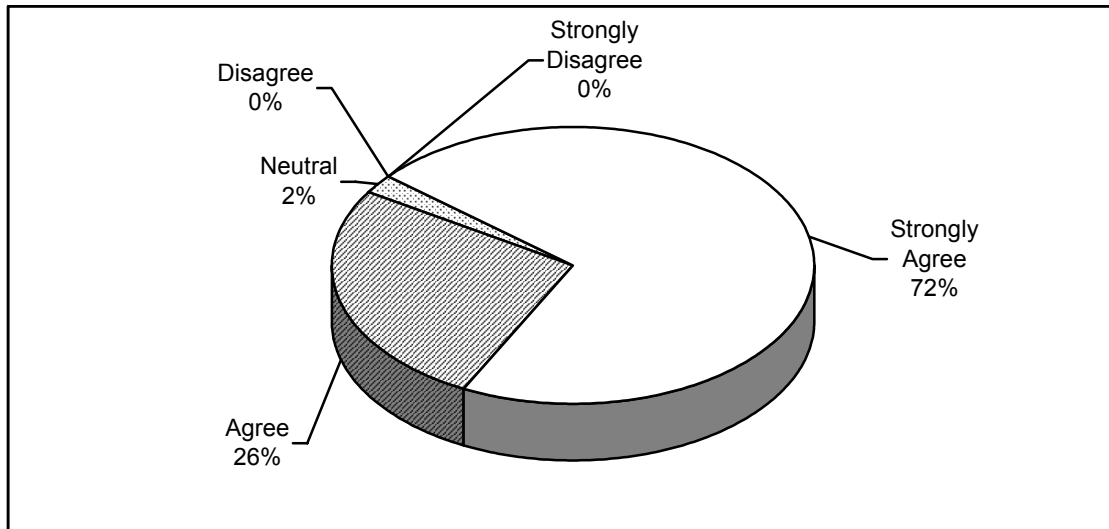


Figure 5. Preference for Accredited Tissue Bank

- 4. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards (n = 227).

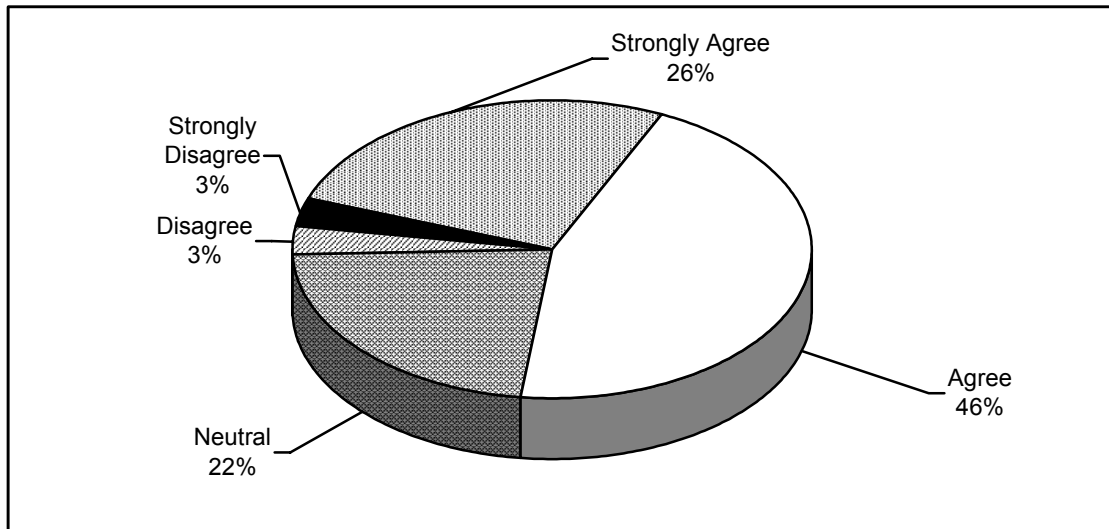


Figure 6. Fee for Service—Screening for Quality Standards

- 5. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring (n = 227).

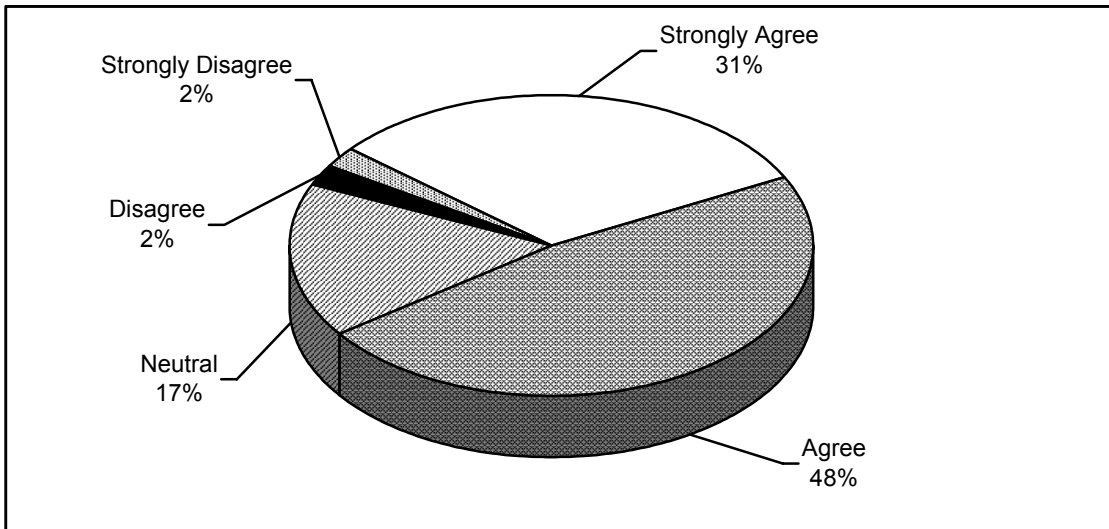
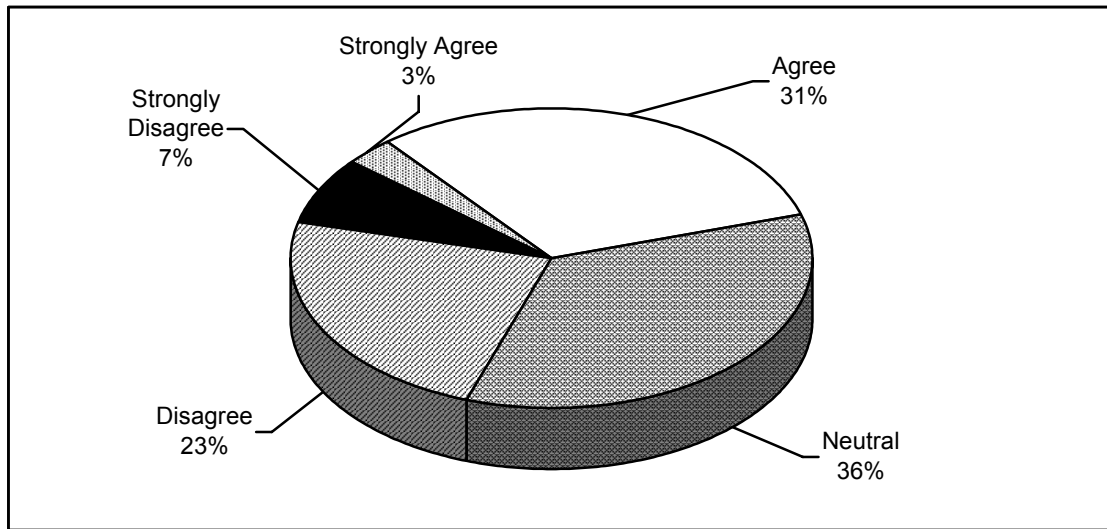


Figure 7. Fee for Service—Tracking and Adverse Outcome Monitoring

6. Tissue banks should be able to generate profits on products they produce from donated tissue (n = 231).



**Figure 8. Tissue Banks Should Generate Profits?**

The following table highlights the trends in responses to the previous 6 questions by grouping the “strongly agree” and “agree” and grouping “strongly disagree” and “disagree”.

**Table 41. Summary of User Preferences Re: Characteristics of Tissue Banks**

	% Strongly Agree or Agree	% Strongly Disagree or Disagree	% Neutral
Preference for not-for-profit TB	74%	6%	20%
Preference for Canadian vs. U.S. TB	94%	1%	5%
Preference for Accredited TB	98%	0%	2%
Fee for service model with screening providers for quality standards	72%	6%	22%
Fee for service model for recipient tracking/ monitoring outcomes	79%	4%	17%
TB generates profits	34%	30%	36%

## Trends and Emerging Technologies Affecting Use of Allograft Tissue

All Demand survey respondents were asked to identify trends and technologies that would impact the use of allograft tissue. The following summary by tissue type provides the information documented on surveys.

**Table 42. Trends and Technologies Affecting Change in Use of Allograft Tissue**

Tissue Type	Trend—Increased Use of Tissue	Trend—Decreased Use of Tissue
<b>Bone/Cartilage</b>		
Cancellous bone (ground and chips)  Demineralized bone  Structural bone  Osteochondral, Peri-articular grafts	Increase in obesity, aging population, osteoarthritis, osteoporosis  Increasing number of procedures: <ul style="list-style-type: none"> <li>• revision of hip/knee arthroplasties</li> <li>• impaction grafting</li> <li>• peri-prosthetic fractures</li> <li>• limb salvage (tumours, trauma)</li> <li>• open wedge osteotomies</li> </ul> Lower tolerance for 2 <sup>nd</sup> site surgery (autograft)  Increased use of specific products (dematerialized bone, bone morphogenic protein, coral, calcium phosphates/sulphates)  Increase in use of combination products (allograft, BMP, osteo-synthetic, bovine)  Trend toward anterior spine surgery which more commonly requires allograft bone  Miniaturized instrumentation for spine surgery for children  Trend toward articular surface repair with osteochondral grafts	Use of bone substitutes (eg. calcium sulphate and synthetic products)  Use of bone graft substitutes in spine surgery (eg. calcium phosphate for fusions)  Use of metal cages in spine surgery  Use of disc arthroplasty  Development of collagen templates for cartilage  Improved modular joint prostheses  Genetic development (stem cell, cloning) for bone defects  Prohibitive cost, concerns about disease transmission and lack of access to allograft tissue  Paediatric orthopaedic surgery—parents concerned about use of allograft bone especially in relation to “commercial” bone banks  Development of biologics such as rh BMP-2, polymer structural resolutions may replace structural allograft

Tissue Type	Trend—Increased Use of Tissue	Trend—Decreased Use of Tissue
	<p>Increased demand for instrumented bone, eg. femoral rings for spinal fusion, struts, dowels, spacers for anterior cervical fusion</p> <p>Development of biologics such as rh BMP-2, polymer structural resolutions may replace structural allograft (results in increase in DMB but a decrease in structural bone)</p>	
<b>Tendons</b>		
<p>Achilles Hamstring Patellar Posterior tibialis Anterior tibialis</p>	<p>Increase in obesity, and aging population</p> <p>Lower tolerance for 2<sup>nd</sup> site surgery (autograft)</p> <p>Increasing number of ligamentous repairs (knee, ankle)</p> <p>Increased use of tissue augmentation (eg. rotator cuff repair)</p>	<p>Prohibitive cost, concerns about disease transmission and lack of access to allograft tissue</p>
<b>Soft Tissue</b>		
<p>Meniscus Fascia</p>	<p>Increasing number of meniscal transplants</p> <p>Lower tolerance for 2<sup>nd</sup> site surgery (autograft)</p>	<p>Prohibitive cost, concerns about disease transmission and lack of access to allograft tissue</p>
<b>Cardiovascular</b>		
<p>Cardiac valves Conduits (valved and non-valved) Pericardium</p>	<p>Expect increased numbers of Ross procedures, requiring pulmonary allograft valve</p>	<p>Chronic lack of appropriate sizes of allograft valve (very small, very large)—changing to use of Contegra conduit for RV-PA conduit</p> <p>New fixation methods and bioprostheses for valve replacements</p> <p>Improve outcomes/durability using xenograft (porcine valve)</p> <p>Tissue engineering for aortic, pulmonary valves and conduits</p>

Tissue Type	Trend—Increased Use of Tissue	Trend—Decreased Use of Tissue
<b>Skin</b>		
Skin	Increased survival of patients with major burns	Use of skin/synthetic substitutes  Overall, decreasing numbers of burn patients (adults and children)
<b>Ocular</b>		
Corneas Sclera Amniotic membrane	<p>New procedure will be done more frequently—deep lamellar endothelial keratoplasty (DLEK)</p> <p>Use of limbal stem cells for ocular surface reconstruction</p> <p>Increasing numbers of ocular surface disorders</p> <p>Increased number of requests for amniotic membrane for corneal disease/surface repair</p> <p>Increased number of surgeons performing transplants although many are reaching retirement age</p> <p>Aging population with increasing posterior lamellar keratoplasty</p> <p>Increased use of laser surgery</p> <p>Increasing numbers of revisions of Penetrating Keratoplasty</p>	<p>Development of artificial corneas</p> <p>OR availability/time is a constraint</p>

## **Demand Surveys—Key Observations**

### **Response Rate**

- Response rates for the 5 surveys varied from a low of 19.6% for the orthopaedic survey to a high of 37% for the cardiac survey.
- The 4 surveys sent to smaller targeted samples (ocular, cardiac, neurosurgeons and burn units) had response rates from 32%–41%.
- The orthopaedic survey was sent to the “universe” of surgeons. The response rate may have been affected by interest in or use of allograft tissue.

### **Common Uses of Allograft Tissue and User Groups**

- Survey data supported the information collected in Key Informant Interviews, related research and the Environmental Scan.
- Musculoskeletal tissue (bone, tendons, soft tissue) is of interest to a wide range of specialists including orthopaedic surgeons, trauma surgeons, oncologists, sports medicine specialist, neurosurgeons, oral surgeons and periodontists.
- A range of spine surgery procedures using allograft bone and soft tissue are used by more than one User Group, namely orthopaedic surgeons and neurosurgeons.
- A number of the procedures identified require allograft tissue that is not currently accessible or available in sufficient quantity in Canada (e.g. meniscal transplants, osteochondral transplants, use of amniotic membrane, and very small <12mm valves for cardiac surgery).

### **Respondent Demand**

- Musculoskeletal tissue (bone, tendons, soft tissue) is commonly used by both orthopaedic and neurosurgeons. Both groups use cancellous bone, small structural grafts and demineralized bone.
- Survey data indicated that neurosurgeons do not use allograft tendons, but do use fascia lata.
- It was noted that both groups use autografts for a variety of procedures requiring bone, tendons and soft tissue.
- The range of cardiovascular tissue used included a significant proportion of conduits (37% of tissue used).
- The reported use of corneas by survey respondents indicated that the yearly number of corneal transplantations was approximately 50 per surgeon. This may reflect a bias, i.e. those who responded tended to be high volume users.
- Data reported from Canadian Burn Units showed a trend of decreasing numbers of seriously burned patients, resulting in lower demand for allograft skin.



## Extrapolated Respondent Demand

- Using CIHI sources, the number of potential users in each User Group was determined using provincial ratios. The extrapolated data for 4 of the 5 groups (orthopaedic, cardiac surgeons, neurosurgeons, corneal surgeons), highlights the provinces that would potentially have the highest demand for tissue, namely Ontario, Quebec, British Columbia and Alberta. The high volume provinces for allograft skin reflect the geographical location of Canadian Burn Units. They are Ontario, Alberta, Manitoba and Nova Scotia.
- Extrapolating respondent demand across 3 ranges results in the following totals of annual demand for allograft tissue:
  - Low range—34,442 grafts
  - Medium range—48,616 grafts
  - High range—62,098 grafts
- In each range, the orthopaedic surgeon User Group accounts for 69% or greater of overall demand.

## Predicted Demand

- Predicted increases in allograft tissue use over the next 1–2 years across User Groups ranges from a low of 3% for cardiovascular tissue to a high of 36% for soft tissue (fascia lata) used by neurosurgeons.
- When predicted increases in allograft tissue use over the next 1–2 year period are applied to the extrapolated respondent demand, predicted annual usage of allograft tissue increases as follows:
  - Low range—42,589 grafts
  - Medium range—60,435 grafts
  - High range—72,210 grafts

## Access and Sources for Allograft Tissue

- Neurosurgeon respondents indicated that for 20% of procedures requiring allograft fascia, an alternative was used.
- Paediatric cardiac surgeons have a high demand for smaller valves and have difficulty accessing these sizes. As a result some surgeons are switching to alternatives such as the Contegra™ graft. Cardiac surgery for adults may require very large valves on an emergency basis and often do not have a selection of valves to choose from.
- Several groups (orthopaedic, neurosurgeons, cardiac surgeons) indicated that xenografts were used as alternatives to allograft tissue.
- Access to ocular tissue was commented on by 2 respondents who were dissatisfied with the lack of tissue which resulted in cancelling OR cases.

- The percentage of procedures where an alternative is used when allograft was preferred, ranges from a low of 4% for neurosurgeons to a high of 30% for cardiac surgeons.
- Of 198 respondents, 57% reported accessing 100% of their tissue from Canadian tissue banks, 15% from United States tissue banks and 19% from a variety of sources.
- Eight percent (8%) reported accessing 100% of their tissue from “other sources”; the majority of these responses were local Surgical Bone Banks. Interestingly the respondents did not perceive these to be “Canadian tissue banks”.
- The most relevant factor related to purchasing tissue outside of Canada was the lack of available tissue in Canada.

## User Preferences for Characteristics of Tissue Banks

- The highest rated preferences (98% and 94%) were for accredited and Canadian tissue banks.
- A majority of respondents agreed that the features of not-for-profit, provider screening for quality standards, and a model for recipient tracking and adverse outcome monitoring were preferable.
- The respondents were split on whether or not tissue banks should generate profits.
- The selection of a tissue supplier was most strongly influenced by the existence of a quality assurance program and a demonstrated safety record. Overall, price was the least important compared to other characteristics.

## Trends and Technologies Affecting Demand

- An aging population, prevalence of obesity and conditions such as osteoarthritis and osteoporosis were cited as factors that will affect demand for allograft tissue.
- Clinical evidence for use of allograft is emerging in a number of domains but there are areas where outcomes are dictating a change in practice. An example of this is in cardiac surgery where the longevity of allograft valves is being compared to xenografts and synthetic products.
- A significant use of bone tissue is required for revisions of total hip and knee procedures. There may be evidence that, if allograft tissue such as osteochondral grafts are used earlier in the course of degenerative joint disease and the procedure becomes part of the treatment algorithm, joint replacements may be avoided later in life.
- The use of autografts, such as iliac crest harvesting for bone is still common practice, however, there appears to be less tolerance for 2<sup>nd</sup> site surgeries with related morbidity. Use of allograft bone would provide an alternative to autograft.
- Development of biologics such as rh BMP-2 (bone morphogenic protein) are noted as having a significant potential/contribution in a number of orthopaedic and neurosurgical applications.

- The emerging use and technology focused on demineralized bone products and combination products (xenograft, synthetic, bone morphogenic protein) will provide users with a wide range of choices for specific procedures.
- Highly specialized bone grafts, such as machined dowels, rings and struts are available and are being used in spine surgery. Other advancements such as the “cage” for reconstruction of the spine are used in conjunction with allograft bone fillers.
- Development of artificial tissues such as the artificial disc and the artificial cornea could reduce demand for these tissues. At the same time, the increase in other advances such as laser surgery is resulting in increased requirements for corneal transplantation later in life.

## Common Uses of Allograft Tissue in Surgical Procedures

In the process of executing the Supply and Demand studies, there have been a number of opportunities to gain an in-depth understanding of the range of procedures for which human allograft tissue is used. This detailed information on the use of tissue has been invaluable in providing the information required for mining existing databases and for developing supply and demand estimates.

Data on specific uses of tissue have been identified in the *Environmental Scan* and literature review, collected from key informants within the CCDT and tissue banking community, from interviews with surgical specialists, and from survey results directly.

The following table presents the type of tissue used for specific procedures and also the range of specialists commonly using the tissue.

**Table 43. Procedures and Specialists Requiring Allograft Tissue**

Tissue Type	Procedure	Specialty
<b>Bone/Cartilage</b>		
Cancellous bone (ground and chips)	Revision of total hip arthroplasty Revision of total knee arthroplasty Open wedge osteotomy	Orthopaedic surgery Oncology
Demineralized bone	Fractures upper limb—radius, scaphoid Fractures lower limb—subtrochanteric, peri-prosthetic	Trauma surgery Sports medicine
Structural bone	Limb reconstruction post trauma/post tumour removal	
Osteochondral, Peri-articular grafts	Bone void filler Limb and joint sparing Joint resurfacing, articular defects Repair—osteoporotic bone fractures Osteochondral repair/transplant Mosaicplasty Ankle fusion/arthrodesis	

Tissue Type	Procedure	Specialty
	<p>Anterior cervical discectomy            Anterior cervical discectomy and fusion            Posterior cervical fusion            Cervical spine decompression            Thoracic spine reconstruction            Lumbar fusion            Corpectomy            Thoracolumbar vertebrectomies            Instrumented lumbosacral fusion            Spinal reconstruction            Postero lateral interbody fusion            Antero lateral interbody fusion            Laminectomy            Spinal cage with bone filler</p> <p>Replacement for bone lost (e.g. post trauma,            post cancer surgery)            Gingioplasty            Alveoloplasty            Partial ostectomy of facial bone,            except mandible            Reconstruction of mandible with            associated resection            Extraction socket preservation            Osseous defects for periodontal            Sinus lift            Grafting associated with dental implants            Ridge augmentation</p>	<p>Spine surgery            Orthopaedic            surgery            Neurosurgery</p> <p>Oral and            maxillo-facial            surgery            Periodontal            procedures</p>
<b>Tendons</b>		
<p>Achilles            Hamstring            Patellar            Posterior tibialis            Anterior tibialis</p>	<p>Anterior cruciate ligament (ACL) repair            Revision of ACL repair            Posterior cruciate ligament (PCL) repair            Revision of PCL repair            Multi ligament repair/reconstruction—knee            Single or multi ligament repair/reconstruction—            ankle            Rotator cuff repair, tissue augmentation</p>	<p>Orthopaedic            surgery            Sports medicine</p>
<b>Soft Tissue</b>		
<p>Meniscus            Fascia</p>	<p>Meniscal transplant</p> <p>Brain tumour removal with fascial transplant            Posterior fossa decompression            Detethering of cord            Craniotomy with fascial transplant</p> <p>Supra-pubic sling surgery</p> <p>Reconstructive surgery</p>	<p>Orthopaedic            surgery</p> <p>Neurosurgery</p> <p>Urology</p> <p>Oral and            maxillo-facial            surgery            Periodontal</p>

Tissue Type	Procedure	Specialty
<b>Cardiovascular</b>		
Cardiac valves Valved and non-valved conduits Pericardium Veins	Ross procedure Norwood procedure Valved conduit for Bentall procedure Aortic valve replacement Pulmonary valve replacement Pulmonary arterioplasty Patch aortoplasty Replacement of ascending aorta & valve Right ventricle to pulmonary artery conduit Aortic root reconstruction Arch reconstruction Transannular patch  Vascular bypass	Cardiac surgery—adult and paediatric       Vascular surgery
<b>Skin</b>		
Skin	Burns—3 <sup>rd</sup> degree, deep 3 <sup>rd</sup> degree Problem wounds Fasciitis Ulcers Temporary closures, eg. radiation wounds Toxic epidermal necrolitis Post traumatic wound	Burns specialists Plastic surgery  Oral and maxillo-facial surgery Periodontal
<b>Ocular</b>		
Corneas Sclera Amniotic membrane	Penetrating keratoplasty Lamellar keratoplasty Keratolimbic allograft Deep lamellar endothelial keratoplasty Corneal surface repair with graft Epikeratophakia Scleral surgery	Corneal transplant surgery Ophthalmology

# 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.
2. Targeted interviews for the Demand study, 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.

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. Results of these interviews as they apply to Supply are reported on in the *Supply of Human Allograft Tissue in Canada—Final Report April 2003*.

### 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 types 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. Results of these interviews as they apply to Supply are reported on in the *Supply of Human Allograft Tissue in Canada—Final Report April 2003*.

Seventeen (17) interviews were conducted from January 2003–April 2003 with representatives/experts in the following specialty areas:

- Surgical bone banking, community hospital
- Surgical bone banking, large teaching hospital
- Orthopaedic surgery, sports medicine, large teaching hospital
- Orthopaedic surgeon, sports medicine, community hospital based
- Orthopaedic surgery, 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
- Skin banking, childrens' 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, nor does it necessarily represent the opinion of any health care organization, professional association or surgical specialty.

## Results of Key Informant Interviews—Demand by Tissue Type

Input received from interviews has contributed to the wide range of results presented in this report. In many cases, the information provided during interviews supported and complimented the data submitted by survey respondents.

In all instances, interviews with key users of allograft tissue were conducted to meet common objectives regardless of the tissue type, as follows:

- to identify the common procedures for which surgeons use allograft tissue;
- to identify factors affecting demand for allograft tissue, including barriers to use, emerging trends and technologies impacting demand;
- to obtain opinions on the predicted increase or decrease in demand for tissue in the future; and where appropriate; and
- to obtain advice on the content of draft Demand surveys and recommended contacts.



Emerging trends and common uses of allograft tissue documented during interviews are detailed in two sections of this report—*Trends & Emerging Technologies Affecting Use of Allograft Tissue* and *Common Uses of Allograft Tissue in Surgical Procedures*. These sections also include procedures and trends reported by survey respondents.

A summary of additional input from interviews by tissue type follows:

### **Musculo-skeletal Tissue (Bone, Tendons, Soft Tissue)**

Key users of these types of tissue included orthopaedic surgeons, neurosurgeons, oral surgeons and periodontists. As study results indicate that orthopaedic surgeons demand a significant majority of all allograft tissue used in Canada, several interviews were conducted with sub-specialty representatives. These included:

- trauma and spine surgeons (dealing with musculo-skeletal injuries);
- sports medicine specialists in community and large teaching hospitals (dealing with joint reconstruction, ligamentous repair); and
- joint replacement specialists (hip and knee).

Demand for musculo-skeletal tissue, as documented from survey results, is currently the highest among all tissue types and will have the most significant growth in the future. These results are further validated by the input received in interviews. The following points highlight these findings:

- Neurosurgeons use bone products and fascia for a wide range of procedures. A significant number of surgeons are currently using autografts from the iliac crest for bone grafts and autograft fascia lata for fascial transplants. As tolerance for second site surgery goes down, the demand for allograft will increase.
- As there is more evidence emerging that supports the use of allograft tissue in specific procedures such as ligamentous, meniscal and osteochondral transplants, the demand for these grafts will increase.
- The significant volumes of annual hip and knee replacement revisions which commonly require allograft tissue will push demand for allograft bone higher in the future.
- Demineralized bone products (DMB) are demanded by a variety of users including orthopaedic surgeons, oral and maxillo-facial surgeons, periodontists, neurosurgeons and trauma surgeons. They are considered to be very safe products. Some users did not immediately recognize that these products contain human tissue. New combination products using DMB are becoming more popular, for example, the combination of synthetic material with DMB.
- Use of bone products in oral surgery and periodontal procedures is very common and increasing. It results in improved outcomes for patients.
- Surgeon preferences for allograft versus alternative graft types may vary based on years since graduation and their experience in other countries such as the United States where allograft tissue is much more accessible. As increasing numbers of Canadian surgeons receive training in these settings demand in Canada can be expected to rise.

- Instrumented and machined bone implants (structural bone) are increasingly used in spine surgery by orthopaedic and neurosurgeons. These structural bone products and technologies are currently not available in Canada and only accessible through commercial companies in the United States.
- Surgical bone from living donors was identified in the Supply Report as an important source for orthopaedic and neurosurgeons for a variety of procedures. Femoral heads are used for a variety of purposes and commonly for revisions or reconstructive joint surgery. Ongoing and increasing demand for this type of tissue is expected. There is clearly a dependency of these users on surgical bone and a perception that this is a low cost, low risk source of allograft bone.

## Cardiovascular Tissue

The demand for cardiovascular tissue was discussed with a paediatric cardiac surgeon and 2 cardiac surgeons who perform surgery on adults. The primary types of allograft tissue that are required include aortic and pulmonary valves of different sizes, conduits and pericardium.

The surgeons that focus on adult surgery were of the opinion that the demand of allograft valves is currently static and may even decrease in future. The main reason for this appears to be the variable outcomes observed with allograft tissue and the fact that alternative products such as xenografts and synthetic products may perform as well or better. For adult surgery the demand for valves can be generally predicted and based on elective surgery requiring a specific type and size of valve. For some procedures, alternative products are available and acceptable (e.g. Dacron for conduits, mechanical valves for aortic valve). However, in some emergency situations such as acute endocarditis, an allograft valve is the only alternative. For pericardial patches and other uses of pericardium, it was noted that surgeons commonly use the patient's own pericardium.

For paediatric cardiac surgery the demand for and use of allograft tissue is common. A variety of procedures such as the Norwood require allograft tissue, in particular for a right ventricular to pulmonary artery conduit. Replacement of the pulmonary valve for the Ross procedure was most commonly cited as the procedure requiring an allograft valve. For paediatric use, the small and very small sizes (< 12 mm) are in high demand and short supply. Advances in the use of other alternatives such as bovine tissue may impact (decrease) the future demand for allograft tissue.

A range of factors appear to influence the decision of a surgeon to select allograft tissue, including: individual preferences, technical experience with transplantation of allograft and emerging evidence on the performance of various tissue types for cardiovascular surgery.

## Ocular Tissue

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

- New procedures such as the deep lamellar endothelial keratoplasty (DLEK) will result in increased demand for corneal tissue.
- Although there is an increasing number of Canadians requiring corneal transplants, wait lists for this surgery are common and affected primarily due to restricted OR time.
- Demand for amniotic membrane for corneal surface repair is increasing.
- There is a concern that a large number of corneal transplant surgeons are within 5–10 years of retirement. This may impact wait lists in the future and decrease demand simply by reducing the number of surgeons able to perform these procedures.

## Skin

Interviews related to the use of allograft skin for burns included specialists at two different centres for adults and children. Both centres specialized in burn treatment and the program directors who were interviewed were plastic surgeons.

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

- Use of allograft skin is primarily for burns (>90% of the time).
- Allograft skin is the “gold standard” for 3<sup>rd</sup> degree and deep 3<sup>rd</sup> degree burns.
- Demand is difficult to predict as it is based primarily on injuries from burns. A centre may have no serious cases in one year and several in the next.
- Trends indicate that the number of serious burns is decreasing over time, likely due to improved safety measures and regulations. This appears to be particularly true for children. Regulations for the type of materials used in night clothing for children, for example, are making a difference in the severity of burns in children.
- Autograft skin is always preferable, if feasible or possible to use.
- Uses for allograft skin other than for burns, such as for wound coverage, may decrease over time with increased use of alternatives such as synthetic and bovine collagen products.

## General Themes from Key Informant Interviews

The following general points were noted:

- During interviews, demand was often expressed in terms of the current situation (i.e. what they are using now) based on existing barriers such as cost, safety and accessibility. Due to existing barriers, surgeons may select autograft bone or fascia or other alternatives, as it is unrealistic to access a supply of allograft tissue.
- As evidence increases for use of allograft tissue for certain pathologies and functional states, standards of practice and treatment algorithms could drive demand for specific types of tissue for different treatment phases. An example of this is the use of osteochondral grafts (of varying sizes) for articular cartilage repair and replacement. This step may be part of the treatment algorithm for knee joints that may ultimately require replacement. Use of the allograft may result in delay of, or need for replacing the joint in the future.
- Many surgeons are performing second site surgeries (autograft procedures) with increasing reluctance. One surgeon noted that his application for a United States grant to conduct a research study was rejected on the grounds that the second site surgeries he would have to perform to retrieve bone were considered to be “unethical”. He went on to indicate that while training in the United States he rarely if ever, performed an iliac crest harvest.

## Demand Versus Known Supply

The table below provides a comparison of the extrapolated demand versus the Known Supply (defined as the supply of allograft tissue being produced by known Canadian tissue banks as detailed in the *Supply of Human Allograft Tissue in Canada—Final Report, April 2003*) of Canadian tissue. The predicted shortfall/surplus across the 3 ranges is as follows:

- Low range—annual shortfall of 23,713 tissues or 69% of total extrapolated demand
- Medium range—annual shortfall of 37,887 tissues or 78% of total extrapolated demand
- High range—annual shortfall of 51,369 tissues or 83% of total extrapolated demand

**Table 44. Summary of Extrapolated Demand Versus Known Supply Across Ranges**

Users	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone Products per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts per Year	Ocular Tissues per Year	Total per Year
Total Extrapolated Demand— Low Range	7,720	3,002	3,724	3,319	8,652	1,128	803	1,089	1,614	3,391	34,442
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus Low Range</b>	<b>(6,217)</b>	<b>(2,461)</b>	<b>(3,301)</b>	<b>(1,785)</b>	<b>(8,652)</b>	<b>(662)</b>	<b>(387)</b>	<b>(840)</b>	<b>596</b>	<b>(4)</b>	<b>(23,713)</b>
Total Extrapolated Demand— Medium Range	11,581	4,503	5,586	4,979	12,978	1,691	1,204	1,089	1,614	3,391	48,616
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus Medium Range</b>	<b>(10,078)</b>	<b>(3,962)</b>	<b>(5,163)</b>	<b>(3,445)</b>	<b>(12,978)</b>	<b>(1,225)</b>	<b>(788)</b>	<b>(840)</b>	<b>596</b>	<b>(4)</b>	<b>(37,887)</b>
Total Extrapolated Demand— High Range	15,441	5,626	6,598	6,639	16,648	2,255	1,204	1,643	1,614	4,430	62,098
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus/ High Range</b>	<b>(13,938)</b>	<b>(5,085)</b>	<b>(6,175)</b>	<b>(5,105)</b>	<b>(16,648)</b>	<b>(1,789)</b>	<b>(788)</b>	<b>(1,394)</b>	<b>596</b>	<b>(1,043)</b>	<b>(51,369)</b>

The following 3 tables contrast the Known Supply of Canadian allograft tissue, as determined by the Supply study, with the extrapolated demand across the 3 ranges by region. The predicted annual shortfall/surplus is also highlighted by tissue product and region (Atlantic, central and west).

**Table 45. Known Supply Versus Extrapolated Demand—Low Range**

Tissue Product	Atlantic			Central			West		
	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus
Cancellous/Surgical Bone	145	576	(431)	859	5,089	(4,230)	499	2,055	(1,556)
Cancellous Ground Bone	467	208	259		1,953	(1,953)	74	841	(767)
Small Structural Grafts	256	242	14	96	2,398	(2,302)	71	1,084	(1,013)
Large Structural Grafts	215	248	(33)	924	2,187	(1,263)	395	884	(489)
DeminerIALIZED Bone Products	0	619	(619)		5,656	(5,656)		2,377	(2,377)
Tendons	78	84	(6)	71	744	(673)	317	300	17
Soft Tissues	179	43	136	74	503	(429)	163	257	(94)
Cardiovascular Tissues	35	76	(41)	152	686	(534)	62	327	(265)
Skin Grafts	1,050	202	848	21	705	(684)	1,139	707	432
Ocular Tissues	281	281	0	1,691	2,166	(475)	1,415	944	471
<b>Total</b>	<b>2,706</b>	<b>2,579</b>	<b>127</b>	<b>3,888</b>	<b>22,087</b>	<b>(18,199)</b>	<b>4,135</b>	<b>9,776</b>	<b>(5,641)</b>

**Table 46. Known Supply Versus Extrapolated Demand—Medium Range**

Tissue Product	Atlantic			Central			West		
	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus
Cancellous/Surgical Bone	145	862	(717)	859	7,636	(6,777)	499	3,083	(2,584)
Cancellous Ground Bone	467	313	154	0	2,929	(2,929)	74	1,261	(1,187)
Small Structural Grafts	256	363	(107)	96	3,596	(3,500)	71	1,627	(1,556)
Large Structural Grafts	215	370	(155)	924	3,284	(2,360)	395	1,325	(930)
Deminerlized Bone Products	0	926	(926)	0	8,489	(8,489)	0	3,563	(3,563)
Tendons	78	126	(48)	71	1,115	(1,044)	317	450	(133)
Soft Tissues	179	65	114	74	752	(678)	163	387	(224)
Cardiovascular Tissues	35	76	(41)	152	687	(535)	62	326	(264)
Skin Grafts	1,050	202	848	21	705	(684)	1,139	707	432
Ocular Tissues	281	281	0	1,691	2,166	(475)	1,415	944	471
<b>Total</b>	<b>2,706</b>	<b>3,584</b>	<b>(878)</b>	<b>3,888</b>	<b>31,359</b>	<b>(27,471)</b>	<b>4,135</b>	<b>13,673</b>	<b>(9,538)</b>

Table 47. Known Supply Versus Extrapolated Demand—High Range

Tissue Product	Atlantic			Central			West		
	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus	Known Supply	Extrapolated Demand—Low Range	Predicted Annual (Shortfall)/Surplus
Cancellous/Surgical Bone	145	1,150	(1,005)	859	10,180	(9,321)	499	4,111	(3,612)
Cancellous Ground Bone	467	396	71	0	3,670	(3,670)	74	1,560	(1,486)
Small Structural Grafts	256	440	(184)	96	4,262	(4,166)	71	1,896	(1,825)
Large Structural Grafts	215	494	(279)	924	4,377	(3,453)	395	1,768	(1,373)
Deminerized Bone Products	0	1,199	(1,199)	0	10,909	(10,909)	0	4,540	(4,540)
Tendons	78	168	(90)	71	1,486	(1,415)	317	601	(284)
Soft Tissues	179	65	114	74	752	(678)	163	387	(224)
Cardiovascular Tissues	35	114	(79)	152	1,037	(885)	62	492	(430)
Skin Grafts	1,050	202	848	21	705	(684)	1,139	707	432
Ocular Tissues	281	366	(85)	1,691	2,828	(1,137)	1,415	1,236	179
<b>Total</b>	<b>2,706</b>	<b>4,594</b>	<b>(1,888)</b>	<b>3,888</b>	<b>40,206</b>	<b>(36,318)</b>	<b>4,135</b>	<b>17,298</b>	<b>(13,163)</b>



The next table provides a comparison of the extrapolated predicted demand (extrapolated demand adjusted for predicted increases in use of allograft tissue over the next 1–2 year period) versus the Known Supply of Canadian tissue. The predicted shortfall/surplus across the 3 ranges is as follows:

- Low range—annual shortfall of 31,860 tissues or 75% of total predicted demand
- Medium range—annual shortfall of 49,706 tissues or 82% of total predicted demand
- High range—annual shortfall of 66,481 tissues or 86% of total predicted demand

**Table 48. Summary of Extrapolated Predicted Demand Versus Known Supply Across Ranges**

Extrapolated Predicted Demand Ranges	Surgical Bone	Cancellous (50 cc packages)	Small Structural Bone	Large Structural Bone	Dem. Bone	Tendons	Soft Tissue	Cardio-vascular	Skin	Ocular	Total per Year
Total Predicted Demand—Low Range	9,727	3,715	4,692	4,182	10,862	1,421	1,092	1,122	1,775	4,001	42,589
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus—Low Range</b>	<b>(8,224)</b>	<b>(3,174)</b>	<b>(4,269)</b>	<b>(2,648)</b>	<b>(10,862)</b>	<b>(955)</b>	<b>(676)</b>	<b>(873)</b>	<b>435</b>	<b>(614)</b>	<b>(31,860)</b>
Total Predicted Demand—Medium Range	14,592	5,572	7,038	6,274	16,293	2,131	1,637	1,122	1,775	4,001	60,435
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus—Medium Range</b>	<b>(13,089)</b>	<b>(5,031)</b>	<b>(6,615)</b>	<b>(4,740)</b>	<b>(16,293)</b>	<b>(1,665)</b>	<b>(1,221)</b>	<b>(873)</b>	<b>435</b>	<b>(614)</b>	<b>(49,706)</b>
Total Predicted Demand—High Range	19,456	6,987	8,313	8,365	20,917	2,841	1,637	1,692	1,775	5,227	77,210
Total Known Supply	1,503	541	423	1,534	0	466	416	249	2,210	3,387	10,729
<b>Predicted (Shortfall)/Surplus—HI Range</b>	<b>(17,953)</b>	<b>(6,446)</b>	<b>(7,890)</b>	<b>(6,891)</b>	<b>(20,917)</b>	<b>(2,375)</b>	<b>(1,221)</b>	<b>(1,443)</b>	<b>435</b>	<b>(1,840)</b>	<b>(66,481)</b>

## Discussion

This report, *Demand for Human Allograft Tissue in Canada—Final Report*, completes the third and final phase of the CCDT Project 4.1 to study Supply and Demand of Allograft Tissue in Canada. Results of the second phase, *Supply of Human Allograft Tissue in Canada* can now be considered in the context of the Demand results. In the previous tables (Tables 44–48), data are presented for comparing supply and demand of different tissue types, the shortfall predicted and regional comparisons.

The following sections focus on tissue specific comparisons of supply and demand incorporating the range of results from the supply and demand studies.

### Cancellous/Surgical Bone

The Known Supply of cancellous bone which includes surgical bone (from living donors receiving hip replacements) and cancellous bone from cadaveric donors in Canada was reported to be 1,503 grafts. As reported in the results of the Supply study, only a subset of surgical bone was accounted for in Known Supply of cancellous bone. An estimation of Unknown Supply of surgical bone was made in the Supply study and the results indicated that there could be in the range of 2,558 to 5,055 additional grafts produced by unknown Surgical Bone Banks in Canada.

The estimation of Current Demand by extrapolating demand data for cancellous bone by orthopaedic surgeons was in the range of 7,720 at the low end to 15,441 at the high end. There is significant shortfall in supply (6,217–13,938) even if you consider the additional supply that may be coming from unknown Surgical Bone Banks.

When regional data is reviewed this shortfall exists in two regions of Canada with the most significant shortfall in central Canada. At low ranges these differences are:

- Atlantic—there is a surplus of supply over demand of 431 grafts
- West—there is a shortfall of supply over demand of 1,556 grafts
- Central—there is a shortfall of supply over demand of 4,230 grafts

Based on this, central Canada would need access to 6 times the supply currently being produced in this region.

At the high end there are shortfalls in all regions:

- Atlantic—there is a shortfall of supply over demand of 1,005 grafts
- West—there is a shortfall of supply over demand of 3,612 grafts
- Central—there is a shortfall of supply over demand of 9,321 grafts

Based on this, central Canada would need access to 12 times the supply currently being produced in this region.

Orthopaedic surgeons predicted that the increase in demand for surgical bone in the next 1–2 years would be approximately 26%. Predicting demand using this rate would estimate demand in the range of 9,727 to 19,456. There is clearly a significant shortage of surgical bone based on the estimated current and predicted demand calculated in this study. One of the most common uses for surgical bone is for the revision of total hip and total knee replacements and demand for this purpose is likely to increase in the future. The data and estimates in the supply and demand studies are based on the use of 1 femoral head or 50 cc's of bone for a revision procedure (based on feedback from key informants). A recent study published in Scotland (Wilson et al, 2002) reports that each procedure for impaction grafting to reconstruct the proximal femur requires 2.4 femoral heads. This number is more than double the estimates used in this study and may mean that estimates are conservative.

The Scottish study also reported that tibial plateaus were retrieved from primary total knee replacements. No reports of using this type of surgical bone were made in the course of executing and completing the supply and demand studies. If tibial plateaus are considered a viable option for surgical bone in addition to femoral heads, there would be a potential supply of surgical bone coming from all primary total hip and total knee replacements in Canada. Based the number of total hip and knee replacements in Canada in 1999–2000 (Hospital Morbidity Database, CIHI), this total would be in the range of 20,000 femoral heads and 22,000 tibial plateaus.

### **Use of Autograft Bone**

An alternative source of bone for orthopaedic and neurosurgical procedures is the autograft, harvested from the anterior iliac crest bone. The Scottish study reports that over 60% of orthopaedic surgeons use this source for joint revision surgery. A key informant reported that over 75% of neurosurgeons in Canada performing spine surgery commonly use iliac crest bone from a second surgical site. A number of studies have been conducted to examine the resulting morbidity in the use of autograft bone. A recent study reports on the chronic donor site pain and long-term functional impairment following post anterior cervical discectomy and fusion (Silber et al, 2003). The study concludes that alternative sources of bone such as allograft should be considered.

Other reports include problems with increased OR and anaesthesia time, increased blood loss and increased length of stay. The demand for allograft bone and/or other substitutes will continue to increase as the tolerance for second site surgery decreases.

## **Cancellous Ground Bone and Structural Bone**

The results of the Demand Surveys indicate that orthopaedic and neurosurgeons are common users of these types of bone. Oral surgeons also use structural bone for reconstructive surgery.

In comparing Known Supply of cancellous ground bone and structural bone to extrapolated demand across User Groups there are significant shortfalls at all ranges. For example, demand for cancellous ground bone at the low range is approximately 6 times the number being produced. At the high end of the range it is 10 times the number. The shortfalls for small structural grafts are greater than those for large structural grafts.

When regional data is reviewed the shortfall at the low end for cancellous ground bone exists in two regions with the most significant shortfall in central Canada where none is produced:

- West—there is a shortfall of supply over demand of 767 grafts
- Central—there is a shortfall of supply over demand of 1,953 grafts
- Atlantic—there is a surplus of supply over demand of 259 grafts

Comparisons of regional supply and demand at the low end for small and large structural bone combined are as follows:

- West—there is a shortfall of supply over demand of 1,502 grafts
- Central—there is a shortfall of supply over demand of 3,565 grafts
- Atlantic—there is a shortfall of supply over demand of 19 grafts

Atlantic Canada has the best ratio of supply to demand. The demand in both central and western Canada is approximately 4 times the supply produced.

User Groups predicted an increase in the range of 17%–26% in demand in the next 1–2 years. Based on the regional data it would be reasonable to expect the most acute shortages of cancellous ground bone and structural grafts in central and western Canada.

## **Demineralized Bone**

Demineralized bone products are a group of allograft bone products that contain human bone matrix proteins (bone morphogenetic proteins—BMPs) that are osteoinductive (help to induce growth of new bone). Some of these products contain particles of whole bone, which are osteoconductive (facilitate blood-vessel incursion and new-bone formation into a defined passive trellis structure). Many of the products containing demineralized bone are made of a combination of synthetic and human derived materials.

Demineralized bone products are increasingly popular and are used extensively by the orthopaedic surgeon and neurosurgery User Groups. They are also used by the Dental Industry (primarily dental surgeons and periodontists).

There is no Known Supply of demineralized bone products being produced by Canadian tissue banks. It is clear from the Supply study that a significant portion of the current Unknown Supply is represented by the importation of demineralized bone products. Interviews with key users of allograft tissue and hospital personnel revealed that demineralized bone products are routinely purchased from commercial providers (mostly United States based companies) and/or their Canadian distributors. The Supply study estimated that over \$12 M dollars may be spent annually by Canadian health care organizations and by users of these products.

Estimation of annual Current Demand for demineralized bone products ranges from 8,652 to 16,648 products per year. When predicted 1 to 2 year increases are applied (26% for orthopaedic surgeons and 23% for neurosurgeons) this range increases to 10,862 to 20,917 products per year. Given the explosive growth in the use of these products in the United States, as reflected in the Environmental Scan, it is likely that trends in Canada will be similar.

The regional split of Current Demand for these products as calculated in the Demand study breaks down as follows:

- Atlantic—619 to 1,199 products
- Central—5,656 to 10,909 products
- West—2,377 to 4,540 products

## Tendons

The Known Supply of tendons produced in Canada is 466. The majority of these were Achilles and patellar tendons (whole and half). Estimations of Current Demand were made by extrapolating the use of tendons across the orthopaedic group that reported using them for a variety of procedures. These procedures include ligamentous repair and reconstructive knee surgery.

At the low range a total of 1,128 tendons would be required and at the high range it would be 2,255. This leaves a shortfall of Known Supply over demand of 662 to 1,789 grafts.

When regional data is reviewed this shortfall exists in all regions of Canada with the most significant shortfall in central Canada (demand 20X that of supply):

- West—there is a shortfall of supply over demand of 284 grafts
- Central—there is a shortfall of supply over demand of 1,415 grafts
- Atlantic—there is a shortfall of supply over demand of 90 grafts

Users predicted an increase of 36% in demand for allograft tendons over the next 1–2 years. This would result in a predicted demand in the range of 1,421 at the low end to 2,841 at the high end, and respective shortfalls of 955 to 2,375.

Predicted increases in demand for tendons was one of the highest reported in the Demand Surveys. With the expected increases in orthopaedic procedures for an aging and active population, this type of allograft tissue will continue to be in short supply if production in Canada does not increase.

## Soft Tissue

The Supply and Demand Surveys focused on the use of soft tissue used by orthopaedic and neurosurgeons. These tissues include fascia lata and meniscus.

Results of the Supply Survey indicated that a total supply of 416 grafts were produced by Canadian tissue banks. The majority of these were fascia and a very small number (9) were meniscus. Estimations of Current Demand were made by extrapolating the use of tissue across the neurosurgeon group which was the primary user of allograft fascia. The national shortfall from low to high range was 387 grafts to 788 grafts.

When regional data is reviewed this shortfall exists in western and central Canada and there is a surplus in Atlantic Canada:

- West—there is a shortfall of supply over demand of 224 grafts
- Central—there is a shortfall of supply over demand of 678 grafts
- Atlantic—there is a surplus of supply over demand of 114 grafts

Demand survey respondents, on average, predicted an increase in demand for fascia of 36% over the next 1–2 years. Incorporating this increase into the extrapolated demand, the ranges required would be 1,092 to 1,637 grafts resulting in a predicted shortfall of 676 to 1,221 grafts.

## Use of Allograft Fascia in Urological Surgery

In review of the literature it was determined that urologists commonly use fascia lata as a sling for bladder neck suspension procedures for urinary incontinence (Vasavada et al, 2002; Singla 1999).

A common use for autologous or allograft fascial slings is for the pubovaginal sling procedure (PVS). The gold standard treatment for female stress urinary incontinence due to intrinsic sphincter deficiency is PVS. Dr. Singla at the University of Nebraska Medical Center advocates for the use of allograft fascia as it reduces his OR time on average by one third, and patients lose one-half as much blood as they do if autologous tissue is used. In addition, hospital stay is reduced as are pain and mobility issues.

Although surveys were not used for this specialty group in the study, CIHI data was used to predict demand for these procedures. The Hospital Morbidity Database was reviewed for the number of cases in Canada in 2000 that could potentially require fascia lata for urological surgery. CCP codes 71.4 and 71.5 for the suprapubic sling operation and retropubic urethral suspension operation respectively, were reviewed. There were 1,351 71.4 codes and 6,804 71.5 codes for year 2000.

If at the most, 25% of these urological procedures required allograft fascia, an additional total of 2,000 grafts would be used by these specialists and the total shortfall in Current Demand could be in the range of 2,300–2,700 grafts.

### **Use of Meniscal Allograft Tissue**

Only 9 grafts of the Known Supply of 416 soft tissues were meniscus. Although it is not possible to estimate the current use of meniscal tissue for transplant based on existing databases, orthopaedic specialists contacted for this study have indicated that the demand for this tissue will increase in the future. There is likely importation of meniscus at this time to meet Current Demand.

### **Cardiovascular Tissue**

The supply and demand studies focused on cardiovascular tissue primarily used by cardiac surgeons for adult and paediatric surgery. These tissues include aortic and pulmonary valves, valved and non-valved conduits and pericardium.

Results of the Supply Survey indicated that a total of 249 grafts were produced at Canadian tissue banks in the past year. It was also estimated that at least 583 additional grafts were imported into Canada, therefore confirming that current use of allograft tissue exceeds Canadian supply. Another survey result demonstrating that demand exceeds supply was that, on average, cardiac surgeons had to use an alternative 30% of the time when they would have preferred to use allograft. In addition, the availability of specific valve sizes when needed is restricted. This affects surgeons performing adult and paediatric surgery (the former requiring large or very large sizes and the latter requiring small or very small sizes).

Two factors which may be affecting the current supply of cardiovascular tissue in Canada are noted below:

1. **Export of Unprocessed Tissue to United States:** Results of the Supply Survey showed that 22% of unprocessed cardiovascular tissues were exported to the United States. Although some centres may have been able to “purchase back” processed tissues, it is likely that there was a net loss of tissue to the United States.
2. **Use of Explanted Hearts for Valves:** A source of supply of allograft heart valves in Canada and other countries is explanted hearts from living donors (hearts removed from a heart transplant recipient). Demand survey results showed that less than 50% of the responding centres use this practice to augment their supply of allograft valves.

A study published by Feindel et al in 1991 stated that “hearts excised from heart transplant recipients are an excellent potential source for aortic homografts” and that “long term freedom of homograft valves from valve-related complications is excellent compared with prosthetic valves”. In this study of 40 patients they found that over 50% of explanted hearts had aortic valves fit for transplantation. This rate is consistent with European studies (Schutt, 1997) who reports a similar rate of successful valve retrievals. This paper also notes that the integrity and viability of homograft valves was better with grafts from heart-beating donors (explanted heart from living donor) than from non-heart beating donors (cadaveric).

Feindel also noted that the successful transplantation of a “recycled heart valve” saved the health facility approximately \$3,000–\$4,000 per patient (in 1991 dollars).

Based on the number of explanted hearts available in Canada in 2001 (CORR data for heart transplantation, CIHI 2001), there would have been 161 aortic and 161 pulmonary valves available for tissue retrieval. Based on a 50% discharge rate (valves discarded for a variety of reasons), Canada’s supply could have included an additional 80 aortic and 80 pulmonary valves.

Estimations of Current Demand for cardiovascular tissue were calculated by extrapolating Demand Survey data across the group of surgeons practicing in Canada:

- Estimations of Current Demand ranged from 1,089 to 1,643 per year
- Based on Known Supply, the shortfall estimation ranged from 840 to 1,394
- This shortfall is in the range of 4 to 5 times the current available supply nationally

Although there is a shortfall of cardiovascular tissue in all regions across Canada, there is a notable difference between regions when estimating how much demand exceeds Known Supply:

- West—demand exceeds Known Supply by 5 to 8 times
- Central—demand exceeds Known Supply by 4 to 7 times
- Atlantic—demand exceeds Known Supply by 2 to 3 times

The shortfall appears to be most acute in central and western regions of Canada.

Demand survey respondents, on average, predicted that the demand for cardiovascular tissue would increase by 3% in the next 1–2 years. Although, compared to other tissue types, this is one of the lower rates of predicted increase, the shortfall is still significant (873 to 1,443). Unless tissue banks in Canada are able to increase the supply of cardiovascular tissue in the near future, health facilities will have to continue to import and pay for tissue from outside of Canada and/or use alternatives to allograft.

Future demand for cardiovascular tissue may be reduced by some of the emerging trends and technology in this area. There were indications from survey respondents that a number of factors may reduce demand, including but not limited to:

- future developments in tissue engineering;
- improved outcomes and evidence that xenograft tissue is as durable or more so than allograft tissue;
- the chronic supply of a variety of heart valve sizes is driving the use of alternatives. These include porcine valves/Dacron composite graft and bovine tissue. One such alternative is the Contegra™ Pulmonary Valved Conduit by Medtronic which is derived from bovine jugular vein and available in Canada under “special access” (Kiaii et al, 2001). This study reports that these conduits are safe to use with good hemodynamic and clinical results; and



- a high level of technical/surgical skill is required to transplant allograft tissue successfully. As the numbers of expert users of allograft tissue decrease over time, fewer surgeons will be available to teach these skills.

## Ocular Tissue

The supply and demand studies focused on a range of ocular tissues including corneas, sclera and amniotic membrane. The user group targeted for Demand surveys were primarily corneal transplant surgeons.

Results of the Supply Survey indicated that a total of 3,387 grafts were produced at Canadian eye banks and tissue banks in the past year. Over 75% of these were corneas and the majority of all ocular tissues were produced by eye banks in 7 provinces. It was also determined that an insignificant number of corneas (13) were imported to Canada from the United States in 2001 (EBAA 2001).

In comparison to supply, demand data extrapolated at the low to mid ranges suggests that supply more or less meets demand (i.e. 3,387 supply for 3,391 demand with a shortfall of only 4). At the higher range, the numbers increase to a demand of 4,430 leaving a shortfall of 1,043.

This higher range of demand may be more realistic if the average wait lists are taken into account. On average corneal transplant surgeons reported wait lists of 53 patients (ranging from 0–180). If this average is applied to all 95 surgeons, the total number of required tissues currently, would be 5,035.

Demand survey respondents reported that, on average, an increase in demand of 18% is expected in the next 1–2 years. Applying this rate to the demand as per wait lists of 5,035 would result in 5,941 ocular tissues. This exceeds the extrapolated predicted demand of 5,227 at the high range presented in Table 48. Based on these comparisons, it appears that using the higher range for calculating current and predicted demand for ocular tissues is most appropriate.

If the national shortfall of ocular tissues from Table 44 is considered at the high range, a total of 1,043 additional grafts are required to meet Current Demand. Considering this data regionally, there are some differences between regions when estimating how much demand exceeds Known Supply:

- West—there is a surplus of 179 supply over demand
- Central—there is a supply shortfall of 1,137
- Atlantic—there is a supply shortfall of 85.

The shortfall appears to be most significant in central Canada (40%) and less in Atlantic Canada (23%). Interestingly, the west appears to have sufficient supply. This contradicts input received in Demand surveys from British Columbia surgeons. Comments focused on the lack of coordination in the system and the significant wait lists (up to 180 patients on one list). This discrepancy in supply and demand is likely related to the significant constraints on corneal surgeons for OR time. That is, even though supply of corneal tissue is available, the surgeons are unable to schedule and perform enough procedures to utilize the tissue and provide their patients with transplants when they need it. The perishable nature of corneal tissue exacerbates this problem.

Other factors that should be considered in relation to future supply and demand of ocular tissue include:

- Demand surveys indicated that there will be a significant increase in demand for amniotic membrane for corneal surface repair. Currently Canada is producing only 133 grafts/year. A predicted increase in demand of 28% over the next 1–2 years will not be met unless processes are put in place to retrieve and process more of this tissue.
- Trends in corneal surgery will result in increased demand for corneal tissue. Deep lamellar endothelial keratoplasty (DLEK) is an emerging procedure that will require corneal tissue.
- The most common corneal transplant procedures requiring ocular tissue are penetrating keratoplasty (PK) and lamellar keratoplasty, comprising ~ 65% of total procedures (EBAA 2001). The number of procedures increased 12% from 1997. A study on the leading indications for PK in Canada (Liu, Slomovic 1997) concluded that the second most common indication for PK was regrant and their rate was 22.3%. With these increases in procedures requiring corneal tissue (12%) combined with an estimated regrant rate of 22%, it is clear that demand for corneal tissue will continue to grow.
- There is concern on the part of corneal surgeons that their specialty group, on average, is approaching retirement. In addition to OR constraints, accessing these specialists in the future may be impacted by the actual number available to perform corneal transplants.

## Skin

The supply and demand studies focused on allograft skin produced by Canadian tissue banks and users in Canadian Burn Units.

Results of the Supply Survey indicated that a total of 2,210 grafts were produced at Canadian tissue banks in the past year. There were no documented exports of allograft skin out of Canada.

In comparison to supply, demand data extrapolated across all 16 Burn Units indicates the requirement of 1,614 grafts nationally. Comparing supply to demand would suggest that there should be sufficient supply to meet demand in Canada with a surplus of 596 grafts. Despite this, it was noted that at least one Burn Unit imports allograft skin from the United States.

Although it appears that there is a surplus of allograft skin nationally, when regional data is reviewed there are some interesting disparities between supply and demand:

- West—there is a surplus of supply over demand of 432 grafts
- Central—there is a shortfall of supply over demand of 684 grafts
- Atlantic—there is a surplus of supply over demand of 848 grafts

Atlantic and western Canada appear to be well served with surpluses in tissue, whereas central Canada produces much less than it uses with a 97% shortfall.

Demand survey respondents, on average, predicted an increase in demand of 10% over the next 1-2 years. Incorporating this increase into the extrapolated demand, the total would be 1,775 resulting in a surplus of 435 grafts.

The Hospital Morbidity Database was reviewed for the number of cases across Canada in 2000 with ICD-9 codes for third degree burns, deep third degree burns and burns covering over 50% body surface area. The total number for 2000 was 1,366. Interpretation of this data is limited as:

- it is not possible to determine the number of grafts used for each case from this data, nor if skin grafting took place; and
- a key informant cautioned use of ICD-9 codes as there was a concern for under-reporting.

Other factors that should be considered in the future as they relate to supply and demand of allograft skin include:

- It is very difficult to predict demand for allograft tissue in burn treatment as it is based on the occurrence of burn injuries.
- Current trends indicate that improvements in safety regulations are resulting in fewer serious burns requiring allograft tissue.
- The challenge will be to establish a level of supply that is considered sufficient to meet the unpredictable requirements for allograft skin.

## Summary

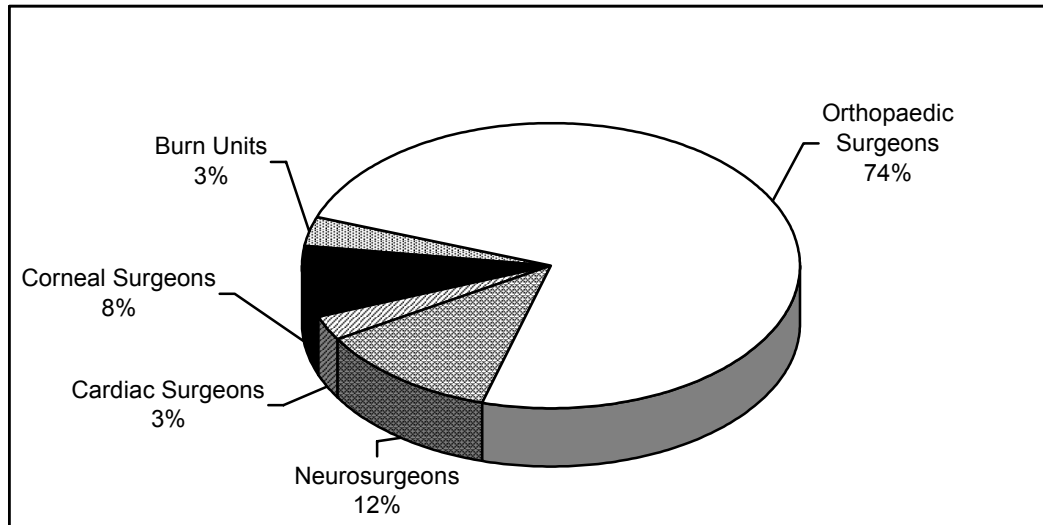
The Demand study has provided estimates of the Current Demand for human allograft tissue in Canada as reflected through survey results sent to 5 prominent User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal surgeons and Burn Units).

When extrapolated across the “universe” of these User Groups, using estimation methods across three ranges, the estimated Current Demand for allograft tissue in Canada ranges from a low of 34,442 grafts per year to a high of 62,098 grafts per year. The actual number likely falls somewhere in between. A summary of the annual Current Demand (across the 3 estimation ranges) by user group/tissue type is presented in the table below:

**Table 49. Summary of Annual Current Demand by User Group and Tissue Type**

Tissue Product	Range of Demand for Orthopaedic Surgeons	Range of Demand for Neurosurgeons	Range of Demand for Cardiac Surgeons	Range of Demand for Burn Units	Range of Demand for Corneal Surgeons
Surgical/Cancel. Bone	7,720–15,441				
Cancel. Bone—50cc packages	2,246–4,493	756–1,133			
Small Struc. Grafts	2,024–4,048	1,700–2,550			
Large Struc. Grafts	3,319–6,639				
Demin. Bone Products	7,339–14,679	1,313–1,969			
Tendons	1,128–2,255				
Soft Tissues		803–1,204			
Cardio. Tissues			1,089–1,643		
Skin Grafts				1,614	
Ocular Tissues					3,391–4,430
<b>Total</b>	<b>23,776–47,555</b>	<b>4,572–6,856</b>	<b>1,089–1,643</b>	<b>1,614</b>	<b>3,391–4,430</b>

To provide readers with an understanding of the estimated Current Demand associated with each User Group in relation to total Current Demand, the following figure reflects the percentage by User Group based on average demand over the 3 estimation ranges.



**Figure 9. Estimated Average Annual Current Demand as a Percentage of Total by User Group**

Data gathered in relation to the predicted increase in use of allograft tissue over the next 1–2 year period would suggest that annual demand could rise to somewhere in the range of 42,589 to 72,210 grafts. It should be recognized that these results do not incorporate use of allograft tissue by the Dental industry.

When compared to the Known Supply of allograft tissue in Canada at 10,729 grafts per year, it is clear that even at the low range, Current Demand far outstrips Known Supply. It is interesting to note that the methods in the Supply study, used to estimate Unknown Supply (supply from unknown Surgical bone Banks and imports), resulted in an estimate of Total Supply that ranged from 26,606 to 40,543 grafts per year. This is certainly not unrealistic given the results of the Demand study.

## The Concept of Future Demand

Future Demand may be thought of as the amount of allograft tissue that will be required to meet the needs of all Canadians all of the time. Future Demand is driven by health conditions and is not dependent on the current constraints limiting the use of allograft tissue within Canada.

$$\text{Future Demand} = \text{Current Demand} + \text{Unrealized Demand}$$

Factors that will influence Future Demand for allograft tissue include the following:

- new health conditions (disease, pathology and types of injury);
- new/emerging technologies;
- increases and decreases in health conditions;
- unidentified treatments for known health conditions; and
- changes in clinical standards and practices.

Future Demand incorporates 2 components:

- Current Demand—the allograft tissue required to meet the needs of Canadians whose course of treatment incorporates allograft tissue transplantation.
- Unrealized Demand—the allograft tissue that would be required to meet the needs of those persons who are not yet receiving treatment and may or may not receive treatment using allograft tissue in the future. This component of demand can represent “pent up” demand or demand that has not yet been identified. Unrealized Demand is impacted by a series of factors, which, if unleashed, could result in changes to the level of Future Demand.

Factors that form constraints, impacting the potential for Unrealized Demand to become realized include the following:

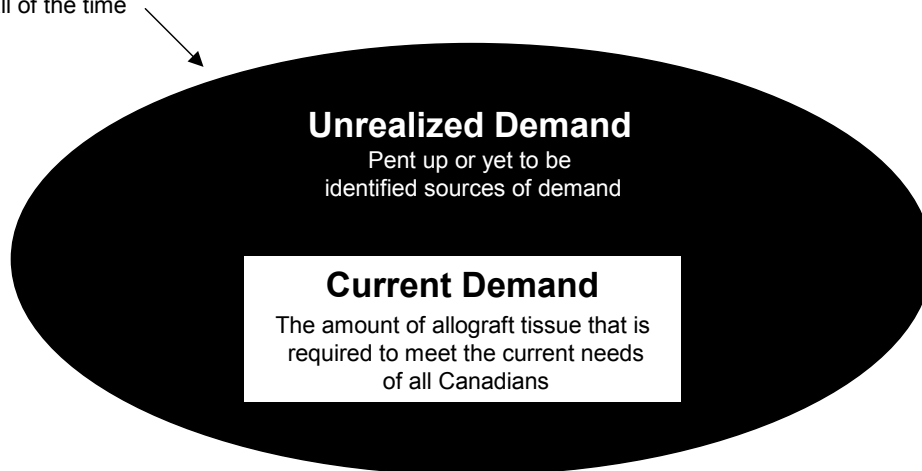
- funding levels to address known health conditions (e.g. waiting lists created by insufficient OR time);
- alternatives to the use of allograft tissues (e.g. xenografts, synthetic substitutes, autografts);
- policies that impact the procurement and use of allograft tissue (e.g. hospital/OR budgets);
- insufficient supply of allograft tissue;
- practices, preferences and perceptions of allograft tissue users (includes both hospital users and the Dental industry);
- public education/perceptions; and
- availability of health care providers.

The following factors can contribute to changes in Current Demand over time:

- changes in government policy impacting the allocation of resources for healthcare;
- changes in hospital case mixes;
- changes in clinical programs/practices;
- changes in physician and public awareness/education;
- changes in the allograft tissue supply;
- changes in perceptions with regard to the safety and accessibility of the allograft tissue supply; and
- changes in the availability of healthcare providers.

## Future Demand

The amount of allograft tissue that is required to meet the needs of all Canadians all of the time



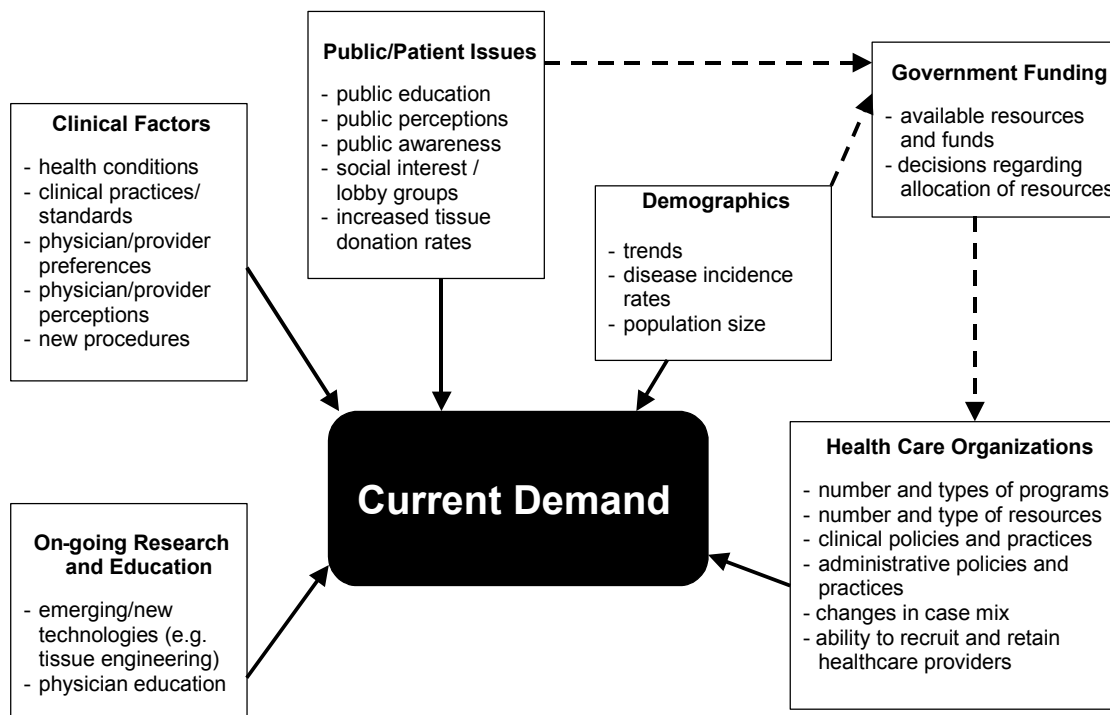
**Figure 10. Components of Demand**

The Demand Project has identified several factors that are currently influencing or constraining the level of Current Demand for allograft tissue in Canada. Examples of these are as follows:

- Healthcare resource constraints resulting in limited OR time and limited budgets for purchasing allograft tissue products.
- Use of alternatives such as autographs, xenografts or synthetic substitutes. The use of alternatives is often a response to limited resources and accessibility and/or concerns about the safety of the allograft tissue supply.
- Historical user preferences.
- The availability of health care providers. Healthcare organizations are having increasing difficulty recruiting specialists who are users of allograft tissue (e.g. corneal transplant surgeons).
- Research influencing clinical practices such as evidence that xenograft and mechanical heart valves are achieving similar outcomes to allograft valves with the advantage of a less complex procedure, which a greater number of cardiac surgeons are qualified to perform.

Factors identified that may impact Future Demand for allograft tissue (i.e. turn Unrealized Demand into Current Demand) are as follows:

- Demographic trends such as the aging population that will require an increasing number of procedures such as hip and knee replacements/revisions, ligamentous repairs, and periodontal procedures.
- Younger surgeons entering the healthcare system whose practices have been influenced by training in the United States where allograft tissue use is the norm.
- The increasing popularity of certain procedures such as meniscal transplants and mosaicplasty.
- Increasing popularity of demineralized bone products and combination products containing demineralized bone.
- The potential for increased health care funding in Canada.



**Figure 11. Factors Impacting Current Demand for Allograft Tissue**



Significant “unleashing” of the above factors will result in an increased requirement for allograft tissue in Canada. To ensure that the tissue banking system is prepared to respond to these changes, demand forecasting will be a critical management activity within a Canadian Tissue Banking Model. The factors identified in this study as most likely to impact demand will provide a foundation, or starting point, for the development of this function. To contribute effectively to both short-term operational, and long-term business planning, the demand forecasting model should include:

- The establishment of Current Demand baseline data.
- A process to scan the external environment to collect advance information (e.g. changes to hospital programs/budgets, government funding).
- The ability to:
  - Incorporate the requirements of users (e.g. number of aortic valves of a specific size)
  - Identify trends and adjust accordingly
  - Provide information at a sufficient level of detail to assist management in optimizing production and inventory management decisions.
  - Provide both near term and long term forecasts (e.g. 1 to 5 years).
- A consistent approach across the Canadian Tissue Banking system (a national approach).

The Demand study has also provided important information about user preferences for the characteristics of a preferred supplier of allograft tissue. Users indicate a strong preference to obtain their tissue from an accredited Canadian tissue bank. There was also strong support for a fee-for-service/not-for-profit model that provides adequate donor screening, ongoing quality assurance, tracking and monitoring.

Cost and lack of access were frequently identified as factors constraining the Current Demand for allograft tissue. Many users expressed frustration with the manner in which cost is evaluated indicating that there are many costs incurred by the health care system that are very real and which represent the cost of not having an adequate allograft tissue supply to meet the needs of Canadian patients. These costs include the following:

- Procedures which are repeated due to failure, thought to be related to inability to access and utilize allograft tissue.
- Costs associated with autograft procedures (e.g. iliac crest harvest). These include longer OR time, additional anaesthesia, 2 procedures versus 1, and 2<sup>nd</sup> site morbidity.
- The cost of providing long term assistance to patients where receipt of an allograft tissue could result in a significant improvement in independence and quality of life (e.g. a cornea transplant for a blind person or a large structural graft for an individual who might otherwise be confined to a wheelchair).
- The cost associated with importing products from profit oriented United States commercial tissue suppliers.

In addition, many of the factors driving allograft tissue demand are related to demographic trends driving health conditions for which allograft tissue is indicated and will increase significantly over the foreseeable future. Users have expressed frustration with the lack of planning for this inevitability.

The Demand study provided many opportunities to observe the gaps in relation to data concerning allograft tissue use. The development of a Canadian Tissue Banking Model will provide an excellent opportunity to address these gaps, which include:

- user demand;
- inventory tracking;
- data concerning current use of allograft tissue (graft use—procedure, type of graft);
- donor/recipient tracking; and
- outcomes reporting.

Addressing these gaps in data will provide opportunities to:

- apply equitable allocation algorithms;
- perform research concerning the use of allograft tissue; and
- forecast short and long-term demand.

Through estimating Current Demand, and compiling additional qualitative information, the Demand study represents a key step in addressing the paucity of information concerning the demand for allograft tissue in Canada. In addition, the study provides a foundation on which more detailed studies may be based as the CCDT moves toward as recommendation for a Tissue Banking model of services for Canada.



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**Appendix A**

**Demand Surveys**



**SECTION # 1 – UTILIZATION OF ALLOGRAFT TISSUE PRODUCTS**

In order to estimate the demand for human bone and soft tissue allograft products in Canada we would ask you to provide your average allograft utilization per month when completing questions 1- 6.

- |                                                                                                                                                                           |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
|                                                                                                                                                                           | <b>#</b>                                   |
| 1. What is your estimated use of <u>surgical bone</u> (femoral heads retrieved from live donors) per month? (please write number)                                         |                                            |
| 2. What is your estimated use of <u>pre-packaged cancellous</u> allografts per month? (please write # of packages by package size - package size being #of cc's per pkg.) | _____ of _____ cc's<br>_____ of _____ cc's |
| 3. What is your estimated use of <u>small structural</u> allografts such as dowels, wedges or rings per month? (please write number)                                      |                                            |
| 4. What is your estimated use of <u>large structural</u> grafts such as acetabulum, femurs, struts and humerus per month? (please write number)                           |                                            |
| 5. What is your estimated use of <u>tendons</u> (i.e. achilles, patellar, tibialis, hamstring) per month? (please write number)                                           |                                            |
| 6. What is your estimated use of <u>demineralized bone products</u> per month? (please write number)                                                                      |                                            |

- |                                                                                                                                        |                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 7. Over the next 1-2 years, do you believe that your demand for orthopaedic allograft tissue will increase or decrease? (please check) | <b>Increase</b> <input type="checkbox"/><br><b>Decrease</b> <input type="checkbox"/> |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|

Please estimate and write in by what percentage.

- |                                                                                                                                                        |             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
|                                                                                                                                                        | <b>%</b>    |
| 8. What percentage of your human bone and soft tissue allografts are currently provided by a: (please write %)                                         |             |
| <ul style="list-style-type: none"> <li>• Canadian Tissue Bank</li> <li>• American Tissue Bank</li> <li>• Other (specify)</li> <li>• Unknown</li> </ul> |             |
|                                                                                                                                                        |             |
|                                                                                                                                                        |             |
|                                                                                                                                                        | <b>100%</b> |

- |                                                                                                                                                                                                                                                                                              |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 9. If you obtain human bone and soft tissue allografts from sources other than Canadian Tissue Banks, please rank the following factors in terms of their <u>relevance to your decision to purchase outside of Canada</u> . (please write #1 for most important and # 4 for least important) |  |
| <ul style="list-style-type: none"> <li>• Not available in Canada</li> <li>• Speed and consistency of service</li> <li>• Price</li> <li>• Safety</li> </ul>                                                                                                                                   |  |
|                                                                                                                                                                                                                                                                                              |  |
|                                                                                                                                                                                                                                                                                              |  |
|                                                                                                                                                                                                                                                                                              |  |



**National Survey for Demand of Human Bone & Soft Tissue Allograft Products in Canada - January 2003**

%

10. Of all the procedures you do where your preference would be to use human allograft tissue, for what % must you use an alternative (xenograft, mechanical device, synthetic device) because allograft tissue is not readily available?

**SECTION # 2 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER**

There are many Tissue Banks, both Canadian and American that provide human bone and soft tissue allografts to Canadian surgical programs. Questions 11 to 17 ask you to indicate how strongly each characteristic influences your selection of a supplier / source for these allograft products.

	Reason	Not Important	⇒	Very Important
--	--------	---------------	---	----------------

**Quality**

Please circle number for rating:

- |                                                                                                                            |   |   |   |   |   |   |   |
|----------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 11. Graft Characteristics<br>(ease of application, meets technical expectation)                                            | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. Quality Assurance Program<br>(Tissue Bank has accreditation status or demonstrated quality programs)                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 13. Demonstrated Safety Record<br>(Tissue Bank has a record of taking action to minimize the risk of disease transmission) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Service**

Please circle number for rating:

- |                                                                                               |   |   |   |   |   |   |   |
|-----------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 14. Speed of service delivery<br>(tissue is distributed/received within acceptable timelines) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 15. Consistency of service<br>(service is provided dependably & reliably each time)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 16. Availability of tissue<br>(sufficient tissue is always available to meet needs)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 17. Price<br>(price is lower than competitors)                                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Questions 18 to 23 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

- |                                                                                                                                                                   |                          |                 |                |              |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------|----------------|--------------|-----------------------|
| 18. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, I would give preference to the not-for-profit Tissue Bank. | <b>Strongly Disagree</b> | <b>Disagree</b> | <b>Neutral</b> | <b>Agree</b> | <b>Strongly Agree</b> |
| 19. Given a choice between a Canadian and an American Tissue Bank with comparable quality products I would give preference to the Canadian Tissue Bank.           | <b>Strongly Disagree</b> | <b>Disagree</b> | <b>Neutral</b> | <b>Agree</b> | <b>Strongly Agree</b> |
| 20. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited Tissue Bank.          | <b>Strongly Disagree</b> | <b>Disagree</b> | <b>Neutral</b> | <b>Agree</b> | <b>Strongly Agree</b> |

**National Survey for Demand of Human Bone & Soft Tissue Allograft Products in Canada - January 2003**

21. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
22. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
23. Tissue banks should be able to generate profits on products they produce from donated tissue.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**

**SECTION # 3 TRENDS & EMERGING TECHNOLOGIES**

24. Are there trends for emerging technologies, which, when available will increase or decrease your demand for human bone and soft tissue allografts? Please name the trend / technology and note applicable procedures / application below:

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!  
 PLEASE FAX TO CIHI, ATTENTION KIM at (416) 481-2950 BY FEBRUARY 17, 2003**

**FOR FURTHER INFORMATION CONTACT:  
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**National Survey for Demand of Allograft Tissue Products for Neurosurgery in Canada - March 2003**

**SECTION # 1 COMMON USES OF ALLOGRAFT TISSUE FOR NEUROSURGERY**

1. For what neurosurgical procedures are human allografts used currently? Please name the procedure, provide the approximate number of these procedures you perform per year, and the type(s) of allograft tissues that are used in the procedure. Also, for each procedure, please indicate the percentage of procedures for which allograft tissues are required (e.g. 100% or less).

2.

Procedure	# of Procedures per Year	Type(s) of Allograft Tissue Used in Procedure (please check all that apply)	% of Procedures Requiring Allograft Tissue
a.		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata <input type="checkbox"/> Tendons <input type="checkbox"/>	
b.		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata <input type="checkbox"/> Tendons <input type="checkbox"/>	
c.		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata <input type="checkbox"/> Tendons <input type="checkbox"/>	
d.		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata <input type="checkbox"/> Tendons <input type="checkbox"/>	
e.		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata <input type="checkbox"/> Tendons <input type="checkbox"/>	

2. If you had access to a safe, reliable and cost effective source of Canadian allograft tissue, in appropriate quantities, would your use of **cancellous bone allografts** increase? (Please check)

Yes   
 No   
 Not used   
 %

If **Yes**, please estimate and write in by what percentage.

**National Survey for Demand of Allograft Tissue Products for Neurosurgery in Canada - March 2003**

3. If you had access to a safe, reliable and cost effective source of Canadian allograft tissue, in appropriate quantities, would your use of **Bone Matrix (demineralised or otherwise) containing human allograft bone** increase? (Please check)
- Yes   
 No   
 Not used

%

If **Yes**, please estimate and write in by what percentage.

4. If you had access to a safe, reliable and cost effective source of Canadian allograft tissue, in appropriate quantities, would your use of **structural bone allografts** increase (eg. bone dowels, wedges, rings)? (Please check)
- Yes   
 No   
 Not used

%

If **Yes**, please estimate and write in by what percentage.

5. If you had access to a safe, reliable and cost effective source of Canadian Allograft Tissue, in appropriate quantities, would your use of **human allograft fascia** increase? (Please check)
- Yes   
 No   
 Not used

%

If, **Yes** please estimate and write in by what percentage.

6. If you had access to a safe, reliable and cost effective source of Canadian allograft tissue, in appropriate quantities, would your use of **human allograft tendons** increase? (Please check)
- Yes   
 No   
 Not used

%

If **Yes**, please estimate and write in by what percentage.

**SECTION # 2 SOURCE(S) & ACCESS TO ALLOGRAFT TISSUE FOR NEUROSURGERY**

7. What percentage of your allograft tissue is currently provided by a: (please write %)
- Canadian Tissue Bank
  - American Tissue Bank
  - Other (specify)
  - Unknown

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**100%**

**National Survey for Demand of Allograft Tissue Products for Neurosurgery in Canada - March 2003**

8. If you obtain allograft tissue from sources other than Canadian Tissue Banks, please rank the following factors in terms of their relevance to your decision to purchase outside of Canada.

(please write #1 for most important and # 4 for least important)

- Not available in Canada
- Speed and consistency of service
- Price
- Safety

%

9. Of all the procedures you do where your preference would be to use human allograft tissue, for what % must you use an alternative (xenograft, mechanical device, synthetic device) because allograft tissue is not readily available?

--

10. In your opinion, what are the main reasons why you don't use allografts when they are the preferred choice for a surgical procedure? Please write in reasons, using page 5 if necessary.

--

**SECTION # 3 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER**

Both Canadian and American tissue banks provide allograft tissue to Canadian neurosurgical programs. Questions 11 - 17 ask you to indicate how strongly each characteristic would influence your selection of a supplier / source for these allograft products.

	Reason	Not Important	⇒	Very Important
<b>Quality</b>				

Please circle number for rating:

- |     |                                                                                                                        |   |   |   |   |   |   |   |
|-----|------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 11. | Graft Characteristics<br>(ease of application, meets technical expectation)                                            | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. | Quality Assurance Program<br>(Tissue Bank has accreditation status or demonstrated quality programs)                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 13. | Demonstrated Safety Record<br>(Tissue Bank has a record of taking action to minimize the risk of disease transmission) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Service**

Please circle number for rating:

- |     |                                                                                           |   |   |   |   |   |   |   |
|-----|-------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 14. | Speed of service delivery<br>(tissue is distributed/received within acceptable timelines) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 15. | Consistency of service<br>(service is provided dependably & reliably each time)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 16. | Availability of tissue<br>(sufficient tissue is always available to meet needs)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 17. | Price<br>(price is lower than competitors)                                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**National Survey for Demand of Allograft Tissue Products for Neurosurgery in Canada - March 2003**

Questions 18 to 23 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

18. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, I would give preference to the not-for-profit Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
19. Given a choice between a Canadian and an American Tissue Bank with comparable quality products I would give preference to the Canadian Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
20. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
21. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
22. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
23. Tissue banks should be able to generate profits on products they produce from donated tissue.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**

**SECTION # 4 TRENDS & EMERGING TECHNOLOGIES**

24. Are there trends or emerging technologies, which, when available will increase or decrease your demand for allograft tissue? Please name the trend / technology and note applicable procedures / application below:

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

**National Survey for Demand of Allograft Tissue Products for Neurosurgery in Canada - March 2003**

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

25. Other comments on the future of allograft tissue use in neurosurgery:

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!  
 PLEASE FAX TO CIHI, ATTENTION JANICE at (613) 729-1394 BY MARCH 28<sup>th</sup>, 2003**

**FOR FURTHER INFORMATION CONTACT:  
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**National Survey for Demand of Cardiovascular Allograft Tissue Products in Canada - March 2003**

**SECTION # 1 COMMON USES OF CARDIOVASCULAR ALLOGRAFT TISSUE**

1. For what cardiac surgical procedures are human allografts commonly used? Please name the procedure and the type of cardiovascular tissue used (eg. valves, pericardium, conduits, other). Also, please indicate how many grafts, on average, you use per year for each of these procedures.

Procedure	Type of Allograft Tissue	# Grafts/Year
a.		
b.		
c.		
d.		
e.		

2. Please check which size of valve you most frequently use for replacement in your surgical practice. Check more than one size if applicable. Check which size of allograft valve is in short supply/most difficult to obtain.

Valve Size	Size of Graft Commonly Used	Size of Graft Most Difficult to Obtain
<b>Small</b> < 14mm		
<b>Medium</b> 15mm – 20mm		
<b>Large</b> 21mm – 24mm		
<b>Extra large</b> > 25mm		

3. For valve replacements, please estimate by what percentage you use mechanical, xenograft or allograft valves.

Comments on factors affecting your decision to use one type vs another:

<b>%</b>	
<b><u>Aortic</u></b>	
<b>Mechanical</b>	_____
<b>Xenograft</b>	_____
<b>Allograft</b>	_____
<b><u>Pulmonary</u></b>	
<b>Mechanical</b>	_____
<b>Xenograft</b>	_____
<b>Allograft</b>	_____

**National Survey for Demand of Cardiovascular Allograft Tissue Products in Canada - March 2003**

4. Of all the procedures you do where your preference would be to use human allograft tissue, for what % must you use an alternative (xenograft, mechanical device, synthetic device) because allograft tissue is not readily available? \_\_\_\_\_
5. In your opinion, what are the main reasons why you don't use allografts when they are the preferred choice for a surgical procedure? \_\_\_\_\_

6. Over the next 1-2 years, do you believe that your demand for cardiovascular allograft tissue will increase or decrease? (please check)

Increase   
Decrease

\_\_\_\_\_ %

Please estimate and write in by what percentage.

**SECTION # 2 SOURCE(S) & ACCESS TO CARDIOVASCULAR ALLOGRAFT TISSUE**

7. What percentage of your cardiovascular allografts is currently provided by a: (please write %)

- Canadian Tissue Bank \_\_\_\_\_
- American Tissue Bank \_\_\_\_\_
- Other (specify) \_\_\_\_\_
- Unknown \_\_\_\_\_

100%

8. If you obtain cardiovascular allografts from sources other than Canadian Tissue Banks, please rank the following factors in terms of their relevance to your decision to purchase outside of Canada. (please write #1 for most important and # 4 for least important)

- Not available in Canada \_\_\_\_\_
- Speed and consistency of service \_\_\_\_\_
- Price \_\_\_\_\_
- Safety \_\_\_\_\_

**SECTION # 3 SUPPLY OF CARDIAC VALVES FROM TRANSPLANT RECIPIENTS**

9. Does your cardiac surgical program retrieve heart valves from the hearts removed from heart transplant recipients (for the purposes of tissue banking/future transplantation of allograft valves)? Yes or No

10. If **No**, what are the main reasons why this is not done?

**SECTION # 4 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER**

Both Canadian and American tissue banks provide cardiovascular allograft tissue to Canadian cardiac surgical programs. Questions 11 – 17 ask you to indicate how strongly each characteristic would influence your selection of a supplier / source for these allograft products.

	Reason	Not Important ⇨ Very Important
<b>Quality</b>		

Please circle number for rating:

- |                                                                                                                            |   |   |   |   |   |   |   |
|----------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 11. Graft Characteristics<br>(ease of application, meets technical expectation)                                            | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. Quality Assurance Program<br>(Tissue Bank has accreditation status or demonstrated quality programs)                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 13. Demonstrated Safety Record<br>(Tissue Bank has a record of taking action to minimize the risk of disease transmission) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Service**

Please circle number for rating:

- |                                                                                               |   |   |   |   |   |   |   |
|-----------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 14. Speed of service delivery<br>(tissue is distributed/received within acceptable timelines) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 15. Consistency of service<br>(service is provided dependably & reliably each time)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 16. Availability of tissue<br>(sufficient tissue is always available to meet needs)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 17. Price<br>(price is lower than competitors)                                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**National Survey for Demand of Cardiovascular Allograft Tissue Products in Canada - March 2003**

Questions 18 to 23 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

18. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, I would give preference to the not-for-profit Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
19. Given a choice between a Canadian and an American Tissue Bank with comparable quality products I would give preference to the Canadian Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
20. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
21. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
22. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
23. Tissue banks should be able to generate profits on products they produce from donated tissue.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**

**SECTION # 5 TRENDS & EMERGING TECHNOLOGIES**

24. Are there trends or emerging technologies, which, when available will increase or decrease your demand for cardiovascular allograft tissue? Please name the trend/technology and note applicable procedures/application below:

Increase/Decrease Demand	Trend/Emerging Technology	Procedure/Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

**SECTION # 6 RESPONDENT PROFILE**

25. Please indicate your age range :

- < 30
- 30 – 40
- 41 - 50
- 51 – 60
- 61 +

26. Please indicate which province you work in:

- |                             |                              |
|-----------------------------|------------------------------|
| <input type="checkbox"/> BC | <input type="checkbox"/> QC  |
| <input type="checkbox"/> AB | <input type="checkbox"/> NB  |
| <input type="checkbox"/> SK | <input type="checkbox"/> NS  |
| <input type="checkbox"/> MB | <input type="checkbox"/> PEI |
| <input type="checkbox"/> ON | <input type="checkbox"/> NF  |

27. Other comments on the future of allograft tissue use in cardiovascular surgery:

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!  
PLEASE FAX TO CIHI, ATTENTION JANICE at (613) 729-1394 BY MARCH 28<sup>th</sup>, 2003**

**FOR FURTHER INFORMATION CONTACT:  
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**National Survey for Demand of Ocular Allograft Products in Canada – March 2003**

**SECTION # 1 – UTILIZATION OF ALLOGRAFT TISSUE PRODUCTS**

In order to estimate the demand for ocular allograft products in Canada please provide your annual allograft utilization when completing questions 1- 3.

- |                                                                                                                                                                                                        |          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
|                                                                                                                                                                                                        | <b>#</b> |
| 1. What was your estimated use of <u>corneas</u> over the most recent 12 month period?<br>(please write number)                                                                                        | _____    |
| 2. What was your estimated use of <u>sclera</u> over the most recent 12 month period?<br>(Please write number)                                                                                         | _____    |
| 3. What is your estimated use of pieces of <u>amniotic membrane</u> over the most recent 12 month period? (Please write number)                                                                        | _____    |
| 4. Please fill out the table below indicating whether you believe you will experience an increase/decrease for each type of ocular allograft tissue over the coming 1-2 years, and estimate by what %. |          |

<u>Tissue Type</u>	<u>Increase/Decrease</u> <u>(Please check)</u>	<u>% Change</u>
Corneas	Increase <input type="checkbox"/> Decrease <input type="checkbox"/>	
Sclera	Increase <input type="checkbox"/> Decrease <input type="checkbox"/>	
Amniotic Membrane	Increase <input type="checkbox"/> Decrease <input type="checkbox"/>	

5. What percentage of your ocular allografts are currently provided by a: (please write %)
- Canadian Tissue Bank \_\_\_\_\_
  - American Tissue Bank \_\_\_\_\_
  - Other (specify) \_\_\_\_\_
  - Unknown \_\_\_\_\_

**100%**

- |                                                                                                                                                 |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------|
|                                                                                                                                                 | <b>#</b> |
| 6. How many patients are <u>currently on your wait list</u> for procedures that would require an ocular allograft tissue. (Please write number) | _____    |



**National Survey for Demand of Ocular Allograft Products in Canada – March 2003**

7. If you obtain ocular allograft tissues from sources other than Canadian Eye Banks, please rank the following factors in terms of their relevance to your decision to purchase outside of Canada.

(Please write #1 for most important and # 4 for least important)

- Not available in Canada
- Speed and consistency of service
- Price
- Safety

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**SECTION # 2 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER**

There are many Eye Banks, both Canadian and American that provide ocular allografts to Canadian surgical programs. Questions 8 to 14 ask you to indicate how strongly each characteristic influences your selection of a supplier / source for these allograft products.

	Reason	Not Important	⇒	Very Important
<b>Quality</b>				

Please circle number for rating:

- |     |                                                                                                                     |   |   |   |   |   |   |   |
|-----|---------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 8.  | Graft Characteristics<br>(ease of application, meets technical expectation)                                         | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 9.  | Quality Assurance Program<br>(Eye Bank has accreditation status or demonstrated quality programs)                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 10. | Demonstrated Safety Record<br>(Eye Bank has a record of taking action to minimize the risk of disease transmission) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Service**

Please circle number for rating:

- |     |                                                                                           |   |   |   |   |   |   |   |
|-----|-------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|
| 11. | Speed of service delivery<br>(tissue is distributed/received within acceptable timelines) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. | Consistency of service<br>(service is provided dependably & reliably each time)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 13. | Availability of tissue<br>(sufficient tissue is always available to meet needs)           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 14. | Price<br>(price is lower than competitors)                                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Questions 15 to 20 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

- |     |                                                                                                                                                         |                          |                 |                |              |                       |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------|----------------|--------------|-----------------------|
| 15. | Given a choice between a profit and a not-for-profit Eye Bank with comparable quality products, I would give preference to the not-for-profit Eye Bank. | <b>Strongly Disagree</b> | <b>Disagree</b> | <b>Neutral</b> | <b>Agree</b> | <b>Strongly Agree</b> |
| 16. | Given a choice between a Canadian and an American Eye Bank with comparable quality products I would give preference to the Canadian Eye Bank.           | <b>Strongly Disagree</b> | <b>Disagree</b> | <b>Neutral</b> | <b>Agree</b> | <b>Strongly Agree</b> |

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17. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited Eye Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
18. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
19. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
20. Eye banks should be able to generate profits on products they produce from donated tissue.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**

**SECTION # 3 TRENDS & EMERGING TECHNOLOGIES**

21. Are there trends (e.g. ageing population, disease rates) or emerging technologies (e.g. new procedures, substitutes), which will increase or decrease your demand for ocular allografts? Please name the trend / technology and note applicable procedures / application below:

Increase / Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

**SECTION # 4 RESPONDENT PROFILE**

22. Please indicate your age range :

- < 30
- 30 – 40
- 41 - 50
- 51 – 60
- 61 +

23. Please indicate which province you work in:

- BC                       QC
- AB                       NB
- SK                       NS
- MB                       PEI
- ON                       NF

**24. Other comments on the future of allograft tissue use in corneal surgery:**

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!  
PLEASE FAX TO CIHI, ATTENTION JANICE at (613) 729-1394 BY MARCH 21<sup>st</sup>, 2003**

**FOR FURTHER INFORMATION CONTACT:**

**Janice Miller & Colleen Zebchuck  
CCDT / CIHI Project Consultants  
(613) 729-7885**

**[miller.janice@sympatico.ca](mailto:miller.janice@sympatico.ca)    [czebchuck@rogers.com](mailto:czebchuck@rogers.com)**

National Survey for Demand for Allograft Skin Products in Canada – March 2003

**SECTION # 1 – UTILIZATION OF ALLOGRAFT TISSUE PRODUCTS**

	1. How many patients who required allograft skin were admitted to your burn centre during each of the following calendar years (please write number of patients)	2. What was your program's estimated use (per year) of <u>skin grafts</u> for each of the following calendar years? (please write number of skin grafts)
	<i>Please provide statistics for all 5 years if possible, or for the most recent year(s)</i>	<i>Please provide statistics for all 5 years if possible, or for the most recent year(s)</i>
<b>Year</b>	<b>#</b>	<b>#</b>
2002	_____	_____
2001	_____	_____
2000	_____	_____
1999	_____	_____
1998	_____	_____

3. Over the next 1-2 years, do you believe that your program's demand for allograft skin will increase or decrease? (please check) Increase   
Decrease

Please estimate and write in by what percentage.

%

\_\_\_\_\_

%

4. What percentage of your program's skin allografts are currently provided by a: (please write %)

- Canadian Tissue Bank \_\_\_\_\_
- American Tissue Bank \_\_\_\_\_
- Other (specify) \_\_\_\_\_
- Unknown \_\_\_\_\_

100%

%

**National Survey for Demand for Allograft Skin Products in Canada – March 2003**

5. If there were no barriers in relation to accessing allograft skin (i.e. you could access safe tissue when you wanted it, in the quantities you require) by what percentage would you estimate your program's annual use would increase? (please write %)
6. For the procedures performed by your program, where the preference would be to use human allograft tissue, for what % must an alternative be used because allograft tissue is not readily available? (please write %)
7. If you obtain allograft skin from sources other than Canadian Tissue Banks, please rank the following factors in terms of their relevance to your decision to purchase outside of Canada.  
 (please write #1 for most important and # 4 for least important)
- Not available in Canada
  - Speed and consistency of service
  - Price
  - Safety

**SECTION # 2 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER**

There are many Tissue Banks, both Canadian and American that provide allograft skin to Canadian burn units and surgical programs. Questions 8 to 14 ask you to indicate how strongly each characteristic influences your selection of a supplier / source for these allograft products.

	Reason	Not Important	⇒	Very Important				
<b>Quality</b>								
		<b>Please circle number for rating:</b>						
8.	Graft Characteristics (ease of application, meets technical expectation)	1	2	3	4	5	6	7
9.	Quality Assurance Program (Tissue Bank has accreditation status or demonstrated quality programs)	1	2	3	4	5	6	7
10.	Demonstrated Safety Record (Tissue Bank has a record of taking action to minimize the risk of disease transmission)	1	2	3	4	5	6	7
<b>Service</b>								
		<b>Please circle number for rating:</b>						
11.	Speed of service delivery (tissue is distributed/received within acceptable timelines)	1	2	3	4	5	6	7
12.	Consistency of service (service is provided dependably & reliably each time)	1	2	3	4	5	6	7
13.	Availability of tissue (sufficient tissue is always available to meet needs)	1	2	3	4	5	6	7
14.	Price (price is lower than competitors)	1	2	3	4	5	6	7

**National Survey for Demand for Allograft Skin Products in Canada – March 2003**

Questions 15 to 20 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

- 15. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, we would give preference to the not-for-profit Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
- 16. Given a choice between a Canadian and an American Tissue Bank with comparable quality products we would give preference to the Canadian Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
- 17. Given a choice between an accredited and non-accredited bank with comparable quality products we would give preference to the accredited Tissue Bank.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
- 18. We would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
- 19. We would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**
- 20. Tissue banks should be able to generate profits on products they produce from donated tissue.  
**Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree**

**SECTION # 3 TRENDS & EMERGING TECHNOLOGIES**

21. Are there trends or emerging technologies, which, when available will increase or decrease your program's demand for allograft skin? Please name the trend / technology and note applicable procedures / application below:

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

**22. Other comments on the future of allograft tissue use for treatment of burns:**

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!  
PLEASE FAX TO CIHI, ATTENTION JANICE at (613) 729-1394 BY MARCH 21<sup>st</sup>, 2003**

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