The Canadian Council for Donation and Transplantation

Evaluation of Surgical Bone Banking and Utilization in Canada

Report and Cost Benefit Analysis

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Foreword

Tissue banking is a relatively underdeveloped resource in Canada resulting in variability in the access of Canadians to quality tissue grafts and resultant concerns about the safety and supply of human allograft tissue in Canada. The annual demand is estimated at least five times the Canadian supply and the need appears to be growing faster than the Canadian supply.

Surgical bone, most commonly referring to femoral heads, appears to be a significant component of the tissue supply from Canadian tissue banks, perhaps in part due to limited numbers of deceased donors and limited tissue processing capabilities of existing tissue banks. In order to better understand the level of surgical bone banking in Canada, the Canadian Council for Donation and Transplantation (CCDT) Tissue Committee undertook a project to quantify the supply of surgical bone and to identify key issues affecting maximization.

This project is a part of the Tissue Committee's strategy to develop a framework for action at local, provincial/territorial and national levels that will result in a sustained, systematic approach to tissue banking and transplantation in Canada.

Potential improvements identified during this initiative include the development of a shipping model of surgical bone banking where femoral heads from orthopaedic departments that do not have tissue banks are shipped to regional established surgical bone banks. In return for shipping femoral heads to surgical bone banks, the participating hospitals would receive femoral heads at a discounted rate compared with purchasing tissue from Canadian tissue banks or international sources.

Another opportunity for increasing supply is an improvement in the average rejection and deferral rate could allow the average estimated demand for surgical bone to be met with Canadian supply. The promotion of national standardization in surgical bone banking, including quality assurance procedures, obtaining consent, medical and social screening, and testing requirements will assist in this endeavor.

Marc Germain MD PhD
Chair, CCDT Tissue Committee

Acknowledgements

Critical to the success of this project was the contribution of all of the orthopaedic surgical departments, surgical bone banks and comprehensive tissue banks that participated in the interviews and surveys that are part of this study.

We would like to specifically thank Ms. Debbie Gaskin (LHSC and SJHC Tissue, Organ, and Cell Bank, Coordinator) and Mr. Jim Mohr (past Chair, CCDT Tissue Banking and Transplantation Committee) for their efforts and support throughout the project.

We would also like to express our sincere gratitude to Ms. Muriel Shewchuk (former Director, Surgical Suites, Calgary Health Region) for sharing her considerable knowledge and experience in surgical bone banking.

We would also like to thank Dr. Robert McGraw (former Head, Orthopaedic Surgery, Vancouver General Hospital), Dr. George Galea (Tissue Services Director, Scottish National Blood Transfusion Service, Edinburgh) and Ms. Debbie Newman (American Association of Tissue Banks) for their participation and insight.

Executive Summary

Introduction

The Canadian Council for Donation Transplantation (CCDT) commissioned an evaluation of surgical bone banking in Canada in order to:

1. Attempt to determine the number of surgical bone banks and their tissue volumes not identified in previous CCDT work,
2. Obtain a sense of surgical bone potential,
3. Obtain a sense of the actual donation rates of surgical bone,
4. Identify and analyze key issues in surgical bone banking, and
5. Provide a high level cost benefit analysis of surgical bone banking.

Methodology

Between March 21st and May 10th 2005, 173 orthopaedic departments were contacted to determine the number of surgical bone banks operating in Canada. Each orthopaedic department was interviewed for the number of femoral heads obtained per year, information on operational practice, femoral head donation and rejection rates, banking costs and key issues affecting the ability to maintain operation of the surgical bone banks. A literature review was performed to highlight issues not raised in the interviews. Data from the Canadian Joint Replacement Registry was used to estimate the number of femoral heads available from total hip replacements. Issues identified in the interviews were analyzed and grouped into key drivers and outcomes. The drivers and outcomes were used to assess potential models for increasing the surgical bone supply in Canada.

Key Metrics

Description	Number or Percentage
Number of surgical bone banks operating in Canada	26
Number of orthopaedic departments participating in surgical bone banking	33 / 173 (19%)
Total number of hip replacements performed in Canada each year (i.e. number of femoral heads available before deferral and rejection)[i]	19,797
Average combined rejection and deferral rate (including surgeon rejection at time of surgery)	49%
Possible number of viable femoral heads that could be banked annually (based on current combined referral and rejection rates)	10,091 (51%)
Actual number of femoral heads referred for donation	4317 / 19,797 (22%)
Realized annual supply of viable femoral heads	2233 / 10,091(19%)
Average estimated demand for surgical bone	11,581
Estimated average annual shortfall of femoral heads	9348

Key Issues: Drivers and Outcomes

The main issues identified as driving current practice in surgical bone banking included the following:

- Difficulty in meeting accreditation, quality standards and regulatory requirements.
- Surgeon preference for femoral heads appears high.
- Most surgical bone banks are under funded (some received no funding).
- Increased use of allograft procedures is placing more demand on both surgical bone banks and tissue banks to supply bone tissue.
- The majority of femoral heads (83%) were obtained in surgical bone banks located within orthopaedic training hospitals.

The main outcomes of current practice in surgical bone banking included the following:

- Operations of a surgical bone bank are becoming increasingly complex given recent changes in quality and regulatory requirements.
- Human resources are low and/or strained.
- Purchasing of femoral heads from the US is increasing, in part due to orthopaedic budgets allowing the purchasing of US allograft tissue and low supply of Canadian femoral heads.
- Cost of surgical bone banking is not well established (or known in several banks) given the lack of standardized practice guidelines and in-hospital budgeting.
- Surgeon involvement in surgical bone banking is low in non-training orthopaedic hospitals.
- There is a wide variation in rejection and deferral rates across Canada, ranging from 32% to 69%.

Costs and Operational Factors

- The average reported cost for a femoral head from a surgical bone bank from donation to distribution was $913 CDN.
- In-hospital surgical bone banking is more cost effective than purchasing femoral heads from the US (average cost ~$1260 per femoral head) and may be as cost effective as obtaining femoral heads from Canadian tissue banks (average cost ~$1050 per femoral head).
- It is possible for new in-hospital surgical bone banks to operate economically, however there are significant start-up issues to overcome, in particular staff training, meeting Health Canada regulations, quality system development and obtaining the participation of other hospital departments (e.g. for serology).

Living Donation

- Unlike deceased donation, surgical bone is obtained through living donor consent, which has been reported to be as high as 90 to 95% for surgical bone.
- Obtaining consent for this type of tissue is not a barrier (although it must be staffed appropriately) and is not as challenging on donor families or donation coordinators.

Part I:

Surgical Bone Donation Rates, Banking and Utilization in Canada

Surgical Bone Donation Rates, Banking and Utilization in Canada

Introduction

The Canadian Council for Donation and Transplantation (CCDT) undertook an exploration of the current donation rates and utilization of surgical bone in Canada, specifically the donation and utilization of femoral heads obtained from total hip replacement (THR) surgery. The scope of the study pertained to live donors only and not to femoral heads obtained from deceased donors.

The main tasks were to:

- Attempt to identify surgical bone banks not identified in previous CCDT work,
- Attempt to obtain tissue volumes at each surgical bone bank,
- Obtain a sense of surgical bone potential, and
- Obtain a sense of the actual donation rates of surgical bone.

Following is a description of the methodology used and the results for each task.

Methodology

Task 1: Identification of Surgical Bone Banks

In order to locate surgical bone banks not previously identified in CCDT reports or databases, several sources of information were cross-referenced to generate a list of hospitals that could potentially be operating a bone bank.[ii]

Potential sites for surgical bone banks were surveyed based on the capability of a facility to perform total hip replacements. These sites were selected because each surgical site that performs total hip replacements has the potential to either operate, or donate tissue to, a surgical bone bank.

The Canadian Medical Directory (MD Select 2004) was used to identify nearly all[iii] orthopaedic surgeons and the locations of practice in 2004. The location of where the surgeons were practicing was then cross-referenced with the Canadian Health Facilities Directory (Southham 2005) to locate the hospitals in the cities where the orthopaedic surgeons were practicing.

Once the hospitals were identified, each hospital was either contacted directly or the hospital web site was reviewed to determine if total hip replacements were being performed and a final list of potential sites for surgical bone banks was generated based on the ability to perform a total hip replacement.

Finally, each hospital that had the capability to perform total hip replacements was contacted to:

1. Inquire if they are operating a surgical bone bank,
2. Obtain data on the average number of femoral heads and retention/rejection rates, and
3. Conduct a discussion of issues effecting the operation of the surgical bone banks.

A number of previously unknown (to CCDT) surgical bone banks were found and are discussed below.

Task 2: Surgical Bone Potential and Actual Rates

The estimate of the potential and actual femoral head donation was based on three sources of information:

1. Data from the Canadian Joint Replacement Registry (CJRR 2004),
2. An estimate of the number of orthopaedic departments currently operating or contributing to a bone bank, and
3. Estimates from operating surgical bone banks on their tissue deferral and discard rates.

Data from the CJRR (2004) was used to provide an estimate of the actual number of total hip replacements performed in Canada. This number represents the total number of femoral heads that could be referred in Canada, if the capacity existed to process the tissue.

One-hundred and fifty three orthopaedic administrative centres (representing 173 individual departments) that could potentially donate a femoral head to a surgical bone bank were contacted and a brief telephone survey of each was performed to determine what percentage of these centres is currently contributing to a surgical bone bank.

The CJRR (2004) data provides the maximum number possible of all femoral heads that could be collected. The telephone survey data provides the actual number of orthopaedic departments that could be contributing to the supply at the time of publication of this report.

Results

Identification of Surgical Bone Banks and Tissue Volumes

Table 1 contains the number of surgical bone banks previously identified by CCDT and the number of previously unknown to CCDT surgical bone banks found during the hospital interviews conducted for this study, by province. Appendix 1[1] contains a list of the names and location of each surgical bone bank by province.

For the purposes of this study, a surgical bone bank is defined as one that currently obtains and banks femoral heads from live donors undergoing total hip replacements in Canada. A tissue bank that distributes femoral heads solely from another source (e.g. US tissue banks or deceased donors) is not considered to be a surgical bone bank.

One-hundred and fifty three orthopaedic departments and regional administrative health centres that have orthopaedic staff capable of performing a total hip replacement were contacted. This represents 173 hospitals in Canada where a total hip replacement could be performed.[iv]

At the time of publication of this report, responses were obtained from 145 (84%) of the hospitals, with 28 hospitals (16%) yet to report. The majority of non-responses were from Ontario (n=19).

[1] Note: Appendices referenced in this document are available on-line at www.ccdt.ca/english/publications/final.html.

There are currently five provinces that do not operate surgical bone banks which represents a significant loss of femoral head donation potential.

Projected from the current donation rates, the actual number of viable femoral heads available to be released for distribution is not expected to exceed 2500 given the current number of surgical bone banks operating in Canada.

Table 1: Number of Surgical Bone Banks with Reported Tissue Volumes

Province or Territory	Previously Known to CCDT	New Surgical Bone Banks Identified	Current Number of Surgical Bone Banks Operating	Current Confirmed Provincial Tissue Volumes of Viable Femoral Heads† Available for Distribution
BC	4	0	2	275
AB	1	1	2	675
SK	0	2	2	164
MN	0	0	0	0
ON	13	4	17	694††
QC	1	1	2	350†††
NB	1	0	1	75
NL	0	0	0	0
NS	0	0	0	0
PEI	0	0	0	0
N.W.T, Nunavut and Yukon	0	0	0	0
Totals	20	7	26	2233

† The Current Provincial Tissue Volume represents the actual number of femoral heads retained after donor screening is completed and a femoral head is accepted in to the tissue bank.

†† This number is the total of 13 of the 17 bone banks reporting at the time of this publication.

††† One of three surgical bone banks in Québec had not yet reported at the publication of this report.

Surgical Bone Donation Potential and Referral Rate

Table 2 includes the total number of total hip replacements as projected by the Canadian Joint Replacement Registry (CJRR 2004) and the current actual referrals to surgical bone banks operating in Canada, obtained during the telephone interviews with the surgical bone banks.

Table 2: Provincial Summary of Surgical Bone Referrals

Region	Total Hip Replacements 2000-2001 (CJRR 2004)	Current Provincial Referrals to Operating Surgical Bone Banks	
BC	2892	550	19%
AB	2036	1106	54%
SK	885	458	52%
MN	867	0	0%
ON	8078	1353	17%
QC	3188	700	22%
NB	514	150	29%
NL	218	0	0%
NS	781	0	0%
PEI	110	0	0%
Territories	29	0	0%
Unknown	189	---	---
National Total	**19787**	**4317**	**21.82%**

The referral rate to operating surgical bone banks is limited by the number of orthopaedic surgeons potentially contributing to the banks; usually located only in their own hospital where the surgical bank is located, or in a few cases, donations from a set of smaller regional health centres. Based on the responses from the telephone interviews with the orthopaedic departments, only 33 hospitals were confirmed to be currently operating or contributing to a surgical bone bank out of the 153 hospitals contacted, or 22% of potential hospitals that could potentially be contributing.

The current referral rate is not expected to be higher than 25% of all total hip replacements performed in Canada if non-responders are considered.

Provinces that did not conduct surgical bone banking reported a strong reliance on US sources for, or processing of, bone grafts.

Actual Surgical Bone Donation Rates

In order to determine the donation rates, two questions were asked of the surgical bone banks:

1. How many femoral heads are collected, and
2. What is the average deferral rate and criteria used to reject the tissue?

There were some significant differences in how deferral rates were determined between surgical bone banks. Some surgical bone banks accounted for all screening activities while others only considered biological testing as part of "rejection" or deferral[v] of tissue. For purposes of this study, the term "rejection rate" refers to the combined loss of potential donations arising from both deferrals (i.e. medical, social and lack of consent) and rejected tissue (i.e. losses from subsequent testing, e.g. 180 day follow up serology). Despite the differences in perception of rejection and deferral criteria, the screening steps listed in Table 3 occur for all donated femoral head tissue. Table 3 also lists the average rejection rates for each step reported by the surgical bone banks.

Table 3: Surgical Bone Rejection Rates

Screening Step	Rejection Loss (%)
Obtaining Consent	5
Medical and Social Screening	10-20 est.*
Initial serological testing	10
180 serological testing	10-20 est.*
Average (n=19) *No surgical bone bank could report a specific percentage	

Figure 1 contains a histogram of the reported rejection/deferral rates (n=19/26). Most surgical bone banks (n=11/19) are experiencing rejection rates around 50%.

Figure 1: Surgical Bone Combined Deferral and Rejection Rates

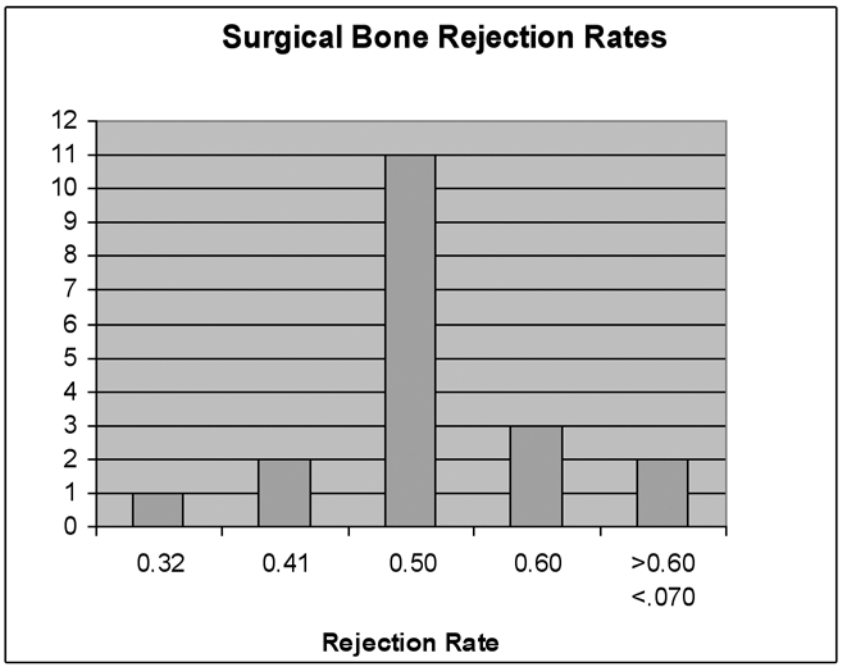


Figure 2 contains a comparison of rejection rates by region. The lowest rejection rates (32 and 33%) were both from large, well established surgical bone banks operating in Eastern Canada that have small geographic areas of donation potential. The highest rejection rates (65 and 69%) were from surgical bone banks that experienced a high proportion of rural femoral head donation, where the 180 day serological testing requirement was expressed as the most prevalent reason for the higher losses, given the difficulty of obtaining follow up blood testing in rural areas.

When viewed by region however, the rejection rate between provinces varies between 40 and 50%, with the exception of Saskatchewan. It should also be noted that the higher rate seen in Saskatchewan is noted to be due to the current storage capacity at one bank and not due to banking procedures (i.e. they do not have the funding for more cryogenic storage and can only retain a portion of all viable femoral heads).

Figure 2: Rejection Rates by Region

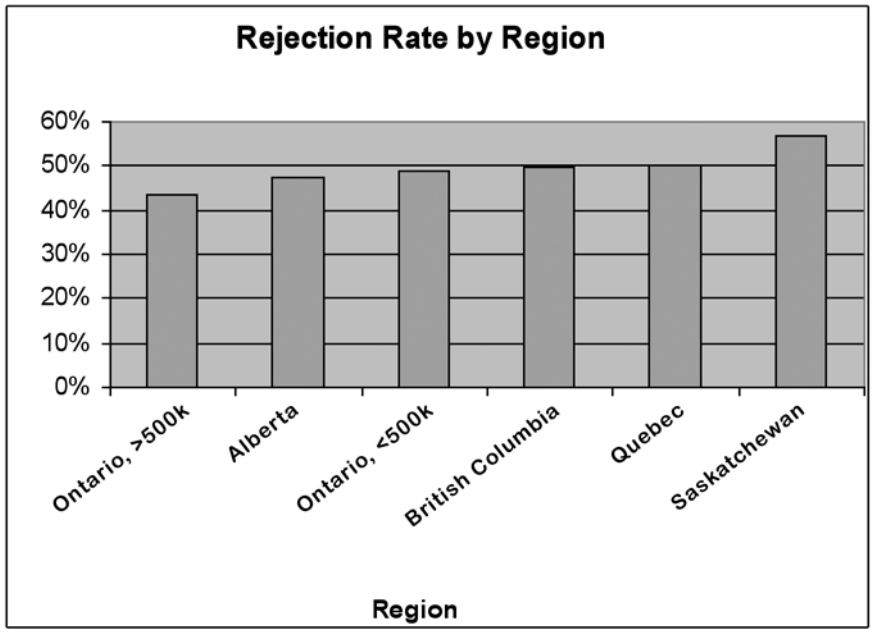
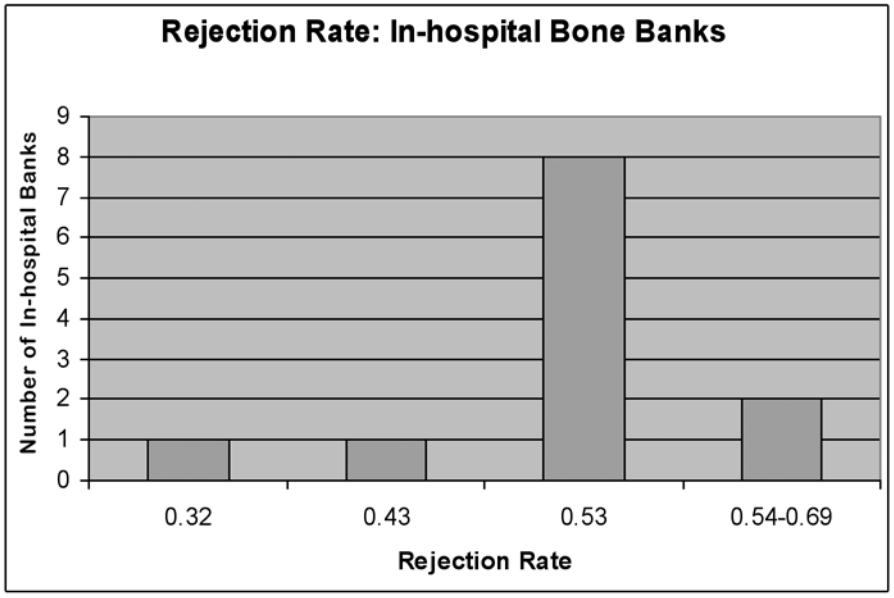


Figure 3 and Figure 4 below compare the rejection rates between in-hospital bone banks (n=13) and comprehensive tissue centres that also collect surgical bone (n=6).

The rejection rate of in-hospital bone banks closely resembles Figure 1, with most (n=8) in-hospital bone banks experiencing an average rejection rate of approximately 47%.

Figure 3: Rejection Rate of In-hospital Bone Banks



Comprehensive tissue banks (n=6) have a similar rejection rate to in-hospital bone banks, averaging a rejection rate of 51%.

Figure 4: Rejection Rate of Comprehensive Tissue Banks (surgical bone only)

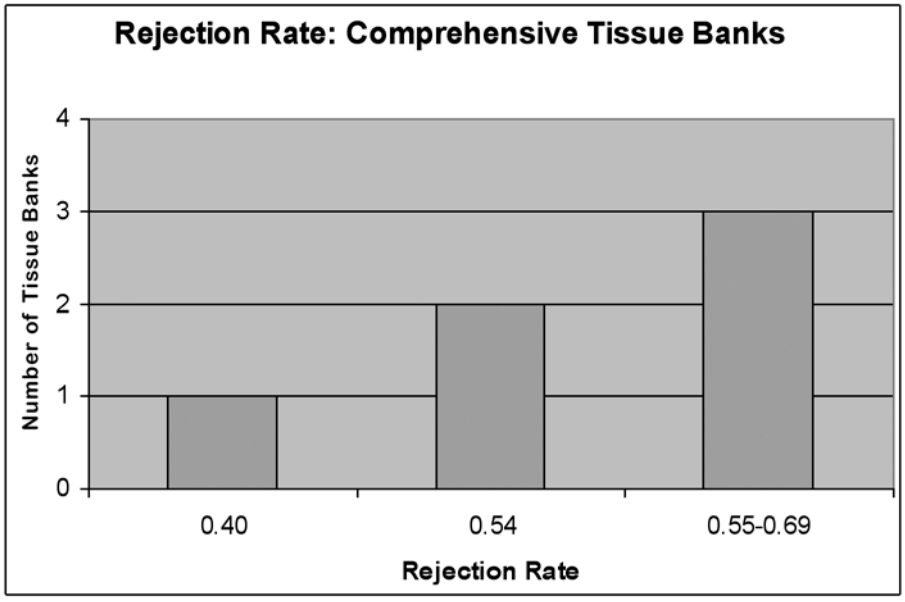


Table 4 contains the actual donation rates reported by currently operating surgical bone banks.

Based on CJRR (2004) data on the number of total hip replacements in Canada, and the average rejection/deferral rate reported from surgical bone banks, it is estimated that there is a potential of 10,091 viable femoral heads that could be released for distribution in Canada.

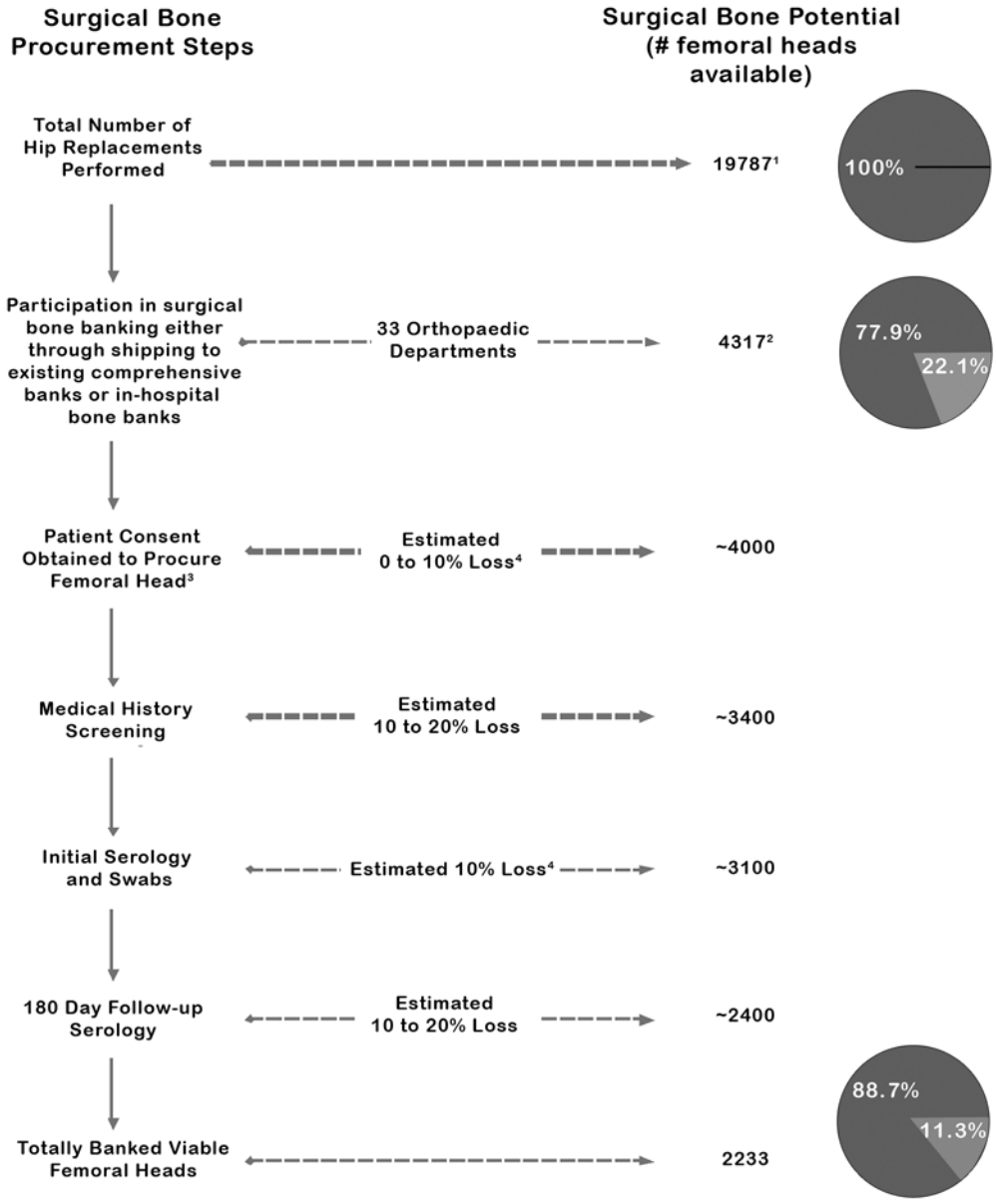
The actual number reported at the time of publication of this report is 2233 femoral heads; however this number is not expected to be beyond 2500 femoral heads if numbers were obtained from all banks.

Table 4: Actual Surgical Bone Released for Distribution

Region	Estimated Potential After Deferral/ Rejection (CJRR THR No. X Av. Retention 51%)	Actual Number of Femoral Heads Released for Distribution	Estimated Remaining Viable Femoral Heads that could be Released for Distribution in Canada if Full Donation Potential was met.
BC	1475	275	1200
AB	1038	675	363
SK	451	164	288
MN	442	0	442
ON	4120	694	3426
QC	1626	350	1276
NB	262	75	187
NL	111	0	111
NS	398	0	398
PEI	56	0	56
Territories	15	0	15
Unkn.	96		96
Totals	10090	2233 (22.1%)	7858 (77.9%)

Figure 5 below summarizes the current surgical bone procurement outlook in Canada. The largest influence on surgical bone bank potential is the low number of orthopaedic departments actually participating in surgical bone banking. The estimated losses from deferral and other rejection criteria are also shown in Figure 5.

Figure 5: Current Canadian Surgical Bone Procurement



1 CIHI 2004

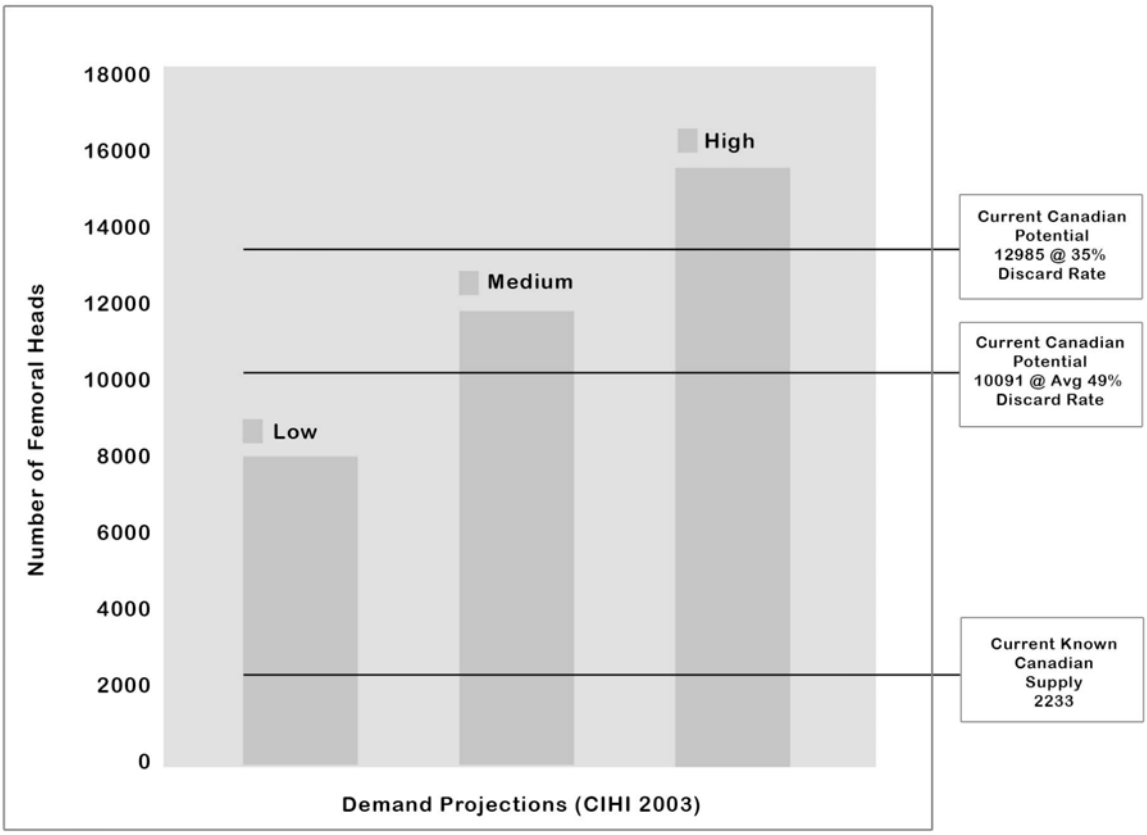
2 4317 femoral heads were obtained by the 33 participating hospitals, prior to medical and blood screening.

3 Surgical bone consent practices vary. Some banks obtain all femoral heads first and then try to obtain consent, while others obtain consent first and only then procure femoral heads.

4 Estimates provided by two Canadian comprehensive tissue banks that collect surgical bone.

Figure 6 describes the projected demand for surgical bone vs. the potential supply in Canada. The Canadian Institute for Health Information (CIHI May 2003) has estimated the demand for surgical bone to vary between a low of 7720, median of 11581 and a high of 15441 femoral heads. The current known supply of 2233 femoral heads clearly cannot meet the low projected demand. There is however the potential to meet or exceed the median projected demand, if all surgical bone from total hip replacement could be donated to a surgical bone or comprehensive tissue bank. Furthermore, if the lowest discard rates reported could be reproduced across Canada, the possibility exists that 84% (12985/15441) of the highest projected demand for surgical bone could be met.

Figure 6: Surgical Bone Demand vs. Supply Potential



Summary

The summary findings for this section are:

- 26 Surgical bone banks were identified (6 previously unknown to CCDT)
- Reported Total number of femoral heads referred = 4317
- Reported Total number of femoral heads retained for distribution = 2233
- National average combined deferral and rejection rate reported by surgical bone banks (n=19/26) = 49%

Estimated remaining number of viable femoral heads that could have been donated = 7762

- Total number of orthopaedic departments responding to interviews for this study that are capable of or are conducting THRs = 153
- Total number of orthopaedic departments contacted contributing bone to a bone bank = 33

Part II:

Issues Identification and Analysis

Issues Identification and Analysis

Introduction

Between March 21st and May 10th 2005 a series of interviews with orthopaedic departments, surgical bone banks and several experts were conducted to:

1. Obtain a sense of surgical bone donation, banking and utilization capacity, and
2. To identify issues related to these activities.

Appendix 2, available on-line at www.ccdt.ca, contains a list of all issues identified from the interviews with orthopaedic departments, surgical bone banks and several experts. All of the issues listed in Appendix 2 were raised by at least one orthopaedic department or surgical bone bank.

Two literature reviews, including an initial review prior to the interviews and a secondary post-interview literature review were conducted to examine issues in more detail and to support the interview results where possible.

A total of 84 issues were identified relating to donation, banking, utilization and other issues, including technology changes, clinical outcomes, surgeon preference, testing, storage, standards and cost.

Methodology

The following methodology was used to analyse the issues raised during the interview phase:

1. Issues were gathered through interviews with orthopaedic departments, surgical bone banks (current and former) and several experts.
2. Issues relating specifically to donation, banking and utilization were analyzed using a number of techniques (defined below). Other issues that emerged during the interviews outside of these areas were also examined (e.g. new surgical techniques that may influence surgical bone banking).
3. The issues were grouped in themes for cause and effect analyses to identify if issues raised are key influences or "drivers" and which issues are key outcomes.
4. Objectives, success measures and outcomes for further cost benefit analysis were developed based on the issues analysis.

Further analysis was conducted separately on specific issues relating to donation, banking, utilization and other issues that emerged during the interviews.

Following is a discussion of specific donation, banking, utilization and other issues that were raised during the interviews. A number of questions were raised by the issues (e.g. assessing the potential effect of changes in orthopaedic technology) and explored in detail to provide detailed information for later cost benefit analysis.

Donation Procedures, Costs and Donation Rate Issues

Cost of Donation

The actual cost of donation will vary between organizations (i.e. in-hospital vs. comprehensive tissue banks) however there are specific steps in the donation of a femoral head that must be followed that are independent of where a donation occurs. These steps can be used to estimate the costs associated with donation.

Following is a list of steps compiled from a number of published reports on donation protocols as well as expert advice. It is interesting to note that La Prairie and Gross (1991) developed a protocol for surgical bone procurement in Halifax that met AATB and other standards (c.1990) that could be updated for use by Canadian hospitals.

It is important to identify the donation costs that are *included and inherent* in the costs of performing a THR:[vi]

- Obtaining a sterile surgical suite for performing a procedure, for both recovery and utilization,
- Physician time, and
- Availability and time for OR staff to assist in the initial packaging of the femoral heads.

Costs for these steps are not (and do not need to be) included in the cost of obtaining a femoral head from surgical bone, which is not necessarily the case with deceased tissue processing. These cost differences are critical when comparing the costs to process a femoral head between stand-alone surgical bone banks, and comprehensive tissue banks that have to process femoral heads from deceased donors outside of an operating room setting.

The typical steps in the donation and procurement of a femoral head are:[vii,viii]

1. Questionnaire screening of potential THR donors by hospital staff, or screening decision by surgeon may also occur.
2. Consent form signature obtained from donor. Physical examination performed or documentation obtained as per bank/hospital procedure.
3. Serological tests, which may include: hepatitis B surface antigen, hepatitis B core antibody (IgM/total), hepatitis C antibody, HIV antibody, WNV screening, HTLV I and II antibody, syphilis serology (e.g RPR), and other possible tests as indicated by patient history. Hemodilution algorithm used when required.
4. Microbiological screening, which may include: aerobic and anaerobic bacteria, mycology.
5. Initial test records filed by responsible person.
6. Procurement steps:
    a. Femoral head removed as part of THR procedure
    b. Excess soft tissue removed by surgeon
    c. Biopsy of soft tissue/swab sent for microbiology testing
    d. Other tissue sent to pathology for examination, if necessary

e. OR staff places femoral head in sterile container(s) as per bank/hospital procedure

f. Antibiotic or disinfectant solution may be added (e.g. Proviodine 10%) to sterile container

g. X-ray or other sizing measurement (e.g. reamer sizing) performed as per bank/hospital procedure

h. OR staff completes donation documentation– copy of documentation is returned to bank and another copy may be retained on donor hospital chart

i. Packaged femoral head taken out of sterile area and placed in a foam container with ice for immediate transport, or is placed directly in freezer

j. Receipt and log in for storage

k. Femoral head transported to minimum -40C freezer.

7. 180 day quarantine of newly banked femoral head proceeds.

8. 180 day follow up serological testing of donor.

9. If tests are negative and all other requirements are met (e.g. release by Medical Director and Quality Assurance), femoral head transferred to release inventory.

Other global activities in the process include:

- Meeting Health Canada regulations, Canadian Safety Association (CSA) standards and AATB requirements (if the bank is seeking accreditation),
- Developing and maintaining protocols and procedures,
- Internal auditing,
- Records maintenance,
- Equipment purchase and/or rental, and
- Equipment monitoring.

The costs associated with these procedures may or may not be tracked, or even known, by the hospital or bone bank (Canadian Surgical Bone Banks 2005) but they are likely tracked by the comprehensive tissue banks.

Other costs associated with surgical bone banking may or may not be charged to the bone bank, e.g. having to discard rejected bone or other hospital-specific protocols.

How do you establish the 'true' cost of surgical bone banking, particularly when many surgical bone banks do not track or document all applicable costs? Costs associated with each step are difficult to obtain, as these procedures are often considered to be 'free' as part of the donation process and may not be billable by an OR department directly, and no specific cost data may be kept.[ix] For example, there may not be a separate "bone bank co-ordinator" position – the responsibility may likely be that of the OR Manager and the amount of time spent managing the bone bank operations may not be documented.

There are wide differences in how the costs of operating a bone bank are reported. For example, Hart considered, from a human resource and equipment point of view, that a surgical bone bank

can be set up extremely cost effectively - but only if other existing hospital resources are leveraged and not directly accounted for in the operation of the bank (Hart el al April 1986; Hart el al May 1986).

Depending on the hospital resources available, setting up a bone bank in a hospital to handle both deceased tissue donation and surgical bone can be expensive if dedicated resources are required, and tracked, for operation of the bank (Dopplet et al. 1981). Hart et al. (May 1986) estimated a direct cost of $5000 to set up a surgical bone bank at a small Phoenix community hospital, while Dopplet et al. (1981) estimated an annual operating budget of $50,000 for the Massachusetts General bone bank or an average cost of $2000 per graft implant.

A cost range estimate based on primary interview data and from literature review was used (see Appendix 5, available on-line at www.ccdt.ca, for complete survey) in order to provide a probable range of the costs associated with surgical bone donation.

Because of the lack of published accurate cost information from Canadian surgical bone banks, the data in Appendix 5 was refined by a fax survey of all current surgical bone banks in Canada. The survey in Appendix 5 was intended to provide a probable range of costs that a tissue bank would have to incur, and serve as a starting point for more accurate basis for decisions regarding the cost of surgical bone banking. Table 5 provides the responses received (n=11/26 banks).

Table 5: Surgical Bone Banking Activity Cost Estimate Survey Results

Typical Femoral Head Donation Steps	**Estimated Average Cost per femoral head (based on literature review)**	**Description**	**Facility Survey Cost Estimate**
Medical History Screening and Obtaining Consent	$30	**Typical steps:** Medical history screening, obtaining consent 1 hour (based on average RN wage)	Not tracked –performed by surgeon (n=1) Not tracked – not indicated who screens (n=6) $30 (n=2) $68.15 $60
Initial swabs and serology	$130	**Typical current tests:** hepatitis B surface antigen, hepatitis B core antibody; hepatitis C antibody; HIV I and II antibody; HTLV I and II antibody, syphilis serology; aerobic and anaerobic bacteria plus mycology	Not tracked (n=7) $200 $205 $130 $60

Typical Femoral Head Donation Steps	Estimated Average Cost per femoral head (based on literature review)	Description	Facility Survey Cost Estimate
Additional testing requirements	$100	West Nile	Not tracked (n=8) $100 $170 $110
Procurement			
Femoral head removed	none	Part of total hip replacement (THR)	Not tracked (n=9) Pathology tests: $100 $50
Excess tissue removed by surgeon or OR staff	Not reported	Part of total hip replacement (THR)	
Soft tissue sent for microbiology testing	none	Part of total hip replacement (THR)	
Other tissue sample sent to pathology	none	Part of total hip replacement (THR)	
Femoral head chipped/swabbed for microbiological testing	$366	Please note: these costs are for the time for OR staff (other than surgeons) to complete the typical procurement steps performed while in the OR Test costs listed above.	Not tracked (n=10) $400 $30 for materials only
OR staff places femoral head in container			
Antibiotic solution added			
Sizing measurement			
OR staff completes documentation (one copy stays with femoral head)			
Packaged femoral head removed from sterile OR			
Bone bank notified			

Typical Femoral Head Donation Steps	Estimated Average Cost per femoral head (based on literature review)	Description	Facility Survey Cost Estimate
Materials	$15	Container and bags for femoral head storage	Not tracked (n=7)
	$15	Swabs	$26.73
	$10	Antibiotic storage solution	$40
	$40 total		$15
			$50
Storage	$67	**Typical steps:**180 day quarantine in freezer This would include the capital or rental costs and utilities to run the freezer excluding LN2 Backup $67 based on $5000 rent and utilities, for 75 viable femoral heads per year	Not tracked (n=7) $100 $67 $190.85 $140
180 day testing	$130	Identical to initial tests performed	Not tracked (n=6)
	$30	1 hour staff time to locate patient records and arrange for testing	$130 (+200 sterilization – see below) $150 (n=2) $160 $90
Quality Assurance	$177	**Typical steps:** development and maintenance of procedures; internal auditing; accreditation maintenance; equipment monitoring	Not tracked (n=7) $200 $177 (n=2) $182.60
Final Distribution	$30	**Typical steps:** records check; arrange for shipping; packaging 1 hour staff time Adverse event reporting	Not tracked (n=7) $40 $45.43 $30 (n=2)

Please see Appendix 7, available on-line at www.ccdt.ca, for additional survey results.

Based on the literature review and cost survey results in Table 5, the estimate of surgical bone banking costs are summarized below in Table 6.

Costs will vary depending on internal procedures, but the greatest difference between a surgical bone bank and a comprehensive tissue bank will be in how labour costs are estimated, the cost of maintaining a quality system compliant with CSA and/or AATB standards, and if the femoral head is processed inside or outside of the OR.

It is interesting to note that all of the highest reported costs in Table 6 were from comprehensive tissue banks, and all of the lowest reported costs were from in-hospital surgical bone banks.

OR Staff and Surgeon procurement time has been highlighted because, as discussed earlier, this cost is inherent in the cost of a total hip replacement and does not have to be charged to the procurement of a surgical bone donation. This is the single largest cost saving vs. comprehensive tissue bank procurement of femoral heads from deceased sources. The procurement costs not only have cost saving in staff salary, but also in the use of a sterile OR for procurement; i.e. a clean room does not have to be set up specifically to obtain the bone tissue.

The average cost in Table 6 to obtain a femoral head was $913.15; however these costs include comprehensive tissue bank costs that also obtain surgical bone. The lowest costs in Table 6 probably do not reflect all of the costs involved, because as can be seen from the survey results in Table 5, it appears that tracking costs is not the norm for in-hospital bone banks. The actual typical costs of obtaining a femoral head at an in-hospital bone bank are likely between the $734.00 determined from the literature review and the average cost of $913.15 reported from the surgical bone bank survey.

Table 6: Surgical Bone Banking Costs

Banking Activity	Highest Reported Cost	Lowest Reported Cost	Average from Survey	Average from Literature Review
Medical History Screening and Obtaining Consent	68.15	30.00	47.04	30.00
Initial Swabs and Serology	205.00	60.00	148.75	130.00
Future/other testing (West Nile)	170.00	100.00	126.67	100.00
Procurement (surgeon involvement)	0.00	0.00	0.00	0.00
Procurement (pathology)	100.00	50.00	75.00	0.00
Procurement (OR staff)*	400.00	0.00	400.00	366.00
Materials	50.00	26.73	32.35	40.00
Storage	190.85	67.00	124.46	67.00
180 Day Testing	160.00	90.00	136.00	160.00
Quality Assurance	200.00	177.00	186.53	177.00
Final Distribution	45.43	30.00	36.36	30.00
Sub Totals	**1589.43**	**630.73**	**1313.15**	**1100.00**
Total without OR staff time*	**1189.43**	**630.73**	**913.15**	**734.00**

The major costs related to surgical bone banking are: labour, quality assurance and laboratory testing. There are some published international reports that can be used as benchmarks, e.g. laboratory processing of a femoral head in New Zealand: $272 US (Carter 1999) but each active and potential bank will have to assess testing costs for their particular centre.

There have been previous cost estimates conducted for the CCDT that addressed some cost aspects associated with tissue banking which included surgical bone banking. Goss Gilroy Inc. (2003:46-48) estimated the costs per donor for musculoskeletal tissue for four Canadian surgical bone banks. Also provided are the total costs reported for femoral heads specifically (ibid. p.67). The Canadian average to process a femoral head was $885 +/- 645. The average cost to process musculoskeletal tissue on average was $598 +/- 217. It was suggested that the difference (approximately 47% higher cost for processing a femoral head) between musculoskeletal tissue in general and femoral heads specifically was due to higher fixed costs required to process femoral heads (ibid. 67). The average charge to purchase a femoral head from a tissue bank in Canada was $ 917, while the cost to purchase a femoral head from the US ranged between $1216 to $1517 Canadian (ibid. 72). The reported numbers from the survey in Table 6 correspond with

the Goss Gilroy findings (although it is not known if the same banks were surveyed for both projects, as the participants in the Goss Gilroy survey were not identified).

Current Capacity

The surgical bone bank survey questions in Table 5 also tried to address whether or not surgical bone banks were at or below current capacity, if adding more equipment would be enough to increase capacity, and what other resources they would need to increase their current capacity.

In terms of current capacity, 8 out of 11 surgical bone banks answered yes to the question "Do you have the capacity to bank more femoral heads than you currently do?". One bank responded that they could increase by as much as 200%, three could increase by 100%, two by 50% to 100%, with the remaining respondents unsure of the exact amount they could increase banking capacity.

When asked "If you were able to obtain more equipment for storage, could you increase the number of femoral heads your bank retains?", the response from 7 out of 11 banks was no.

Based on the responses to the two questions above, equipment does not seem to be a limiting factor in increasing current capacity for most surgical bone banks.[x]

When asked, "Is there anything else you would need to increase the number of femoral heads your facility banks?", the response from four banks was: space, staff, commitment from surgeons and funding.

Quality Assurance Costs

One of the key costs identified by Goss Gilroy Inc. (2003) was Quality Assurance. This raised the next question related to cost: What effect will meeting CSA and/or AATB tissue standards have on the cost of surgical bone banking?

A marked attribute of surgical bone banking is the small amount of equipment and supplies required. Also notable is the ability to leverage staff time of people already involved in the OR procedure. The main costs centre on: testing, staff training and meeting standards and regulations.

The cost of setting up a Health Canada/CSA/AATB compliant bank however can be significant, particularly in terms of human resource requirements.

In a discussion with the AATB, the following average costs and requirements were provided for Canadian Tissue Banks seeking AATB accreditation (Debbie Newman 2005):

> *The AATB accreditation process takes about nine months, after receipt of the bank's procedures. We ask that a bank be in compliance with AATB Standards for at least six months prior to the AATB inspection and that a bank have at least five records to review. A very general timeline (might be):*

Develop and approve procedures	*5 months*
Train employees to procedures	*3 months*
Complete AATB accreditation application	*2 months*
AATB accreditation process	*9 months*
Total time to achieve accreditation	*19 months*

It was noted that it may take a smaller bank with limited human resources closer to a year to develop and approve the required procedures, which would stretch out AATB accreditation to approximately 26 months (ibid.). The average time, from submission of completed SOP's to accreditation, was 11 months (ibid.).

The AATB does not have a standard set of SOP's available for purchase, but they were aware of consultants available to help develop compliant procedures (ibid.).

In terms of costs, the average fee the Canadian banks paid in 2004 was $3322 (ibid.). AATB fees are based upon the net income of a tissue bank. Other fees include a $2000 application fee which is due when the bank applies for accreditation and with each three-year accreditation renewal application.

The set-up cost for establishing an AATB accredited / CSA compliant surgical bone bank would certainly be less than setting up a comprehensive tissue bank, but would contain the same basic requirements. Assuming a similar timeline and one FTE staff member(s) to lead the development of a new bank, the costs for setting up a new surgical bone bank that meets AATB accreditation requirements would be as shown in Table 7 below.

Table 7: Estimated Tissue Bank Accreditation Costs

AATB Accreditation Costs - Tissue Bank

Salary & Fees			**Totals ($CDN)**
Staff salary & benefits	$30/hr; 140 hr/mo.	4200	
Accreditation fee (AATB)		3322	3322
Application fee (AATB)		2000	2000
Development & Accreditation			
Development and approval of procedures		5 months	21000
Training other staff		3 months	12600
Complete AATB accreditation application		2 months	8400
AATB accreditation process		9 months	37800
			85122

CSA Cost Estimate - Tissue Bank

Salary & Fees			**Totals**
Staff salary & benefits	$30/hr; 140 hr/mo.	4200	
Development & Accreditation			
Development and approval of procedures		5 months	21000
Training other staff		3 months	12600
			33600

While not equivalent, CSA standards are similar to AATB standards and can be used as a point of comparison. CSA does not require accreditation but there would be other associated costs (e.g. internal auditing) that would be required, particularly for evidence of compliance to CSA standards for Health Canada. CSA compliance for surgical bone banking alone is assumed not to be greater than the average costs for accreditation of a small tissue bank.

The cost to establish a CSA compliant surgical bone bank, in all Canadian orthopaedic departments that perform total hip replacements can be estimated using the data in Table 7. If all orthopaedic departments in Canada were encouraged to develop CSA compliant tissue banking systems, the maximum expected cost to meet the quality requirements would be approximately:

150 departments x $33,600 / department = $5.04 million

Costs of Not Conducting Surgical Bone Banking

Surgical bone has several distinct advantages:

a. Very high donation consent rates of between 90-95% (Canadian Surgical Bone Banks 2005),

b. A large and increasing donation potential (Tomford et al. 1999; CIHI 2004), and

c. The ability to utilize existing hospital resources outside of surgical bone bank budgets (particularly surgeon time and a sterile procurement/utilization area).

Femoral head processing presents issues when it occurs outside of the OR setting. For example, bone graft processes performed in a comprehensive tissue bank are cost effective due to the large amount of bone that can be obtained from a single donor, which can justify the costs of clean room processing. Setting up a clean room for a single femoral head would likely be cost prohibitive.

Alternatives to not conducting surgical bone banking are:

a. Bone graft material must be purchased from Canadian or other international sources,

b. Bone graft substitutes must be purchased, or

c. Deceased donor bone procurement must be increased.

Option C is outside the scope of this study, but should be considered, given the very strong core competence in this area in several Canadian sites.

Bone allograft can be purchased from Canadian tissue banks (in particular from comprehensive tissue banks). As noted above, the average cost to purchase a femoral head in Canada, prior to the implementation of the CSA Z900.1 and Z900.2, was estimated at an average of $917.

The low cost estimate to purchase femoral heads from US tissue banks is approximately $1100 CDN + shipping at current exchange rates[xi] (see Appendix 6, available on-line at www.ccdt.ca, for sample US tissue pricing). An example of current shipping rates for dangerous goods (i.e. dry ice) from the US to Canada for Los Angeles to Vancouver is $188.84 + tax.[xii] The cost to ship the same item from Halifax to Vancouver is $124.60, which is the highest cost for a shipment in

Canada. The minimum difference in cost between shipping in Canada vs. shipping from the US to Canada is approximately $77.

Dangerous goods packaging is required in terms of labelling and waybills, however highly specialized dangerous goods packaging materials are not required and would be equivalent for shipping across Canada or from the US (e.g. a vented cooler, dry ice, vented shipping box and appropriate labelling).[xiii]

The reported costs to process tissue, depending on how OR staff can be utilized and how costs are required to be tracked, may range from a reported $350 at a stand alone surgical bone bank to $1200 if processed at a comprehensive tissue bank, as noted in Table 6. The 'true' cost of processing a femoral head in a stand alone surgical bone bank if all associated costs are tracked is estimated to range from $734 to $913 as noted in Table 6.

The costs then of not conducting surgical bone banking in Canada are:

Cost of not conducting SBB in Canada = US surgical bone cost – Canadian Surgical Bone Cost

For comparison with stand alone surgical bone banks, the cost is:

[$1100 US tissue cost + $77 difference in shipping cost] – [($734+914)/2 CDN tissue cost]

= $353 CDN.

This represents the savings over the lowest price for a femoral head, at current exchange rates (~1.25 at time of publication).

For comparison with comprehensive tissue banks, the cost is:

Cost of not conducting SBB in Canada = US surgical bone cost – Canadian Tissue Bank Cost

[$1100 US tissue cost + $77 difference in shipping cost] – [$1025[xiv] CDN tissue cost]

= $152 CDN.

One of the key issues is that surgical bone banks operating in Canada (which developed prior to current changes to Health Canada regulations) may be reaching their current funding and human resource capacity, therefore their femoral head processing capacity (Canadian Surgical Bone Banks 2005; Table 6 survey results).

There may, however be ways to leverage the existing core strengths of orthopaedic departments, tissue banks and existing surgical bone banks to increase the surgical bone supply in a sustainable way using existing funds used to currently purchase tissue from US tissue banks. This potential is discussed further in Part 3 Cost Benefit Analysis.

Given that there may be a potential cost savings of at least $353 per femoral head if Canadian supply can be utilized from stand alone surgical bone banks and $152 from other Canadian tissue banks, we have developed several models that are presented in Part 3 that address the current strengths and potential building blocks afforded by the current Canadian system.

Non-cost related issues

Infection rates after donation of femoral heads is clearly an issue of concern (Aspenberg 1998) and varies depending on the source of the bone and the kinds of tests conducted. The rejection rate can vary considerably, both within Canada and internationally. For example, an Australian bone bank has reported a 22% positive culture rate of the surgical bone donors they tested, and suggest that the contamination may be higher than is being normally reported (Sommerville, 2000). Conversely it has been suggested that false positives in testing are occurring from contamination during tests (Salmela et al. 2002), which would lead to a higher rejection rate than is required. A number of issues are contributing to the loss of femoral heads, including incomplete patient data and lack of ability to follow up with the donor at the 180 day stage contribute as much or more than biological testing (Sugihara et al. 1999).

Identification of Banks, Processes, Costs and Issues for Procuring Bone

Identification of Banks

The actual number of tissue banks was identified in Part 1 of this report. The different models of surgical bone banking are identified below in Part 3, which provides a province by province summary of surgical bone banking activity.

A number of international models were found through the literature reviews, but two had particular potential applicability to the Canadian context, given the similarities in social health care models and geographic constraints - Finland and Scotland.

Finland has developed a model of surgical bone banking centred in Turku, Finland (Aho 1998), which has the following elements:

- Included medical history and serological screening, with 3 month follow up test,
- A collection program from orthopaedic hospitals within 60km radius of the bank, not just the hospital OR,
- Small collection numbers – 415 femoral heads collected between 1972-1995,
- Ability to process, culture and store @ -80 C, and
- A low rejection rate of 24% due to:
  - Positive bacterial culture (47/560 = 8.4%)
  - Technical failures (72/560 = 12.9%)
  - Stored more than 5 years (15/560 = 2.7%).

This model is interesting in the Canadian context, in that procurement from a regional area to a central bank is potentially more cost effective and has a higher probability of being implemented than setting up an in-hospital bone bank in every orthopaedic OR in Canada.

How can the approximately 140 Canadian orthopaedic departments not contributing surgical bone banking find a way to participate in surgical bone banking? The Finnish model above may be applicable in Canada. For example, given the high cost of establishing a QA system, it may be more cost effective to promote 14 regional collection centres with 10 contributing hospitals

rather than try to establish 140 in-hospital bone banks, or a similar regional or centralized collection model.

Scotland (Galea 1998) has established a different model, with 5 in-hospital surgical bone banks centrally administered by the Scottish National Blood Transfusion Service.

The Scottish National Blood Transfusion Service (SNBTS) model for surgical bone banking has the following characteristics:[xv]

- Procurement of approximately 1500 femoral heads for a population base of 5.5 million. In Canada, this would equate to a donation level of approximately 8200 femoral heads.
- These levels of procurement are achieved by having bone bank nurses in most hospitals in the country who review all the medical notes of all possible bone donors.
- Due to stringent medical and quality criteria, SNBTS defers approximately 50% of all donors seen. This level has not changed over the years and corresponds with that seen in Canada.
- There are future testing concerns (similar to recent West Nile concerns in Canada) that may start to effect donation rates, e.g. vCJD concerns will likely modify donation potential. For example, SNBTS has recently introduced a deferral on transfused donors resulting in approximately 20% donor loss, which may be difficult for SNBTS to replace.

There are a number of potential options available for administration of current and new Canadian surgical bone banks:

- Stand alone self-administered banks,
- Central administration of a number of in-hospital bone banks (similar to the Scottish model),
- Administration within an existing comprehensive tissue bank or surgical bone bank, and
- Formation of regional surgical bone collection and centrally located administration (similar to the Finnish model).

Canadian surgical bone banks currently have examples of all four models operating in various part of Canada. These models are discussed further in Part 3 below.

Donation Process

Canadian surgical and other tissue banks are often not informed of all potential surgical bone donors occurring in their hospitals.

There are international examples of potential donor notification for surgical bone and other tissue. For example, Scotland has a system that ensures the bone bank is being notified of almost all potential donors (Galea 1998; Galea 2005). To increase the procurement of femoral heads obtained from living donors, a program involving training of staff and collection of femoral heads has been organized to include district hospitals within a 60 km radius from Turku, Finland (Aho et al. 1998).

Canada could potentially build on the network established by the Canadian Joint Replacement Registry which currently tracks the majority of replacement hip and knee joints implanted each year in Canada (CJRR 2004). If Admissions data could be accessed by the CJRR, a database of potential femoral heads would be available. Given that the surgeons are involved in the determination of the need for surgery, if the surgeons could be encouraged to obtain consent for a 'surgical bone donor database', identification of potential donors would be possible and surgical bone banks could be notified or have access to a database that could provide that information.

Identification of Surgical Procedures that Utilize Bone Tissue and Alternative Sources of Bone Tissue

Surgical bone is used in a wide range of orthopaedic procedures. Table 8 lists the most common procedures identified during the literature reviews and expert interviews.

Table 8: Utilization of Surgical Bone

Procedure	Estimated Percentage of Surgical Bone Utilization	Estimated Amount of Surgical Bone Required	Reference
Hip revision (including compaction grafting)	64	N/A	Aho et al. 1998
	83	N/A	Tampere 2005
	N/A	1 to 2	Shewchuk 2005
	N/A*	N/A	Norman-Taylor 1997
	N/A*	1 to 5	Galea et al. 1998
			McGraw (2005)
Fracture repair	12.4	N/A	Aho et al. 1998
	12	N/A	Tampere 2005
Cavity filling – massive tumour repair	2.3	N/A	Aho et al. 1998
	2	N/A	Tampere 2005
Spinal fusion	<1%	N/A	Aho et al. 1998
	N/A	Up to 5	Shewchuk 2005
Foot and ankle repair	N/A	N/A	Myerson et al. 2005

* Authors did not report any other uses as hip revision utilized the vast majority of surgical bone.

The most influential procedure is the use of femoral heads for hip revisions (Gross et al. 2002b). A recent technique called "impaction grafting" which uses up to 5 femoral heads per procedure is causing greater demand for femoral heads due to an apparently higher success rate (Galea 1998; Blom et al. 2005).

Oncology procedures also utilize large volumes of surgical bone. Cancellous and cortical chips are most commonly used for: "filling cavitary defects in host bone following curettage of a skeletal lesion". They are most commonly used in the management of lesions that simulate neoplasms (aneurismal and unicameral bone cysts), benign bone neoplasms (giant-cell tumors

and chondroblastomas), and occasionally even low-grade bone lesions (grade-I chondro-sarcomas)" (Dion 2002).

Foot and ankle procedures are also increasingly using more surgical bone (Myerson et al. 2005). Traditionally autograft bone has been used for these procedures from the iliac crest but due to complications there is increasing interest in using femoral head allograft for foot and ankle procedures. Foot and ankle procedures that are now using surgical bone include (ibid.):

- Subtalar arthrodesis (Calcaneal fracture)
- Calcaneal osteotomy (Flatfoot)
- Calcaneocuboid arthrodesis (Flatfoot, trauma)
- Hallux metatarsophalangeal arthrodesis (Failed hallux valgus surgery)
- Tibiocalcaneal arthrodesis (Neuroarthropathy)
- Ankle arthrodesis (Trauma)
- Tarsometatarsal arthrodesis (Trauma)
- Fibular osteotomy (Malunion of ankle), and
- Medial cuneiform osteotomy (Flatfoot).

As can be seen from Table 8 above, there is little published information on the amount of surgical bone used during a procedure (for some procedures, particularly oncology repair, the variation in defects make this highly variable).

Bone Substitutes

Another issue that was identified during the interviews (Canadian Surgical Bone Banks 2005; Canadian Orthopaedic Departments 2005) and the literature reviews involved improvements in the quality and safety of banked bone and the development of surgical techniques that have enhanced the use of structural allograft bone and morsellised bone (Dion et al. 2002). Dion et al. (ibid.) consider it imperative that technologies to facilitate use of allografts continue to be developed due to the improved clinical outcomes. Bone grafts are now used in virtually every aspect of reconstructive orthopaedics from simple treatment of fractures to extensive limb salvage procedures and complex spinal reconstructions (ibid.).

The need for allograft tissue will be impacted by the use and safety of bone graft substitutes. Bone graft substitutes should be judged in terms of their ability to provide components of osteoconduction, osteoinduction, promote osteogenic cell development and provide structural integrity where applicable (Gazdag et al. 1995). Ceramics including hydroxyapatite and tricalcium phosphate (TCP) are produced commercially and can serve as bone graft expander and/or filler particularly in compressing applications; however, bone must be protected while ceramic is incorporated (ibid). A composite of particulate ceramic, bone marrow, and DBM that incorporates all three regenerative components may be just as effective as allograft bone (ibid.).

One of the most interesting developments in the next decade will be the potential wide spread use of a variety of biologic products to augment bone grafts using recombinant human growth factors (Safdar et al. 2005). There are other bone substitute potential developments that may have significant implications in the future for use in procedures like impaction grafting for

revision THR, as can be seen in the development of a recent biphasic ceramic allograft substitute, called 'BoneSave' (Blom et al. 2005). No difference was detected after 18 months between 100% BoneSave, a mix of 50% allograft/50% BoneSave or 10% allograft/90% BoneSave (ibid.) suggesting that there is at least the long term potential for replacing or reducing the need for human allograft.

Supply and Demand Projections

While it appears that the development of bone substitutes is well underway, only one of approximately 170 orthopaedic departments surveyed currently relied solely on the use of bone substitutes (Canadian Orthopaedic Departments 2005).

CIHI (May 2003: 74) has projected a low, medium and high range for the known supply of surgical bone vs. an extrapolated demand, based on stakeholder interviews conducted in 2003. The CIHI surgical bone shortfall projections from that study are represented below in Table 9. The CIHI (ibid.) study predictions are a low demand of 7720, a medium demand of 11581 and a high demand for surgical bone of 15441 femoral heads respectively.

Table 9: Projections for the Supply and Demand of Surgical Bone

Known Supply	**Surplus / (Shortfall)**			**Cost Implications (000's)**		
	Low (demand = 7720)	**Medium** (demand = 11584)	**High** (demand = 15441)	**Cost to Purchase Shortfall from US** (@ av. $1288 landed)*	**Cost to Process in Canada if Capabilities were Available** (@ av. $824 landed)	**Cost Difference Saving/ (Expense) vs. US Purchase**
1503†	(6217)	(10,078)	(13938)	8007 12980 17952	5458 8848 12237	2549 4132 5715
2233††	(5487)	(9351)	(13208)	7067 12044 17105	4521 7705 10883	2546 4339 6222
Maximum Potential Supply	**Surplus / (Shortfall)**			**Cost Implications (000's)**		
9980†††	2260	(1604)	(5461)	Excess 2065 7033	-- N/A N/A	-- N/A N/A
11986††††	4266	402	(3455)	Excess Excess 4450	-- -- N/A	-- -- N/A

† (CIHI 2003)

†† (Canadian Surgical Bone Banks, 2005)

††† Projection based on CIHI (2004) numbers of THR with 50% rejection rate (19977/2=9980)

†††† Projection based on CIHI (2004) numbers of THR with 40% rejection rate (19977*.6=11986)

* See average US purchasing and shipping costs above.

The known tissue supply column lists the supply identified by CIHI (May 2003) and by Peak Consulting in 2005 (Canadian Surgical Bone Banks 2005). While approximately 730 more femoral heads were identified in the known supply, there is still a large projected shortfall based on demand surveys conducted by CIHI (April 2003; May 2003).

There are several options for addressing the shortfall:

- Canadian surgical bone banking capability can be increased,
- Use of bone substitutes can be increased,
- Use of deceased bone tissue can be increased, and
- US purchasing of tissue can be employed.

Based on interview responses (Canadian Orthopaedic Departments 2005; Canadian Surgical Bone Banks 2005) the use of US tissue products is increasing. There is also increasing demand on tissue banks providing deceased tissue (ibid.).

CIHI (May 2003:51) has characterized the current sources of allograft by orthopaedic surgeons as:

- 17% of orthopaedic surgeons request all tissue from the US
- 18% of orthopaedic surgeons request all tissue from Canadian or US sources
- 53% of orthopaedic surgeons buy all tissue from Canadian sources

with the remainder of requests from 'unknown' or 'other' sources. Given the current high demands on Canadian deceased sources and declining numbers of surgical bone banks in Canada,[xvi] it is improbable with current tissue banking models that the demand could be met in Canada by deceased sources alone. Based on current availability of US tissue, and increasing preference for US products, it is possible that the majority of the increasing demand in Canada could be met by US tissue banks. However it should be noted that Canada would not have control over this bone tissue supply and could potentially be at risk if demand cannot be met by US suppliers.

Table 9 projects the possible costs if the shortfall of femoral heads in Canada were to be met by just purchasing from the US There are significant cost savings available if Canadian surgical bone can be procured. For example, if the Medium demand for femoral heads projected by CIHI (May 2003) are used, a shortfall of approximately 9351 femoral heads will occur this year in Canada. This represents approximately $12 million Canadian in bone tissue purchased from the US. If the same volume of surgical bone could be obtained in Canada, there would be a cost saving of almost $4.1 million.

Can the cost savings of obtaining femoral heads in Canada be used to generate investment in the current surgical and comprehensive tissue banks to increase the donation and procurement of surgical bone in Canada?

Currently in Canada the budgets used to purchase bone tissue are separate from the budgets to operate tissue banks, making it difficult to link the potential cost savings of procuring Canadian surgical bone.

A model is presented in Part 3 below that will attempt to realize the cost savings of procuring Canadian surgical bone vs. US purchasing.

If rejection rates similar to those seen in for example in Ontario of 35% to 40% could be reproduced in the rest of the country and surgical bone donation potential similar to that in Scotland could be developed, significant cost savings and the ability to meet the low and medium CIHI demand projections for surgical bone could be met in Canada with a Canadian supply.

Given the potential cost savings, the following question arises:

> *How much would it cost to generate the ability to obtain the surgical bone potential identified in Table 9? Can the cost to increase the Canadian surgical bone supply be met with the cost difference between Canadian capability and purchasing from the US?*

A model is presented in Part 3 below that attempts to answer this question.

Other Issues Identified

A number of other issues were identified that can have an effect on donation, banking and utilization of surgical bone.

Technology Issues

Concern was expressed by one comprehensive tissue bank over potential technological changes in minimally invasive surgery, in particular the re-surfacing of femoral heads instead of total hip replacement. The concern is that if hip-resurfacing becomes the standard practice, the supply of surgical bone will be lost. There are a number of companies that have developed hip resurfacing technologies (see for example http://www.jri-oh.com/jri_hip_resurfacing.php), however the current approved indications for use do not include osteoarthritic hip replacements and are quite specific to a type of disease that is not a source of surgical bone:

> *Metal-metal hip resurfacing… is indicated for hip arthritis in which the articular cartilage has deteriorated and, therefore, the acetabulum (socket) must be replaced. At the present time, metal-metal hip resurfacing devices are the subjects of ongoing clinical trials in the US and they are classified as "category B-1 investigational" devices by the FDA. As a result of this status, availability is limited to a relative handful of surgeons throughout the country (Schmalzried et al. 2004).*

There are some forms of the procedure currently in use (hemi-surfacing) and there are good candidates for using this in the traditional hip-replacement groups (osteoarthritis, osteonecrosis), but the current focus is on patients <50. Hip resurfacing will likely not replace THRs in patients over 65 within the next 5 years, which is the majority of donors for femoral heads.

With advances in hip resurfacing technology and with improvements in bone graft substitutes, however, the long term 10 year + horizon may likely see major changes in femoral head supply and utilization.

Other technological issues that arose may be quite effective for increasing the storage capacity of current surgical bone banks. One surgical bone bank suggested looking at simple ways of maximizing tissue, e.g. cutting the femoral heads in half to help reduce waste in procedures that do not need an entire head. Another surgical bone bank suggested making the simple change from plastic containers to plastic bags to maximize freezer space. A comprehensive tissue bank suggested more training for physicians on tissue maximization and lowering waste. These simple techniques and best practices were not found to be widely known among surgical bone banks.

There are many simple and cost effective ways of establishing effective communications – e.g. newsletters, internet news groups, etc. where best practices could be shared. For example, the current storage capacity of femoral heads in Canada could potentially be doubled by cutting femoral heads in half and storing them in bags rather than plastic containers, if surgical bone banks were made aware of the technique.

A number of other issues were raised during the interviews (Canadian Surgical Bone Banks 2005) and in the literature reviews. A number of these issues have been touched upon above, but are included here in order to provide a complete discussion of the issues raised.

Clinical Issues

Total hip replacements are occurring in younger and younger patients – the need for revision surgeries is going to increase and subsequently the demand for allograft tissue is going to increase (Graham and Stockley 2004).

One comprehensive tissue bank indicated that there was no perception in difference in clinical outcomes with deceased vs. fresh frozen allograft in their orthopaedic departments.

One comprehensive tissue bank noted that irradiated tissue may not have high surgeon acceptance and was not considered a desired processing step.

Surgeon Preference

One comprehensive tissue bank and several surgical bone banks indicated that surgeons have high preference for femoral heads, particularly for revision hips, spinal and some maxillo-facial surgeries.

One comprehensive tissue bank indicated that surgeons will use other sources if they have to (e.g. other bones or substitutes).

A number of surgical bone banks also noted a growing reliance on advanced US tissue products.

Also, one comprehensive bank noted that since most surgical bone is being obtained at orthopaedic teaching hospitals, the added time to process femoral heads in to chips (e.g. with a bone mill) was accepted practice at a teaching institution, as residents were often involved in the process.

Testing Requirements

One surgical bone bank indicated that the 180 day follow up testing required from surgical bone donors is a double standard when compared with the requirements for cadaveric tissue testing. Given current advances in Nucleic Acid Testing, a study comparing results from NAT testing vs. current surgical bone testing practices (initial serology and 180 day follow-up) could be encouraged to establish if a change in surgical bone banking standards could be recommended. If NAT could be shown to be as or more accurate than two serology tests performed 6 months apart, it would reduce the loss due to inability to follow up with potential donors and significantly increase the potential supply of femoral heads in Canada.[xvii]

Differences in Rejection Rates

There may be an urban-rural split occurring with the reported rejection rates and the location of tissue banks. One comprehensive tissue bank indicated that the loss of bone due to the inability to find donors after 180 days for follow up testing was much more difficult for donors in rural areas. Surgical bone banks with a higher rural component (e.g. in the West) had a higher rejection rate (50-60%+) than those for example in Toronto (closer to 35%).

Standards and Accreditation

Some Canadian tissue banks have or are working toward AATB accreditation while others will comply with Health Canada regulations. One surgical bone bank indicated this may make cooperation between banks operating under different standards difficult.

The move to greater regulation of tissue by Health Canada has contributed to the closure of smaller banks (e.g. Grand Prairie, Kelowna, Vernon) that could not handle the extra workload to comply.

Two comprehensive tissue banks indicated that the 2003 CSA standards were "not good enough" and AATB is more applicable and a safer standard to follow. They also indicated that they valued being able to receive accreditation, which is not an option with the current CSA standards.

One former surgical bone bank indicated that they perceived a "risk" of packaging and shipping responsibility that keeps them from contributing femoral heads to a bone bank. This particular bank closed due to the inability to meet the new Health Canada regulations and was resistant to the idea of participation in further surgical bone banking activities. They currently purchase from other Canadian comprehensive banks or from the US, but no longer contribute to surgical bone banking.

Utilization Prediction

One comprehensive tissue bank indicated that it is difficult for tissue banks to predict future utilization demands, which depend on many factors: e.g. type of deficit (e.g. with tumour surgery) and the type of surgery being performed (e.g. impaction, spinal, etc).

Costs Perceptions

One comprehensive tissue bank indicated the costs to package, screen and test a femoral head at ~$200 Canadian. The approximate cost to buy a femoral head from a US bone bank was believed to be ~1500-1800 Canadian by several surgical bone banks. One comprehensive tissue bank indicated that they believed that it is more cost effective to run a surgical bone bank than to buy from the US

Supply Centres

Some tissue banks are acting as supply centres for other hospitals. A high willingness from two larger well established comprehensive banks was indicated to explore ways of accepting surgical bone from smaller centres.

Supply Potential

The vast majority (78%) of hospitals capable of performing a total hip replacement are not conducing surgical bone banking or sending the tissue for banking.

Reliance on Other Banks

Reliance on the US for surgical bone by province ranged from 100% in one province to 0% in another (with expressed clear resistance to the idea of reliance on the US).

Alternatives Being Explored by Tissue Banks

One comprehensive tissue bank indicated that they were considering ways of increasing the donation of deceased spine tissue as another source of cancellous bone.

One comprehensive tissue bank has centralized the administration of the banking activities to increase efficiencies. One comprehensive bank in a different province indicated that they would appreciate and participate in a provincially centralized effort.

Storage

Most common reported practice for storage of surgical bone was deep freezing to -80C for 3-5 years.

Freeze drying was not considered a viable alternative due to high equipment cost.

Issues Summary

Given the number of issues raised, the issues were grouped into 15 themes for further analysis. For example, a number of issues relating to banking costs were raised, however they all have a similar theme, i.e. "cost". Appendix 3, available on-line at www.ccdt.ca, contains the grouped issues.

Themes specific to a particular phase (e.g. donation) are identified and the common themes (i.e. issues that occurred in more than one area of donation, banking, utilization or other) are also identified. A number of common themes were raised in two or more areas of donation, banking, utilization or other issues, including:

- Surgeon Involvement
- Surgeon Preference
- Operations
- Costs and Purchasing
- Geographic Constraints
- Testing Requirements
- Accreditation, Standards and Regulations, and
- Hospital Resources.

Other key themes raised during the interviews were:

- Donation Potential
- Screening
- Reliance on US Tissue Banks
- Funding
- Product Quality
- Bone Substitutes, and
- Increased allograft procedures.

Cause and Effect Analysis of Surgical Bone Banking Themes

A technique called an Interrelationship Diagraph (ID) was used to obtain a sense of which themes and issues are key drivers and to identify which themes or issues are outcomes (Brassard and Ritter 1994).

This technique is particularly useful for comparison of a large number of issues and identifying cause and effect relationships between the issues. Each theme is compared to the others and it is determined if there is an overriding causal or influential relationship.

For example, it was determined that there is a causal relationship between Surgeon Preference for surgical bone and Surgeon Involvement in surgical bone banking, and that Surgeon Preference is an influence on surgeon involvement. Surgeon Preference is then considered to be

a cause of or influence over Surgeon Involvement. By questioning the potential relationship between themes in this way, the themes with a high number of influences (i.e. key drivers or causes) can be separated from those that are being influenced (i.e. key outcomes).

Typically the themes or issues identified as root causes or drivers are examined first for action planning or further analysis and outcomes can be used as key measurement areas for monitoring change management processes.

Appendix 4, available on-line at www.ccdt.ca, contains the results of the analysis. Table 10 below contains a summary of the results of the analysis.

Table 10: Surgical Bone Banking - Key Drivers and Outcomes

Drivers	Outcomes
Accreditation, Standards and Regulations	Operations of a bone bank
Use of Bone Substitutes	Testing Requirements
Geographic Constraints	Human Resources
Donation Potential	Purchasing of US Surgical Bone
Surgeon Preference	Cost of Surgical Bone Banking
Funding	Surgeon Involvement in Surgical Bone Banking
Product Quality	Screening Requirements
Increase in Allograft Procedures	

Key Drivers

The increasing influence of accreditation (AATB), development of standards (i.e. 2003 CSA standards regarding tissue banking) and proposed changes in Health Canada regulations has been a major cause of changes to surgical bone bank operations. Three former surgical bone banks and representatives from two provincial tissue donation organizations identified this area as the major reason for closure of surgical bone banks over the last 15 years, particularly due to the increased operational burden (Canadian Orthopaedic Departments 2005). Russel et al. (1989) identified 60 surgical bone banks operating in Canada in 1987. There are currently at least 26 surgical bone banks operating in Canada (Canadian Orthopaedic Departments 2005; Canadian Surgical Bone Banks 2005).

The use of bone substitutes emerged as a key issue on the horizon that may have a major impact on the need for surgical bone banks. There are literally dozens of bone substitutes products in clinical development (Gazdag at al 1995; Cato 2003; Blom et al. 2005). For example Gazdag et al. (1995) discuss the clinical development of a composite of DBM, ceramic and bone marrow that showed potential for clinical equivalence to human bone allograft. A wide range of bone substitute products are currently available.[xviii] One orthopaedic department interviewed claimed to be using only bone substitutes and no longer purchased human bone product (Canadian Orthopaedic Departments 2005). All other orthopaedic department respondents indicated that they are using some human tissue (ibid.).

Geography has affected Canadian public systems since Confederation and surgical bone banking is no exception. A wide range of geographic differences emerged, ranging from no surgical bone banking activity in four provinces (Manitoba, Nova Scotia, Newfoundland and Prince Edward Island) to one very successful regional program (Southern Alberta). Regional or provincial participation takes the form of surgical or comprehensive banks providing tissue upon request (e.g. the Regional Tissue Bank in Halifax was found to have provided tissue to orthopaedic departments as far away as British Columbia). Four surgical bone banks in Ontario and Quebec were not aware of other banks, even in their own province (Canadian Surgical Bone Banks 2005). There is currently no official National or Regional organizations linking surgical bone banks. The proximity to US tissue organizations has also had an effect on the need for surgical bone banking, and is discussed further below.

Donation potential was identified as a key issue for two reasons:

1. donation potential alone can determine if Canada is capable of meeting the need for surgical bone; i.e. if there are not enough femoral heads available from total hip replacements (THR) the demand cannot be met, and
2. there is some uncertainly in current projections of the demand for femoral heads (CIHI April 2003; CICI May 2003; CIHI 2004).

Surgeon preference also emerged as a key driving issue. For example, if a surgeon prefers to use more highly processed tissue from Canadian comprehensive tissue banks or US products, there is little incentive in the current system for a surgeon to prefer tissue from Canadian surgical bone banks that currently do not have any advanced processing capability (Canadian Surgical Bone Banks 2005). There does not appear to be any barriers to purchasing US surgical or other bone tissue products, from a budgetary point of view (i.e. no orthopaedic department identified cost of US product as prohibitive). The current estimate of use of US surgical bone is at a minimum 17% of all surgical bone used in Canada but is likely 10 to 25% (CIHI April 2003). In order for Canadian product to be preferred it must meet the same level of service, quality and ease of use as the US product (McGraw 2005). However there is at the same time an apparent strong demand for whole femoral heads in Canada (Canadian Orthopaedic Departments 2005; Canadian Surgical Bone Banks 2005) and this is also evidenced by usage of whole femoral heads from deceased donor tissue banks.

Product quality emerged as an issue linked with surgeon preference. In particular, it was stated that in order to develop surgeon preference for Canadian tissue products, they must match the same level of quality, service and ease of use as US tissue products (McGraw 2005).

Funding for operations was identified by at least one surgical bone bank as being difficult to obtain (Canadian Surgical Bone Banks 2005). There may not be a direct connection between the funding or budgets available to operate a surgical bone bank and the budget to purchase tissue from outside sources.

Finally, there is an increase in the number of procedures using bone allograft (Blackley et al. 2002; Czitrom el at 1996; Dion et al. 2002; Graham et al. 2004; Gordon 1999; Grayson 1992; Gross et al. 2004; Haddad et al. 2000; Myerson et al. 2005; Sufdar et al. 2005; Vangsness et al. 2003). The increasing number of procedures will place even more demand on all bone tissue sources in Canada.

Key Outcomes

The operations of a surgical bone bank are effected by many outside influences, including surgeon involvement, other hospital resources (e.g. pathology, blood bank), changes in standards and regulations, increasing numbers of surgical procedures using allograft, funding, internal costs, geographic area (e.g. how far away donors live from site of surgery), US purchasing trends, screening requirements and product quality requirements.

Successful operation of a surgical bone bank is highly reliant on a large number of factors outside of their control, and they must change operations depending on these factors; for example, testing and screening requirements are mandated from organizations outside of the bone bank.

The cost of surgical bone banking is not well established (CIHI April 2003; Canadian Surgical Bone Banks 2005). Estimates of the 'true' cost of surgical bone banking range from between $350 to $1100, and is highly dependant on how costs are tracked (ibid.). The key issue here is that decisions are being made on whether or not to operate a surgical bone bank without the knowledge of the actual costs involved. Appendix 5, available on-line at www.ccdt.ca, contains the results of a survey of all surgical bone banks regarding how costs are tracked.

Finally, surgeon involvement in a surgical bone bank was determined to be a key outcome of the current surgical bone banking models in Canada. As long as surgeons prefer to purchase bone tissue from outside sources, and a budget is in place to purchase the desired tissue, there is little incentive to be involved in a surgical bone bank.

Part III:

Cost Benefit Analysis

COST BENEFIT ANALYSIS

Current Provincial Surgical Bone Banking Systems

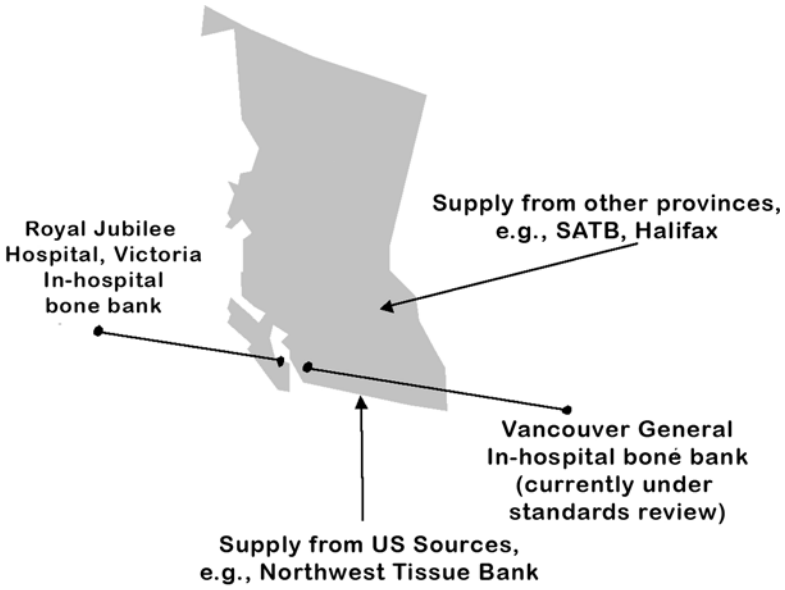
The following models of provincial bone banking activities are based on the interviews conducted with surgical bone banks and orthopaedic departments (Canadian Surgical Bone Banks 2005; Canadian Orthopaedic Departments 2005). There is considerable variation between provinces in the donation, banking and purchasing of surgical bone.

Following is a summary of surgical bone banking practice in each province, followed by a comparison of the generalized models in Canada, and a cost benefit analysis of potential models for increasing surgical bone capacity in Canada.

British Columbia

Figure 7A contains the model for surgical bone banking and procurement in British Columbia.

Figure 7A: BC Surgical Bone Banking



There are currently two surgical bone banks in BC; an in-hospital bank at Royal Jubilee Hospital, Victoria and another at Vancouver General Hospital (VGH). It should be noted that the VGH bank has currently suspended operations pending a standards review, and is expected to begin operations again in the near future.

All orthopaedic departments in BC that use graft tissue also purchase surgical bone from other Canadian sources (e.g. Halifax Regional Tissue Centre) and/or from US tissue banks (e.g. Northwest Tissue Bank).

It should also be noted that two small surgical bone banks closed within the last 3 years due to perceived inability to meet regulatory changes for tissue banking. Lack of funding to meet the regulatory changes was the primary reason stated for closure.

Surgical Banking Summary

Total Estimated THRs: 2892

Estimated viable femoral heads after testing and screening: 1475

Confirmed number of femoral heads procured: 275

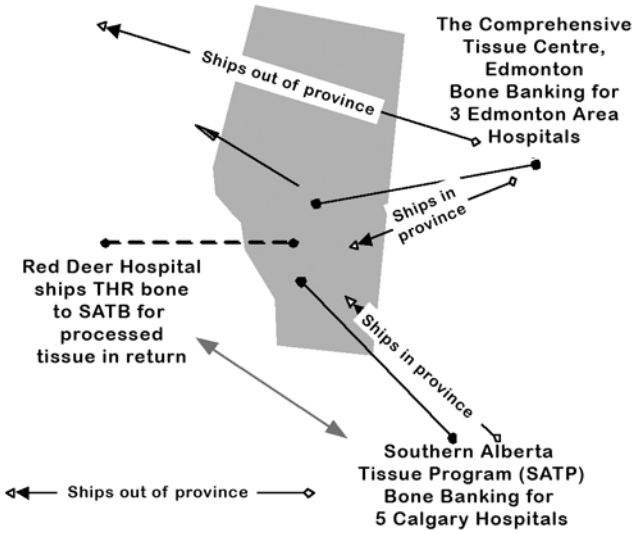
Alberta

Figure 7B contains the model for surgical bone banking and procurement in Alberta.

Alberta has the best coordinated surgical bone banking system in Canada and should be considered the benchmark system for successful surgical bone donation in Canada.

Alberta may be obtaining as much as 65 to 70% of the potential surgical bone available from orthopaedic departments. Two tissue surgical bone programs are operating in Alberta: The Comprehensive Tissue Centre (CTC) in Edmonton and the Southern Alberta Tissue Program (SATP) in Calgary. Both programs accept femoral heads from orthopaedic departments within the city and ship the tissue to a central bone bank.

Figure 7B: AB Surgical Bone Banking



Alberta is also developing regional in-province procurement and shipping capabilities. For example, the SATP accepts femoral heads procured from Red Deer Hospital, which are then processed and stored at SATP and are shipped back to Red Deer when needed. Red Deer is able to participate in bone banking without having to set up in-hospital infrastructure for storage, QA and shipping. SATP is currently actively pursuing this model with other cities in Southern Alberta.

Both the CTC and SATP ship surgical bone out of province to hospitals (e.g. in BC) that request it.

There is a strong willingness in Alberta to build surgical bone capability, e.g. SATB will not participate in purchasing surgical bone from US sources, and none of the departments interviewed indicated the need for US purchasing (although advanced tissue products are likely being purchased, e.g. DBM).

Surgical Banking Summary

Total Estimated THRs: 2036

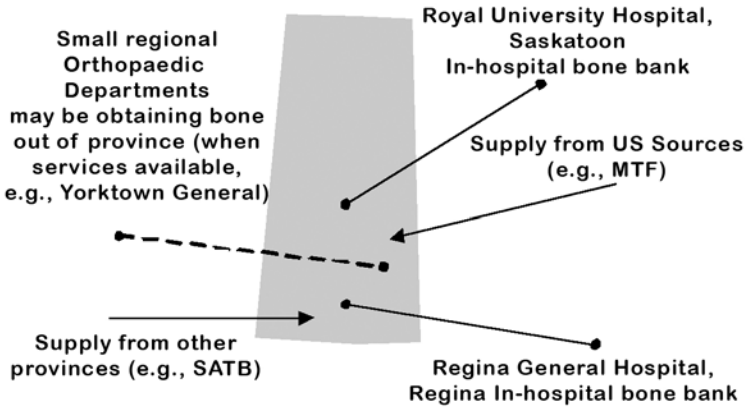
Estimated viable femoral heads after testing and screening: 1038

Confirmed number of femoral heads procured: 675

Saskatchewan

Figure 7C contains the model for surgical bone banking and procurement in Saskatchewan.

Figure 7C: SK Surgical Bone Banking



Saskatchewan has two in-hospital bone banks, one in Regina General Hospital and the other at Royal University Hospital in Saskatoon.

Orthopaedic departments in Saskatchewan also reported the need to purchase femoral heads from other provinces (e.g. SATP) and also from US sources (e.g. Musculoskeletal Transplant Foundation).

Saskatchewan has a number of small orthopaedic departments (e.g. Yorktown General) that could ship femoral heads (similar to Red Deer-SATP) but are likely too small to develop the infrastructure for in-hospital bone banking.

Surgical Banking Summary

Total Estimated THRs: 885

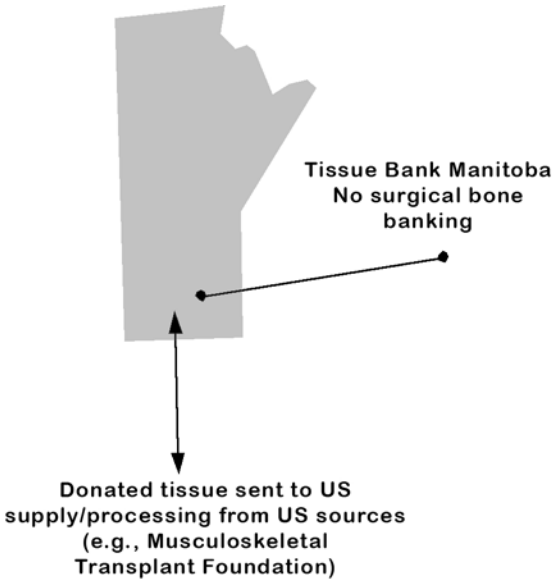
Estimated viable femoral heads after testing and screening: 451

Confirmed number of femoral heads procured: 164

Manitoba

Figure 7D contains the model for surgical bone banking and procurement in Manitoba.

Figure 7D: MN Surgical Bone Banking



Manitoba currently does not have a stand-alone surgical bone bank program. Tissue Bank Manitoba is currently reviewing the potential for a program.

All surgical bone requirements are met through purchasing and potentially shipping/processing relationships with US tissue banks.

Surgical Banking Summary

Total Estimated THRs: 867

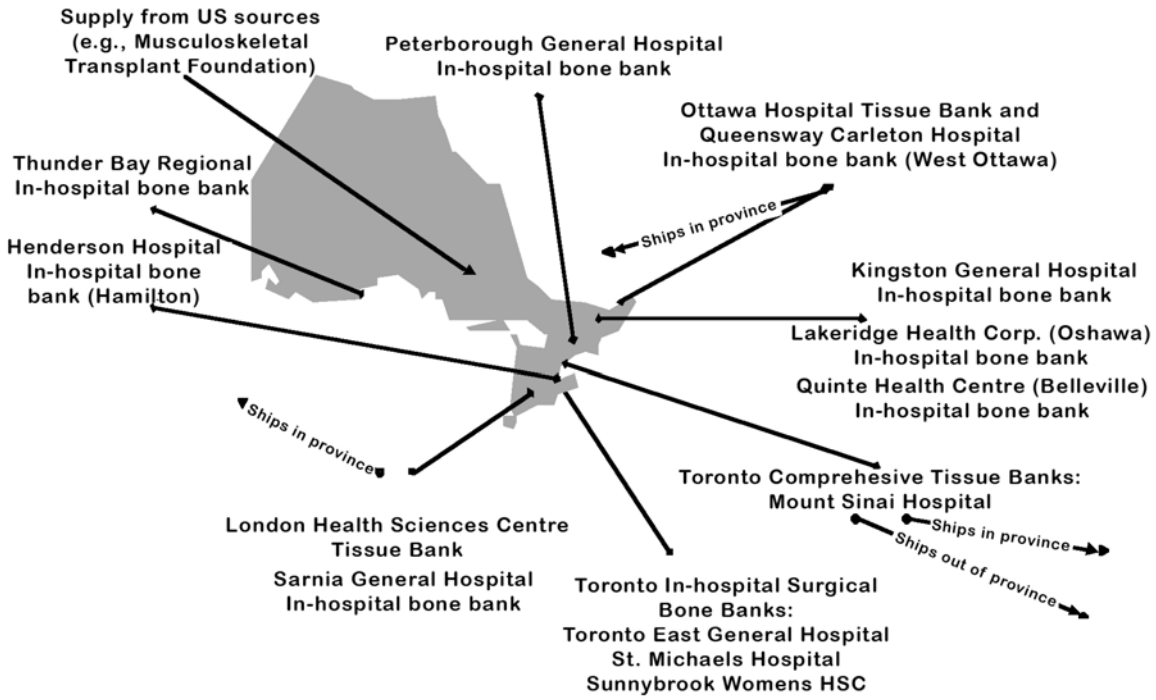
Estimated viable femoral heads after testing and screening: 442

Confirmed number of femoral heads procured: 0

Ontario

Figure 7E contains the model for surgical bone banking and procurement in Ontario.

Figure 7E: ON Surgical Bone Banking



In terms of numbers of surgical bone banks, Ontario has the most infrastructure in Canada. Despite this infrastructure, Ontario is only procuring at most 15% more surgical bone than Alberta, even though Ontario has 4 times the potential number of femoral heads available.

A number of issues are facing smaller Ontario surgical bone banks, including difficulty in meeting recent regulatory changes. At least two of the in-hospital banks identified are in the process of discontinuing operations. On the other hand, there is one new in-hospital surgical bone bank that is starting operations this year.

Several surgical bone programs ship within other areas of the province, including London, Mount Sinai and Queensway-Carleton Hospital. A number of orthopaedic departments indicated a strong reliance on these programs (in particular Mount Sinai) and also on US purchasing (e.g. Musculoskeletal Transplant Foundation).

There were no examples raised in the interviews of orthopaedic departments shipping femoral heads to other hospitals or programs that have surgical bone banks.

Surgical Banking Summary

Total Estimated THRs: 8078

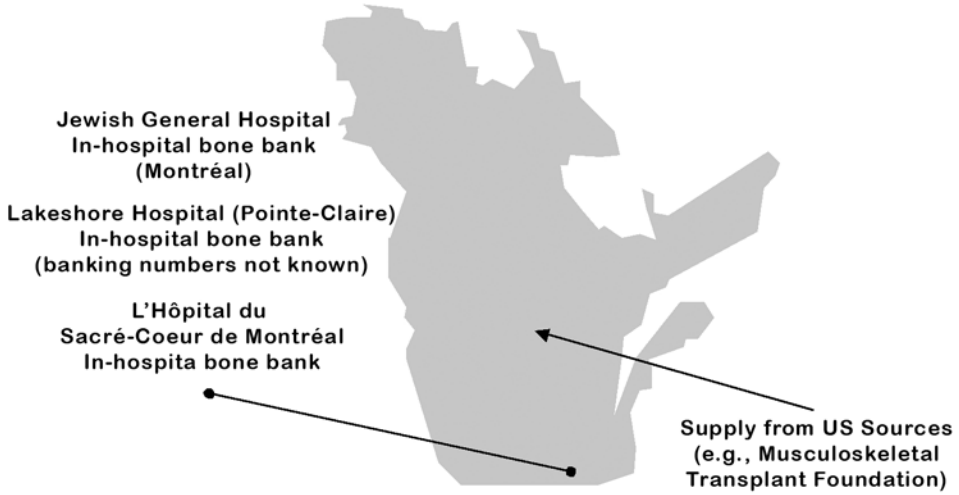
Estimated viable femoral heads after testing and screening: 4120

Confirmed number of femoral heads procured: 694

Québec

Figure 7F contains the model for surgical bone banking and procurement in Québec.

Figure 7F: QC Surgical Bone Banking



Three in-hospital surgical bone banks were identified in Québec, including L'Hôpital du Sacré-Coeur de Montréal, Lakeshore Hospital and Jewish General Hospital. Three Québec orthopaedic departments confirmed purchasing of US surgical bone (e.g. Musculoskeletal Transplant Foundation). A number of orthopaedic departments obtained bone tissue from Histo-Québec.

Surgical Banking Summary

Total Estimated THRs: 3188

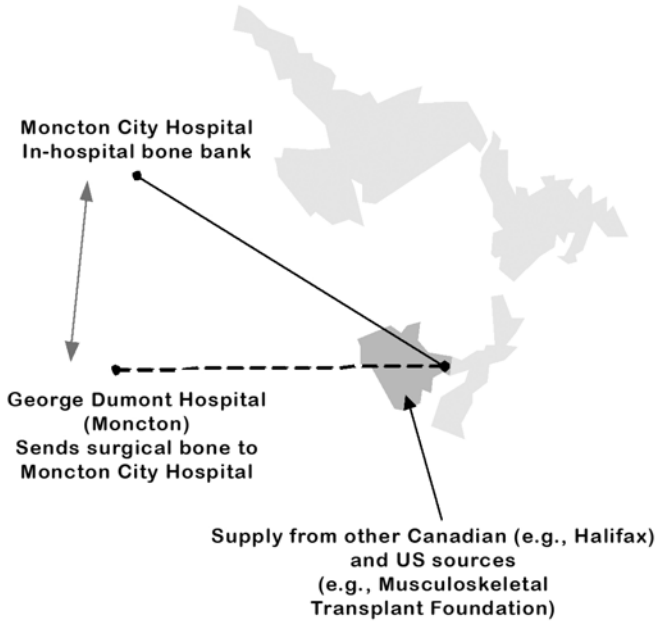
Estimated viable femoral heads after testing and screening: 1626

Confirmed number of femoral heads procured: 350

New Brunswick

Figure 7G contains the model for surgical bone banking and procurement in New Brunswick.

Figure 7G: NB Surgical Bone Banking



One in-hospital surgical bone bank was identified in the Atlantic provinces at Moncton City Hospital. Moncton is also participating in a local shipping program within the city with George DuMont Hospital (i.e. femoral heads are received, then processed, stored and shipped back to George DuMont Hospital when needed). At least one orthopaedic department in New Brunswick purchased surgical bone from the US (Musculoskeletal Tissue Foundation).

Surgical Banking Summary

Total Estimated THRs: 514

Estimated viable femoral heads after testing and screening: 262

Confirmed number of femoral heads procured: 150

Generalized Models Operating in Canada

After reviewing the provincial surgical bone banking systems, four generalized models for the supply of femoral heads to Canadians have been identified and are described below.

In-Hospital Surgical Bone Banks

Most surgical bone banks operate completely within the hospital setting. These are referred to as in-hospital surgical bone banks. They are not associated with larger comprehensive tissue banks. In some cases they receive and ship femoral heads to other hospitals that do not have their own surgical bone bank.

Costs

The costs associated with this model are borne by the hospital and include costs in a number of different hospital departments, including human resources (coordinator, surgical team, banking and shipping team, and quality assurance team), infrastructure (freezers), testing (laboratory), and quality assurance (database).

The cost of procurement and banking of a femoral head in an in-hospital bank is the lowest cost option once banks are established. It must be noted however that considerable financial and human resources are required to establish an in-hospital surgical bone bank.

Also, as discussed in Part 2, the actual costs of operating an in-hospital bone bank are not well known, given the highly integrated nature of in-hospital banks (e.g. they must rely on a number of other departments including pathology, blood bank and laboratory testing) and may not know the costs associated with activities in other departments.

The average costs found for surgical bone banking from the literature review and from a survey of currently operating banks is reproduced in Table 11A below.

Table 11A: Average In-hospital Surgical Bone Banking Costs

Banking Activity	Average from Survey	Average from Literature Review
Medical History Screening and Obtaining Consent	47.04	30.00
Initial Swabs and Serology	148.75	130.00
Future/other testing (West Nile)	126.67	100.00
Procurement (surgeon involvement)	0.00	0.00
Procurement (pathology)	75.00	0.00
Procurement (OR staff)*	400.00	366.00
Materials	32.35	40.00
Storage	124.46	67.00
180 Day Testing	136.00	160.00
Quality Assurance	186.53	177.00
Final Distribution	36.36	30.00
Totals	1313.15	1100.00
Total without OR staff time	**913.15**	**734.00**

* OR staff costs are included for comparison with staff time for deceased procurement activities only. These costs are inherent in the cost of a Total Hip Replacement and should not be included in the final cost calculation for obtaining a femoral head.

Risks

The risks associated with this model of surgical bone banking are:

- That the surgical bone banks don't track their costs and don't receive extra funding to operate.
- That the quality assurance system is difficult to maintain to CSA and/or AATB standards with limited hospital resources (including HR).
- That the system can breakdown without surgical team involvement and other hospital resources (e.g. blood bank or pathology).
- That a surgeon may prefer to purchase all their tissue products from a comprehensive tissue bank or foreign sources.

Benefits

The benefits associated with this model are:

- Control over Canadian tissue supply.
- Fits within the provincial budget and funding structure.
- The potential for full donation exists in the model where hospitals are participating by sending their femoral heads for banking.

Surgical Bone Banks in Comprehensive Tissue Banks

Several surgical bone banks in Canada are part of larger comprehensive tissue banks. Some collect surgical bone from other hospitals and then store, process and provide tissue to supply hospitals on an as needed basis.

Costs

The costs associated with this model include human resources (manager, medical director, surgical team, banking and shipping team, and quality assurance team), infrastructure (freezers), testing (laboratory), and quality assurance (database). Some of these costs are borne by the hospital and some are centralized and borne by the comprehensive tissue bank.

The cost of surgical banking are higher than with in-hospital banks, in particular due to the costs associated with maintaining CSA and/or AATB accredited management systems, and may also be due to more complete cost tracking.

The costs listed in Table 11B also apply to this model of surgical bone banking, but are likely closer to the high cost level reported in the surgical bone bank cost survey (see Appendix 5) of $1100 to $1200 and are comparable in cost to femoral heads from tissue banks that only process deceased tissue.

Table 11B: Comprehensive Tissue Bank Surgical Bone Costs

Banking Activity	High Reported Cost† (probable cost for Comprehensive Banks)	Average from Survey	Average from Literature Review
Medical History Screening and Obtaining Consent	68.15	47.04	30.00
Initial Swabs and Serology	205.00	148.75	130.00
Future/other testing (West Nile)	170.00	126.67	100.00
Procurement (surgeon involvement)	0.00	0.00	0.00
Procurement (pathology)	100.00	75.00	0.00
Procurement (OR staff)*	400.00	400.00	366.00
Materials	50.00	32.35	40.00
Storage	190.85	124.46	67.00
180 Day Testing	160.00	136.00	160.00
Quality Assurance	200.00	186.53	177.00
Final Distribution	45.43	36.36	30.00
Totals	1589.43	1313.15	1100.00
Total without OR staff time	**1189.43**	**913.15**	**734.00**

* OR staff costs are included for comparison with staff time for deceased procurement activities only. These costs are inherent in the cost of a Total Hip Replacement and should not be included in the final cost calculation for obtaining a femoral head.

† These costs are the highest single costs reported from all banks in each category – these do not represent the costs from a single bank but is an aggregate of all of the highest costs reported. It is intended to represent the highest possible costs that could be incurred.

Risks

The risks associated with this model are:

- That the system can breakdown without surgical team involvement and hospital resources.
- That utilizing all resources in a comprehensive tissue bank may not be the most efficient way of processing a single femoral head.

Benefits

The benefits of a surgical bone bank as part of a comprehensive tissue bank are as follows:

- Control over Canadian tissue supply.
- Human and financial resources needed to operate are centralized.
- Product quality is being met.
- Meets Canadian safety standards.
- Fits within the provincial budget and funding structure.
- The potential for full donation exists in the model where hospitals are participating by sending their femoral heads for banking.
- Meets surgeon preference and requirements as surgeon can purchase all tissue needs from one source.

Comprehensive Tissue Banks

Comprehensive tissue banks that process tissue from deceased donors only and do not accept surgical bone exist. These are included in this discussion, as they are a competing source of femoral heads available to Canadian hospitals.

Costs

The costs associated with this model include human resources (director, procurement, banking and shipping team, and quality assurance team), infrastructure (procurement lab, freezers), testing (laboratory), and quality assurance (database).

The cost to process a femoral head is similar to the current cost of purchasing a femoral head from a comprehensive bank that accepts surgical bone. While a detailed breakdown of procurement and banking costs for deceased only banks is outside the scope of this report, the current cost to purchase a femoral head is $1050 from one deceased only tissue bank[xix].

Risks

The risks associates with this model are:

- That the demand for femoral heads is greater than the available supply of femoral heads from deceased donors.

Benefits

The benefits of a deceased tissue bank are as follows:

- No human or financial resources spent on surgical bone banking system.
- Product quality is being met.
- Meets Canadian and/or AATB safety standards.
- Fits within the provincial budget and funding structure.
- Meets surgeon preference and requirements as surgeon can purchase all tissue needs from one source.

US Tissue Banks

A number of hospitals employ a model whereby the demand for surgical bone is met by 100% outsourcing to US tissue banks.

Costs

The only costs involved in this model are the costs to purchase and ship femoral heads from the US to Canada.

The cost to purchase surgical bone from US tissue banks is the highest cost option of all models with the highest level of cost uncertainty.

The lowest cost option for obtaining US surgical bone has been estimated at a minimum of $1188 Canadian at current exchange rates (see Appendix 5 and Part 2 p 24-25), and has been estimated by Goss Gilroy (2003) to be as high as $1216 to $1517 depending on the source and availability of tissue.

The average cost to obtain a femoral head from a Canadian surgical bone bank is estimated at between $734 to $914.

Risks

The risks associated with this model are:

- That the hospital doesn't have control over the supply of tissue.
- Cost uncertainty due to exchange rate fluctuations.
- Public perception (e.g. risk of supply and other issues).
- US demand becomes greater than US supply and tissue supply availability is reduced.

Benefits

The benefits of this model are:

- No human or financial resources spent on surgical bone banking system.
- Product quality is being met.
- Meets safety standards if purchased from AATB accredited tissue bank.
- Fits within the provincial budget and funding structure.
- Meets surgeon preference and requirements as surgeon can purchase all tissue needs from one source.

Comparison of Generalized Canadian Surgical Bone Banking Models

This section compares each model against objectives for a Canadian surgical bone banking system, success measures and anticipated outcomes.

The model(s) that meet(s) the greatest number of objectives, success measures and anticipated outcomes will be investigated for identification of essential building blocks for increasing the current capabilities of the Canadian surgical bone banking system.

Objectives for Surgical Bone Banking in Canada

The following objectives are required for a sustainable Canadian surgical bone banking system:

a. To meet requirements to ensure patient outcomes are met.
b. To meet Canadian demand for surgical bone with Canadian supply.
c. To meet Canadian demand in the most cost-effective way.
d. To ensure a safe supply of surgical bone.

Success Measures for Surgical Bone Banking in Canada

In order to assess the success potential of the models outlined above, the following measures have been developed from the issues identified as outcomes of the interrelationship diagraph analysis conducted in Part 2 (Appendix 4).

The following 6 success measures have been adopted for the selection of models to develop:

a. Actual donation rates increase.
b. Utilization of surgical bone from Canadian banks increases.
c. Surgeons prefer surgical bone products from Canadian tissue banks.
d. Canadian surgical bone costs the same as or less than surgical bone from US tissue banks.
e. Supply meets current Canadian safety regulations.
f. Effect on other hospital resources is at best positive and at worst neutral.

Criteria for Model Selection

In selecting models to develop, the criteria to be used need to reflect the drivers that were identified by the interrelationship diagraph issues analysis conducted in Part 2 (Appendix 3).

The following 7 criteria have been adopted for the selection of models to develop:

a. Must have funding available to operate and meet regulations and standards.
b. Must be competitive with available US products.
c. Must identify champions to move model forward.
d. Must meet Canadian standards and regulations.
e. Must work within Provincial budgets and funding structures.
f. Must be able to access the full potential of donation.
g. Must generate surgeon preference for product.

Comparison of Models against Objectives, Criteria for Model Selection and Anticipated Outcomes

Table 12 below compares each model against objectives for a Canadian surgical bone banking system, success measures and anticipated outcomes.

Each of the four models presented above: in-hospital surgical bone banking, surgical bone banking as part of comprehensive tissue banks, tissue banks that provide deceased femoral heads and US tissue banks, can meet patient outcome needs as long as the appropriate standards are met.

Only two of the models can meet the objective of obtaining surgical bone tissue from a Canadian supply: in-hospital bone banks and comprehensive banks that accept femoral heads.

Table 12: Surgical Banking Model Comparison																	
	System Objectives				Criteria for Model Selection							Anticipated Outcomes/Success Measures					
	Patient Needs	Canadian Supply	Cost Effective	Safe Supply	Funding Available	Competitive with US Products	Champions Identified	Meets Canadian Standards and Regulations	Works within Provincial Budgets and Structures	Accesses Full Potential of Donation	Surgeon Preferred	Actual Donation Rates Increase	Utilization of Surgical Bone from Canadian Banks Increase	Surgeons Prefer Canadian Products	Canadian Surgical Bone Costs the Same or less than US tissue	Supply meets Canadian Safety Regulations	Effect on Hospital Resources is Positive
Models																	
In-Hospital Surgical Bone Bank	√	▼	**1** (most)	√	▼	√ - only for femoral heads	▼	▼	√	▼	▼	√	√	▼	√	√	▼
Surgical Bone Bank in Comprehensive Tissue Bank	√	▼	**2**	√	▼	√ - only for femoral heads	▼	√	√	▼	▼	√	√	▼	√	√	▼
Comprehensive Tissue Bank without Surgical Bone	√	**X**	**3**	√	▼	√ - for femoral heads and chips	▼	√	√	**X**	▼	**X**	**X**	▼	√	√	√
US Tissue Bank	√	**X**	**4** (least)	√	n/a	√	n/a	▼	√	**X**	√	**X**	**X**	**X**	n/a	n/a	√

Legend: √ Meets objective, criteria, or anticipated outcome ▼May meet objective, criteria, or anticipated outcome
X Doesn't meet objective, criteria, or anticipated outcome • Needs more analysis

From the cost data gathered during the literature reviews, interviews and survey of surgical bone banks, the ranking of most cost effective to least cost effective source of surgical bone is: in-hospital surgical bone banking, surgical bone banking as part of comprehensive tissue banks, tissue banks that provide deceased femoral heads and US tissue banks.

All systems are capable of delivering a safe tissue supply.

In terms of competing with US product, the three Canadian systems can all provide un-modified safe femoral heads, and tissue banks that provide deceased femoral heads can provide a range of chips and modified grafts. There is currently no capability in Canada for providing advanced tissue products however (e.g. machined bone, DBM, etc.).

Any initiatives that will increase the utilization of surgical bone are going to require champions to move the initiatives forward. No champions were specifically identified for this project, however there are a number of highly capable and willing persons conducting tissue banking.

Meeting Canadian standards and regulations has been difficult for small in-hospital bone banks. At the time of publication, a number of in-hospital bone banks are considering discontinuing operations due to lack of funding or other resources to meet Health Canada requirements. Canadian comprehensive banks however all meet CSA and/or AATB standards, and all orthopaedic departments that indicated they purchased bone tissue from the US purchase only from AATB accredited sources. It is interesting to note that a number of Canadian tissue banks have developed systems to meet AATB standards.

All four models of surgical bone banking can be funded under current provincial funding structures. Only two models have the potential to access the full donation potential of Canadian surgical bone: in-hospital surgical bone banking, and surgical bone banking as part of comprehensive tissue banks.

Surgeon preference was identified many times throughout the literature reviews, interviews with orthopaedic departments and surgical bone banks, and also in expert interviews. While all models can provide a viable femoral head, and tissue banks that provide deceased femoral heads can provide some modified graft products, there is no capability in Canada to provide advance tissue products available from the US. Until there is Canadian capacity in this regard, advanced US tissue products will be preferred by Canadian surgeons.

As discussed in the cost analysis above, all Canadian sources of surgical bone are believed to be more cost effective than purchasing from the US.

All Canadian sources, either now or in the near future, will meet Health Canada safety regulations.

Finally, the success of all of the models will require that the effect on hospital departments associated with a surgical bone bank be at the very least neutral and at best have a positive impact on the department (e.g. cross charge or other kind of compensation). Tissue banks that provide deceased femoral heads and those that purchase from US tissue banks currently have the least effect on other hospital resources.

No single model currently has the ability to meet all objectives, criteria or outcomes. There are however elements or building blocks in the three Canadian systems that can be leveraged to meet all objectives, criteria and outcomes. These building blocks are discussed below, and three models are proposed to leverage the current strengths of the Canadian models to increase the donation and utilization of Canadian surgical bone.

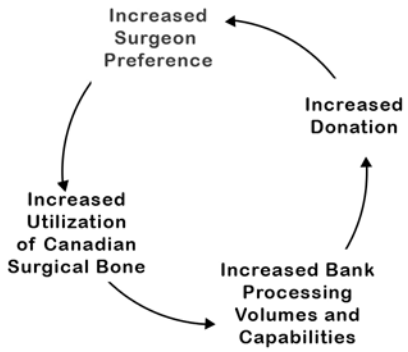
Building Blocks for Increasing the Capabilities for Surgical Bone Banking in Canada

A key building block that could be leveraged for increasing surgical bone banking capacity in Canada is developing surgeon preference for Canadian surgical bone. A model is also recommended that combines the current strengths of the three Canadian surgical bone banking models and employs the building blocks described below.

Increasing Utilization through Surgeon Preference

Figure 8 below outlines the importance of surgeon preference in increasing the utilization of Canadian surgical bone.

Figure 8: Surgeon Preference and Increasing Utilization of Canadian Surgical Bone Supply



As can be seen in Figure 8, increased utilization of Canadian surgical bone (CSB) requires increased surgeon preference for CSB products. Increased utilization and surgeon preference requires increased processing volumes and new processing capabilities. Increased preference, utilization and processing require increasing donation.

In order to increase donation of surgical bone, there must be an increase in surgeon preference - trying to increase donation without increasing capabilities will not increase surgeon preference for CSB. Correspondingly, increasing bank tissue volumes without also increasing new capabilities will also not lead to increased surgeon preference.

Increased utilization by Canadian surgeons will drive new bank capabilities and increased donation (which will require some surgeon/OR participation). The primary assumption is that if equivalent or superior Canadian products exist, surgeon preference will be for new Canadian products over US products.

Key Role of Orthopaedic Teaching Hospitals

Table 13 contains a list of the Canadian Orthopaedic Association (COA) orthopaedic training sites, the location of surgical bone banks and if the surgical bone bank is associated with or located at a COA teaching hospital. Sixteen Canadian Universities have a COA orthopaedic teaching hospital. Fifteen Canadian surgical bone banks (n=15/26) are located at a COA teaching hospital.

Table 13: Location of orthopaedic training hospitals[xx] vs. location of surgical bone banks

Province	COA listed Orthopaedic Training Program	Location of current or in-development Surgical Bone Banks	Currently located at a COA Listed Teaching Hospital[xxi]	Associated Comprehensive Tissue Bank? (✓ = yes)
BC	University of British Columbia	Vancouver (in development)	@ Vancouver General (associated with UBC)	✓
		Royal Jubilee Hospital, Victoria	No	✓
AB	University of Calgary	Southern Alberta Tissue Program (Calgary)	Located on same site with U of C Faculty of Medicine	✓
	University of Alberta	Comprehensive Tissue Centre, (Edmonton)	Royal Alexandra @ U of A	✓
SK	University of Saskatchewan	Royal University Hospital, Transfusion Medicine Dept.	@ University of Saskatchewan	✓
		Regina General Hospital Regina	No	
MN	University of Manitoba	No Surgical Bone Bank	No	
ON	University of Western Ontario	London Health Sciences Centre	@ University of Western Ontario	✓
	McMaster University	Henderson Hospital	Henderson Hospital Part of McMaster's Hamilton Health Sciences Centre,	
	University of Toronto	St. Michael's Hospital	Associated with University of Toronto	
		Toronto East General Hospital	Associated with University of Toronto	
		Sunnybrook Women's College Health Sciences Centre	Associated with University of Toronto	✓
		Mount Sinai Hospital	Associated with University of Toronto	✓
	Queens University	Kingston General Hospital	Queen's University associated with Kingston General	
	University of Ottawa	Ottawa General (Civic site)	Associated with University of Ottawa	

Province	COA listed Orthopaedic Training Program	Location of current or in-development Surgical Bone Banks	Currently located at a COA Listed Teaching Hospital[xxi]	Associated Comprehensive Tissue Bank? (✓ = yes)
		Peterborough General Hospital	No	
		Queensway Carleton Hospital, Neepean	No	
		Thunder Bay Regional Hospital, Thunder Bay	No	
		Quinte Health Centre, Belleville General Hospital, Bellville	No	
		Lakeridge Health Corporation, Oshawa	No	
		Sarnia General Hospital, Sarnia	No	
QC	Université de Montréal	Hôpital du Sacré-Coeur de Montréal	Associated with University of Montreal	
	McGill University	Sir Mortimer B. Davis Jewish General Hospital	Associated with McGill University	
	Université Laval			
	Université de Sherbrooke			
NB		Moncton City Hospital, Moncton		
NS	Dalhousie University			
NF	Memorial University			

The confirmed percentage of total surgical bone banked at or associated with orthopaedic teaching hospitals is 82.5%, or 1843 of 2233 femoral heads. These results support the idea that surgeon preference and involvement are key factors in surgical bone banking.

Orthopaedic teaching hospitals are positioned to play a lead role in any initiative to increase surgical bone banking in Canada.

Recommended Model for Increasing Surgical Banking Capability in Canada

Figure 9 contains a model for leveraging the current strengths of each of the three Canadian sources of femoral heads, in-hospital surgical bone banking, surgical bone banking as part of comprehensive tissue banks and tissue banks that provide deceased femoral heads.

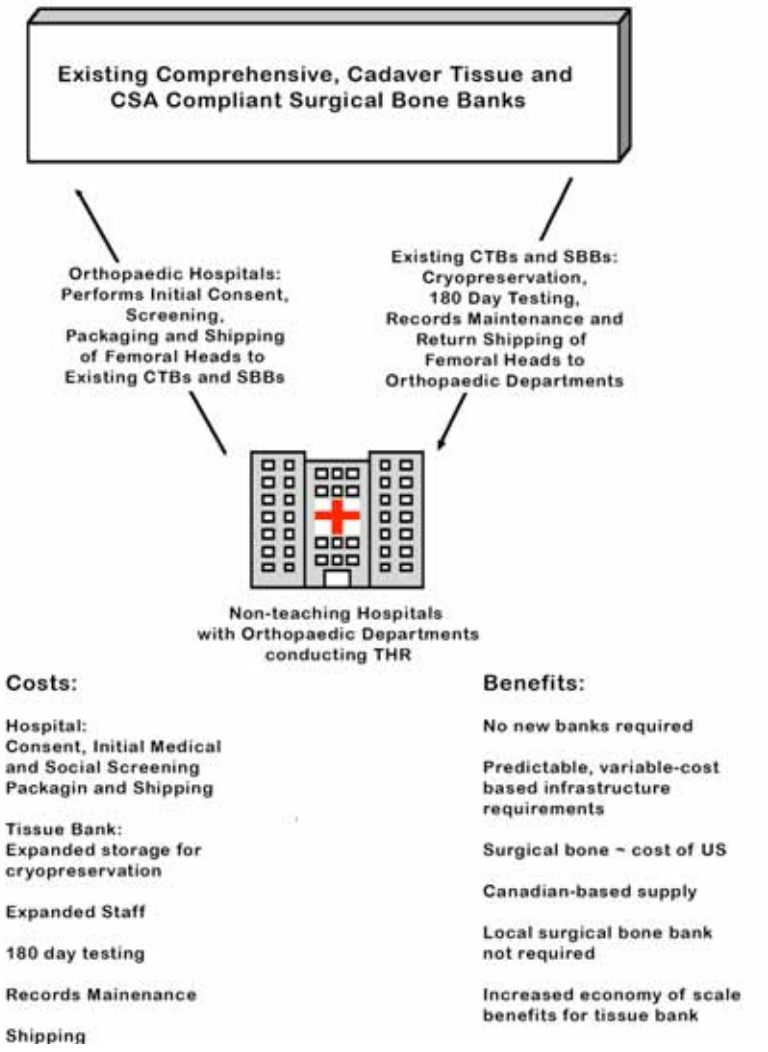
Shipping Model

The shipping model is concerned with combining the current strengths of in-hospital surgical bone banking, surgical bone banking as part of comprehensive tissue banks and tissue banks that provide deceased femoral heads.

In this model, femoral heads are procured at orthopaedic hospitals that do not have a surgical bone bank, and are shipped to either an existing surgical bone bank or to a comprehensive tissue bank (including banks that only process deceased tissue). This model is based on the success of similar efforts in Alberta and New Brunswick here in Canada, and internationally in Scotland.

Orthopaedic departments are the most labour and cost efficient places for obtaining a medical history screening and consent for obtaining a femoral head. Orthopaedic ORs also have the distinct advantage of providing a femoral head at 'no charge' to a bone bank, given that the femoral head is going to be removed in the total hip replacement procedure – no other procurement infrastructure is required. Some testing is also provided at no charge (e.g. some blood screening and pathology examination). Orthopaedic departments also have refrigeration and cryogenic storage on site for storage of their supply of bone graft. OR staff are also able to package and have graft material shipped to another site.

Figure 9: Model for Increasing Surgical Bone Banking Capability in Canada – the "Shipping Model"



A number of in-hospital surgical bone banks in Canada are currently struggling with the costs and operational requirements for long-term storage, 180-day follow up testing, quality assurance and record maintenance requirements, which are areas where comprehensive tissue banks excel. Also, if deceased tissue banks are not required to process the femoral heads there are no processing costs associated with accepting the femoral head. Deceased tissue banks currently often ship whole femoral heads – they could potentially accept femoral heads from orthopaedic departments for that purpose, and utilize deceased donation for more advanced processing.

The benefits of this model are:

- No new surgical bone banks are required.
- Variable-cost based infrastructure requirements are predictable.
- Surgical Bone could be provided at approximately ¾ to ½ the cost of US tissue.
- There would be control and availability of a Canadian-based supply.
- Increased economy of scale benefits for the comprehensive tissue banks.

Table 14 below contains a list of the steps in the "shipping model" with associated costs and responsibilities. Costs per femoral head are essentially split between the orthopaedic department and the surgical bone bank or comprehensive tissue centre, with each group performing the most efficient and cost effective steps at their site.

Table 14: Shipping Model Responsibilities and Costs

Banking Activity	Average Cost to Orthopaedic Department	Average Cost to existing SBB or CTB	Total
Medical History Screening and Obtaining Consent	47.04	0.00	47.04
Initial Swabs and Serology	148.75	0.00	148.75
Future/other testing (West Nile)	126.67	0.00	126.67
Procurement (surgeon involvement)	0.00	0.00	0.00
Procurement (pathology)	75.00	0.00	75.00
Procurement (OR staff)*	0.00	0.00	0.00
Materials	32.35	0.00	32.35
Shipment to SBB/CTB	60		60
Storage	0	124.46	124.46
180 Day Testing	0	136.00	136.00
Quality Assurance	0	186.53	186.53
Final Distribution	0	36.36	36.36
Totals	**489.80**	**483.35**	**973.15**

Break Even Analysis – Shipping Model

The Shipping model requires new capability in an orthopaedic department only in terms of a trained Nurse or Nurse Practitioner to oversee the following steps:

- Medical history screening
- Consent
- Records for initial swabs and serology
- OR activities (procurement and placement in container)
- Temporary storage

- Materials management
- Shipping activities.

All other infrastructure needs exist in an orthopaedic OR.

Table 15 below contains a break-even analysis for the shipping model, which is designed to answer the question:

> *How many femoral heads are required to recover the start up costs of implementing a shipping model between an orthopaedic department and an existing surgical bone bank or comprehensive tissue bank?*

Most provinces rely in part on surgical bone tissue from both Canadian and US sources. In order to find a break-even point for participating in a shipping model, the number of femoral heads per year required to cover start-up costs were determined for savings vs. Canadian and savings vs. US purchasing.

It is also important to note that this analysis does not take in to account for the need to increase full time equivalent (FTE) staff once surgical donation increases. The costing assumes that staff is currently available to perform the tasks, which is typical of a small surgical bone bank.

Table 15: Break-Even Analysis – Shipping Model

Operational Cost per Femoral Head	Average Costs ($)
Medical history& consent	$ 47.04
Initial swabs & serololgy	$ 148.75
Other testing	$ 126.67
Procurement- surgeon involvement	$ -
Procurment- lab & pathology	$ 75.00
Procuremet- OR staff	$ -
Materials	$ 32.35
Storage	$ 124.46
180 dayfollow-up testing	$ 136.00
Quality Assurance	$ 186.53
Final Distribution	$ 36.36
Other	$ -
Total Expenses	$ 913.16
Total Variable Expenses per fermoral head*	**$ 474.84**

Average Cost to Purchase from existing SBB/CTB	$ 1,050.00
Average Savings for in-hospital bank vs. CDN purchase	$ 136.84
Average Cost to Purchase from US source	$ 1,366.50
Average Savings for in-hospital bank vs. US purchase	$ 453.34

* Variable costs estimated at 52% for surgical bone banks [Goss Golroy, 16 Sep. 2003]

Start-up Costs	Average Costs ($)
Equipment	$ 5,000.00
Quality System Development	$ 5,000.00
Staff Training	$ 10,000.00
Interest expense (#7%/year)	$ -
Total fixed start-up costs	**$ 20,000.00**
Amortization period (years)	**5**
Total fixed start-up costs	**$ 4,000.00**

Break-Even Cost Revovery

FH / year to recover start-up cost = (start-up cost/year) / (savings/femoral head)

1) vs. purcasing from Canadian tissue banks

Femoral heads per year required to revover startup costs in 5 year = 29

2) vs. purcasing from U.S. tissue banks

Femoral heads per year required to revover startup costs in 5 year = 9

The key benefit of the Shipping Model is that the amount of new infrastructure required is minimized. Orthopaedic hospitals that participate do not require any new physical infrastructure. Some quality system development (i.e. standard procedures for donation, procurement and shipping) would be required as well as some initial training in the procedures. For existing surgical bone banks and/or comprehensive tissue banks, some expansion of their cryogenic storage would be required. These costs have been estimated in the Start-up costs of the Break-even analysis.

The savings of a Shipping Model vs. current purchasing from existing surgical bone banks or comprehensive tissue banks would allow costs associated with the implementation of a Shipping Model to be recovered after shipping approximately 29 femoral heads per year. Due to the significantly higher cost savings vs. purchasing from the US, the costs associated with the implementation of a Shipping Model would be recovered after shipping approximately 9 femoral heads per year.

The low infrastructure requirements, coupled with leveraging existing strengths of the participating organizations, would see a cost benefit very quickly, probably in the first year for a small to medium sized Canadian orthopaedic department. The low infrastructure needs also provides a hedge against technological changes (e.g. hip resurfacing or bone substitutes) – there is no risk of building up a surgical bone infrastructure in every orthopaedic department that may be obsolete in 10 to 15 years.

Break Even Analysis – Development of New Stand Alone In-hospital Surgical Bone Banks

Some larger Canadian orthopaedic departments may want to develop their own in-hospital surgical bone banking capability. Table 16 below contains a break-even analysis for the development of new in-hospital surgical bone banks.

The development of new surgical bone banking capability has significant costs in terms of new equipment costs (i.e. cryogenic storage), quality system development and HR/training requirements. There are also significant potential hurdles to overcome with developing effective links with other hospital departments (e.g. pathology, blood bank and laboratory resources). Table 16 lists the estimated start up costs for a new surgical bone bank.

In comparison to existing Canadian surgical bone banks and comprehensive tissue banks, the cost savings vs. purchasing from a Canadian source is estimated to require a surgical bone bank of approximately 118 femoral heads per year to recover the initial start-up costs. This would represent one of the largest Canadian surgical bone banks.

In comparison to purchasing from the US, however, the cost savings would allow for a much smaller in-hospital surgical bone bank of approximately 35 femoral heads per year.

The decision to open a new Canadian surgical bone bank will depend significantly on the reliance of a particular province on US bone tissue. However there is nothing preventing an orthopaedic department from participating in a shipping model with banks from other provinces.

Table 16: Break-Even Analysis – New In-hospital Surgical Bone Banks

Break-Even Analysis: Shipping Model - Cost to Orthopaedic Department

Operational Cost per Femoral Head	Average Costs ($)
Medical history& consent	$ 47.04
Initial swabs & serololgy	$ 148.75
Other testing	$ 126.67
Procurement- surgeon involvement	$ -
Procurment- lab & pathology	$ 75.00
Procuremet- OR staff	$ -
Materials	$ 32.35
Storage	$ 124.46
180 dayfollow-up testing	$ 136.00
Quality Assurance	$ 186.53
Final Distribution	$ 36.36
Other	$ -

Total Expenses	$ 913.16
Total Variable Expenses per fermoral head*	**$ 474.84**

Average Cost to Purchase from existing SBB/CTB	$ 1,050.00
Average Savings for in-hospital bank vs. CDN purchase	$ 136.84
Average Cost to Purchase from US source	$ 1,366.50
Average Savings for in-hospital bank vs. US purchase	$ 453.34

Start-up Costs	Average Costs ($)
Equipment	$ 25,000.00
Quality System Development	$ 30,000.00
Staff Training	$ 10,000.00
Interest expense (#7%/year)	$ 15,444.00
Total fixed start-up costs	**$ 80,444.00**
Amortization period (years)	**5**
Total fixed start-up costs	**$ 16,088.80**

Break-Even Cost Revovery

FH / year to recover start-up cost = (start-up cost/year) / (savings/femoral head)

1) vs. purcasing from Canadian tissue banks

Femoral heads per year required to revover start up costs in 5 year = 118

2) vs. purcasing from U.S. tissue banks

Femoral heads per year required to revover start up costs in 5 year = 35

Discussion

Orthopaedic hospital personnel, including surgeons and OR staff, will have a key role in increasing surgical bone banking capacity. Currently there are fifteen (15) Canadian Orthopaedic Association (COA) orthopaedic training sites participating in surgical bone banking. These surgical bone banks obtain over 80% of all femoral heads viable for transplantation that are currently collected across Canada. In order to increase surgical bone banking capacity, surgical bone must also be obtained from non-training orthopaedic hospitals and capacity increased in a number of COA training hospitals.

New surgical bone banks are not required if shipments of femoral heads from non-training orthopaedic hospitals to existing surgical bone banks or tissue banks are promoted. There are a number of similar "shipping models" currently in practice in Canada for other tissues that could be used to develop a pilot and eventually a full program for obtaining all viable femoral heads in Canada. Human resource requirements in non-training orthopaedic hospitals that participate in shipping femoral heads are low and will not require staff with full knowledge and training on all aspects of tissue banking. If femoral heads are shipped to existing banks, an economy of scale

of existing tissue bank human resource capabilities can be utilized for the majority of banking and distribution tasks.

The average annual demand for femoral heads in Canada has been estimated at over 11,500 femoral heads. In order to fully meet Canadian demand with a Canadian tissue supply the average deferral and rejection rates would need to be improved through the promotion of standards and best practices. Based on deferral and rejection rates from larger surgical bone banks (e.g., some have achieved deferral and rejection rates <40%) it should be possible to meet Canadian demand with a Canadian tissue supply. If adopted by Health Canada, the replacement of 180 day follow-up testing by Nucleic Acid Testing (NAT) at the time of donation would remove a key contributor to the deferral rate of surgical bone. Approximately 5 to 10% of surgical bone is deferred due to the inability to perform 180 day follow up tests with donors, particularly in rural areas. NAT testing would eliminate the need for 180 day testing and would allow the average demand for femoral heads in Canada to be met with Canadian supply.

Shipping of femoral heads from non-training orthopaedic hospitals could begin in the short term, particularly for tissue banks located near orthopaedic training centres. For example, a tissue bank would need to develop a protocol and packaging and could begin once quality procedures were approved and OR staff received training on packaging and shipping requirements.

There are significant advantages to promoting increasing surgical bone banking capacity in Canada, including:

- The availability of a large source of safe allograft bone,
- Surgical bone has low recovery costs - a total hip replacement will make a femoral head available regardless of any tissue banking activity,
- Consent is obtained from the living donor, and
- Surgical bone has been reported to be a preferred source of tissue for orthopaedic surgeons particularly for revision hip and spinal fusion surgeries.[xxii]

Femoral heads are being purchased at a greater cost versus developing greater surgical bone banking capacity. Surgical bone banking has moderate cost efficiencies versus obtaining similar tissue from tissue banks, primarily due to the fact that procurement of surgical bone occurs as a by-product of total hip-replacements. The average cost savings per femoral head was estimated at approximately $150 per femoral head[xxiii]. Significantly higher cost savings are possible versus obtaining femoral heads from US sources, which was estimated at $353 per femoral head. If the average annual shortfall of femoral heads in Canada were purchased from the US the amount of tissue purchased would exceed $3 million dollars annually.

Given the human resource efficiencies, high donation potential, demand for safe allograft tissue, potential operational efficiencies, low training requirements and potential cost savings, it is recommended that surgical bone banking be promoted as a viable potential tissue source in Canada, especially in light of low deceased donor rates.

Appendices

For further information related to this report, please refer to the following appendices, available on line at www.ccdt.ca/english/publications/final.html or by contacting the CCDT at the coordinates on the inside title page of this document.

Appendix 1: Canadian Surgical Bone Banks

Appendix 2: Issues Identified During Orthopaedic Department and Surgical Bone Bank Interviews

Appendix 3: Themes in Surgical Banking Issues

Appendix 4: Interrelationship Diagraph and Decisions

Appendix 5: Canadian Surgical Bone Bank Cost Survey

Appendix 6: Sample US Tissue Pricing

Appendix 7: Additional Survey Results.

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Surgical Bone Banking

<u>Banking Practice</u>

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Endnotes

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[i] Canadian Institute for Health Information, "Canadian Join Replacement Registry: 2004 Report, Total Hip and Total Knee Replacements in Canada." Ottawa, 2004

[ii] An initial attempt was made to utilize the Canadian Institute for Health Information (CIHI) Discharge Abstract Database and the Canadian Morbidity Database to locate hospitals performing total hip replacements, however CIHI would not release information on specific hospital activities due to CIHI confidentiality policies.

[iii] The Canadian Medical Directory maintains an accuracy rate of 99% for listings of medical professionals.

[iv] Alberta (n=19) and Newfoundland (n=4) have regional hospitals represented by one administrative centre. These administrative centres were contacted for information on surgical bone banking.

[v] It should be noted that some banks use the term "deferral" to refer to the criteria used to reject tissue, while others used the term "rejection" to refer to the same set of critera.

[vi] Antoniou et al. have estimate the current cost of a THR in Canada to be approximately $7400 (ICD-9-CM 91.51 Total Hip Replacement).

[vii] Steps in femoral head donation compiled from a number of publications, including: AORN 2004; Buckham 1989; Carter 1999; Cruz 1988; Friedlaender 1982;Hart el al 1986 (April); Hart el al 1986 (May); La Prairie et al. 1991; Tomford et al. 1986. Current Canadian practice obtained through expert opinion.

[viii] Utilization costs are discussed below.

[ix] Personal communication, Muriel Shewchuk, Director Surgical Services, Foothills Hospital, Calgary AB, 29 March 2005.

[x] It should be noted that one surgical bone bank in Saskatchewan did note that they were limited by the lack of funding to buy more cryogenic storage, which was a major contributor to a high loss rate.

[xi] Closing US exchange rate, 17 May 2005 @ 1.2661, <http://www.bankofcanada.ca/en/index.html>. Pacific Coast Tissue Bank current fee schedule for freeze dried Femoral Head with neck is $1000 US. From Community Tissue Services the current fee for a Femoral Head w/o cartilage is $878 US. At the current exchange rate, the average cost from these two sources is 1.2661(1000 + 878)/2 = 1100.

[xii] FedEx rate quoted 20 May 2005 for a 1' x 1' x 1' package, dry ice with validated dangerous goods packaging Vancouver to Halifax $124.60 + tax, and for a 1 ½ cu.ft $144.70. For two similar packages from Los Angles or Seattle to Vancouver the costs are $188.84 and $234.04. This gives a cost difference of approximately $77 for an average shipping cost difference.

[xiii] KelEx Agencies Ltd., North Vancouver BC, 20 May 2005. 6 Kg of dry ice recommended for overnight shipping.

[xiv] The reported average from Goss Gilroy 2003 averaged $917, however in discussions with two comprehensive tissue banks in Canada the average cost from these two centres was $1000 and $1050, probably due to higher administrative burden with current regulatory changes. The average from these two banks is being used to try to more accurately reflect current costs.

[xv] Personal communication, Dr. George Galea 2005.

[xvi] Russel et al. (1989) identified 60 surgical bone banks in Canada in 1987, and the current study has identified a possible 24 surgical bone banks (Canadian Surgical Bone Banks 2005).

[xvii] The American Association of Tissue Banks has revised their standards to allow NAT testing in place of 180 day follow-up serology. It remains to be seen if this change will be incorporated in CSA standards.

[xviii] See for example bone substitute products available from : Cortek Inc. < http://www.cortekinc.com/>, Teknimed Inc. < http://www.teknimed.com/>, DePuy Spine Inc., < http://www.depuyspine.com/products/biologicssolutions/healos.asp>, and other companies listed as participants in the 2005 American Academy of Orthopaedic Surgeons annual meeting < https://s12.a2zinc.net/clients/ezaaos/aaos2005/attendee/ExhibitorSearch.asp?SubID=40andkeyword=andGo+Find%21=Search>,

[xix] Personal communication, Jim Mohr, CCDT.

[xx] Canadian Orthopaedic Association, "Orthopaedic Training Programmes," web page < http://www.coa-aco.org/Frameset.html >, accessed 10 May 2005.

[xxi] Review of University and/or Hospital web site. There may be associations with Teaching hospitals not listed, e.g. with the appointments of individual surgeons or other associations not listed on the web sites.

[xxii] Reflects comments received during expert interviews

[xxiii] All figures in Canadian dollars.