



**Eye and Tissue Banking in Canada:
A Leading Practices Workshop
February 8 and 9, 2012**

Canadian Survey Responses

Canadian Blood Services aims to work with the tissue donation and transplantation communities to develop leading practices and recommendations in support of system performance improvement. A key challenge that the Canadian tissue donation and transplantation system currently faces is a lack of consistency in approaches to tissue quality, including variation in donor criteria and tissue specifications.

Canadian Blood Services hosted a leading practices workshop on February 8 and 9, 2012 as a first step in collaborating with the tissue donation and transplantation communities to improve consistency and quality in tissue donor criteria and tissue specifications, eye and tissue banking processes, and overall system performance. A survey was developed to inform workshop discussions, focusing on identifying variance in practices among tissue and eye banks; all banks which attended the workshop participated in the survey.

For the purposes of the workshop, a survey summary was created which included only the responses which reflected areas of variation in practices which would be discussed in workshop sessions. This summary presents the responses to all questions in the survey.

Respondents

The survey was distributed to all Canadian tissue banks, including ocular and surgical bone banks. Surveys were received from a total of 19 respondents (five banks did not attend the workshop and did not submit surveys).

Bank type	Description	No. of responses
Multi-Tissue Banks	Banks which recover two or more distinct tissue types from deceased donors (musculoskeletal, cardiovascular, skin or ocular). These programs may also recover surgical bone.	7
Surgical Bone Banks	Banks which recover from surgical (living) donors only	3
Tissue Banks	Banks which recover one type of tissue from deceased donors excluding ocular (musculoskeletal, cardiovascular or skin). These banks may also recover surgical bone.	5
Eye Banks	Banks which recover only ocular tissue	4
Total		19

- *Four of the seven multi-tissue banks are involved or responsible for ocular tissue recovery*
- *Four of the seven multi-tissue banks recover surgical bone*
- *One of the five tissue banks recovers surgical bone*

Geographical distribution of Canadian survey respondents:

- Nova Scotia;
- New Brunswick;
- Quebec;
- Manitoba (two banks);
- Saskatchewan (two banks);
- British Columbia (two banks);
- Alberta (three banks); and
- Ontario (seven banks).

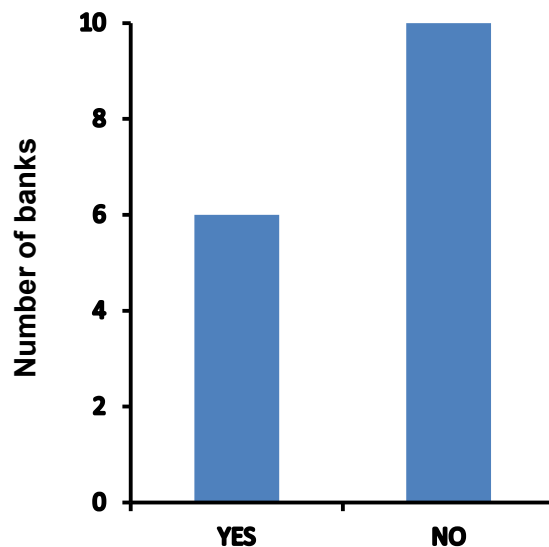
1. Donor identification and referral

1.1 *Approximately what percentage of your overall number of deceased tissue donors in the past 12 months were referred from your Medical Examiner or Coroner Service? “Deceased tissue donors” refers to actual donors where tissue was recovered.*

Percentage of deceased donors (actual donors) referred from ME/C Cases	Number of banks
None	9
< 5%	4
5-10%	1
10-15%	0
15-20%	1
>20%	1
Total	16

This section of questions did not apply to three of the Canadian respondents as they are standalone surgical bone banks.

1.2 *Does your bank or associated organ procurement organisation have a documented standard of practice for tissue donor identification and referral with the medical examiner / coroner service?*

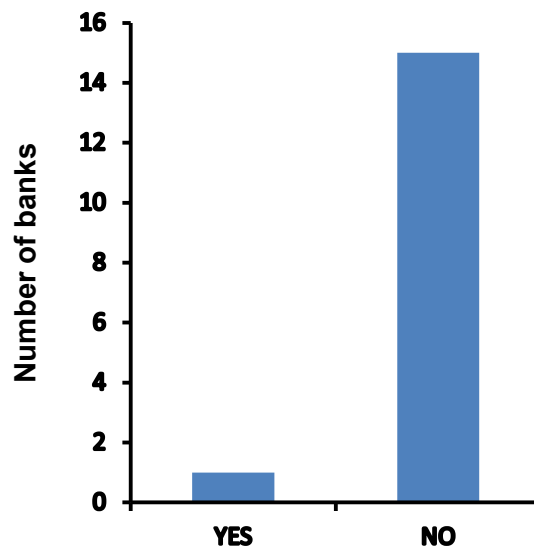


1.2.1 If you answered “Yes” to Question 2.2, indicate which of the following practices or components are in place as part of your relationship with the medical examiner / coroner. Check all that apply.

Six banks have a documented standard of practice as described in 1.2.

Component	Number of banks
A documented process such as a memorandum of understanding which details the roles and responsibilities for both the medical examiner / coroner service and the tissue bank / OPO in relation to donor identification and referral.	3
An identified member of staff who acts as a liaison with the medical examiner / coroner’s office in relation to donor identification and referral.	1
Performance monitoring, such as the number of potential donors within medical examiner and coroner cases compared to the number of actual donors.	2
Educational initiatives directed towards medical examiners / coroners.	3
Educational initiatives directed towards pathologists.	0
Regular attendance at medical examiner / coroner meetings/case reviews/rounds.	0

1.3 Does your bank actively work with, or provide educational opportunities for, funeral professionals?



2. Donor criteria

2.1 Please provide your acceptable age ranges for the following types of donors.

Structural bone grafts

Minimum age	Maximum age
15	65
15 F, 16 M	80
18	75
18	75
18	60
16	50
20	50
16	55 F, 60 M

Adjacent values are the age range for individual banks

Non-structural bone grafts

Minimum age	Maximum age
16	80
15F, 16M	80
15	70
18	80
18	75
18	75
16	50
14	100
16	70

Adjacent values are the age range for individual banks

Surgical bone

Minimum age	Maximum age
15F, 16M	None
None	80
16	None
18	75
None	None
16	85
18	None
14	100
20	None
None	75

Adjacent values are the age range for individual banks

Tendons

	Minimum age	Maximum age
Male	16	60
	16	60
	15	60
	18	75
	18	75
	18	55
	16	50
	14	60
	16	65
Female	15	60
	15	60
	15	60
	18	70
	18	75
	18	50
	16	50
	14	60
	16	65

Adjacent values are the age range for individual banks; age ranges for males and females at each bank are in corresponding order in each part of the table.

Cardiovascular tissue

Question 2.2 was for paediatric cardiac tissue donors only: *For paediatric cardiac tissue donors, please provide your minimum weight requirement (if applicable).*

Minimum age	Minimum weight	Maximum age
-	2.7 kg	55
-	2.7 kg	55
-	2.7 kg	60
Full term	2.7 kg	60
Full term	-	60
Full term	-	60
37 weeks gestation	2.7 kg	60

Adjacent values are the age range for individual banks

Skin

Minimum age	Maximum age
16	65
15F, 16M	65
15	70
18	75
14	100
15	80

Adjacent values are the age range for individual banks

Ocular tissue

Minimum age	Maximum age
18 months	70
18 months	70
2	85
2	75 for corneas, None for whole eyes
2	None
3	70
2	80
2	80
2	75

Adjacent values are the age range for individual banks

2.3 *There is a significant unmet demand for smaller cardiac valves (10-22 mm). Has your program implemented any initiatives to increase the availability of paediatric valves?*

Six banks have implemented initiatives to increase the availability of paediatric heart valves:

- Formation of a recovery team at the hospital (including surgeons) to increase recovery among the hospital's own cases;
- Working closely with the Palliative Care team to increase donation;
- Engaging the processor they work with to see if they can increase their access to cardiac tissue;
- Training nurses and physicians in the Neonatal and Paediatric Departments about donation, and visiting the departments on a regular basis;
- Working with local medical examiner's office to do their own recoveries; and
- Working with the local paediatric facility to increase donation.

2.4 *There are a number of possible exclusion criteria for donors which are left to the discretion of the bank medical director. For each tissue type, identify the two areas that your bank finds the most challenging in making decisions about whether to accept or reject a donor.*

Note: Banks could choose to identify grey areas for both 'tissues in general' and specific tissue types, and many banks cited more than two challenging criteria. Although the responses meant it was not possible to identify the top two areas of concern, there is a clear picture of the challenges banks face when deciding whether to accept or reject a donor where criteria are not identified as mandatory for exclusion.

Tissues – General

Potential exclusion criterion	Number of citations
Death from an unknown cause*	6
Jaundice	4
Septicemia	4
Untreated systemic infection	3
Autoimmune diseases	3
Systemic immunosuppression	1
Trauma to donor area	1
Leprosy	0
Systemic mycosis	0

*Death from an unknown cause is a mandatory exclusion criterion and should not have been included in this question.

Other:

- Documented infection but negative cultures
- Infection
- Behavior risk
- Hospital acquired infection
- Under end of life care with no/minimal intervention
- Poorly documented or unresolved issues

Musculoskeletal

Potential exclusion criterion	Number of citations
History of steroid use	5
Clinically significant metabolic bone disease	4
Osteoporosis	3
Diabetes	2
Rheumatoid arthritis	1
Systemic lupus erythematosus	1
Sarcoidosis	1
Polyarteritis nodosa	0

Other:

- Depends on criteria provided by processor (in the case of a third-party processor)
- Chronic alcohol abuse
- End stage renal failure
- Trauma or open wounds
- Cancer

Cardiovascular

Potential exclusion criterion	Number of citations
Bacterial endocarditis	2
Cardiomyopathy of viral or idiopathic etiology	1
Rheumatic fever	0
Semilunar valvular disease	0
Chagas disease	0

One bank automatically excludes donors for all of the listed criteria except Chagas disease

Other:

- Trauma to chest area
- Genetic/chromosomal condition
- Past history of cardiac issues

Skin

Potential exclusion criterion	Number of citations
Poor skin quality	3
Extensive skin lesions	2
Extensive dermatitis	1
Cutaneous malignancy	1
Skin infections	0
Collagen vascular disease	0
Extensive tattoos	0
Extensive skin / soft tissue trauma	0

Other:

- Depends on criteria provided by processor (in the case of a third-party processor)
- Infection
- Abnormal findings on skin

Ocular

Are there any potential exclusion criteria other than those required by the regulations, which you consider when assessing ocular donor suitability?

Each bank cited a unique concern:

- Slit lamp and specular microscopy findings;
- Intubation longer than seven days or positive sputum;
- Cancer therapy (radiation, chemotherapy);
- Neurological disorders (Multiple Sclerosis, Parkinson's);
- Severe systemic connective tissue disease - challenge to define 'severe';
- Primary brain tumour;
- Down's Syndrome;
- Drowning; and
- Travel outside of Canada.

2.5 Indicate your current practices for the following donor tests:

Test	Number of banks			
	All donors	Based on donor (e.g., "high risk")	seasonal	Do not perform
NAT HIV	18	1	N/A	0
NAT HCV	18	1	N/A	0
NAT HBV	14	1	N/A	4
West Nile Virus	8	1	8	3

2.6 If you perform any donor testing in addition to the tests required by the regulations and the tests listed in Question 2.5, please identify the testing and describe the situation(s) where testing is performed.

Test	Number of banks	Application of testing
HTLV-I/II	16	14 – All donors 2 – Amnion donors
EBV	0	N/A
CMV	2	Amnion donors
HLA	2	Cardiac donors
Toxoplasmosis	1	Amnion donors
ABO and Rh	9	6 - All donors 1 – Cardiac and musculoskeletal donors 1 – Cardiac donors 1 – Depending on sample quality
Other Tests	1 for each bullet in the next column except the first, which is performed by 2 banks	<ul style="list-style-type: none"> • Syphilis for all donors • HepBsAg, HepBcAg, HepCab for all donors • HSV I/II for amnion donors • Total protein, albumin and Duffy A and B for all donors • Pathological examination of musculoskeletal chips for all donors
No Additional Tests	1	N/A

2.7 For each tissue type, indicate your time limits following death for tissue recovery to take place.

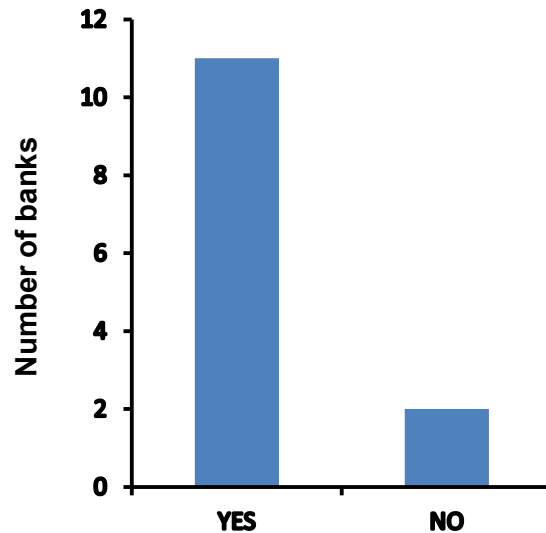
Note: Recovery may be carried out by bank staff or non-bank recovery teams such as those from an organ procurement organisation.

	Body refrigerated within 12 hours of death	Body not refrigerated within 12 hours of death
Musculoskeletal	All banks – recovery within 24 hours	<ul style="list-style-type: none"> • All banks except one – recovery within 15 hours • One bank – recovery within 12 hours
Cardiovascular	All banks – recovery within 24 hours	<ul style="list-style-type: none"> • All banks except one – recovery within 15 hours • One bank – recovery within 12 hours
Skin	All banks – recovery within 24 hours	<ul style="list-style-type: none"> • All banks except one – recovery within 15 hours • One bank – recovery within 12 hours

3. Tissue recovery practices which affect bioburden

3.1 *Do you have a documented standard operating procedure (SOP) for evaluating the suitability of a recovery site, including how to prepare recovery sites?*

Note: This question did not apply to banks which do not have staff that recover tissue, or to standalone surgical bone banks.



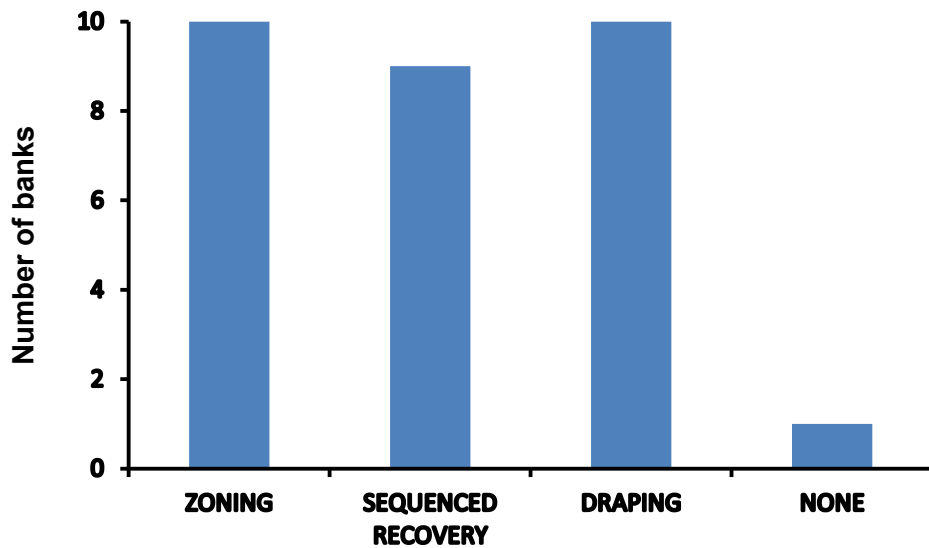
3.1.1 *If you answered “Yes” to Question 3.1, do you have a standard checklist to document the evaluation/preparation of the tissue recovery site?*

Of the 11 banks with a documented SOP as described in 3.1, all but one of the SOPs includes a checklist covering all of the following items. One bank does not assess whether the recovery site is in “good repair”.

- Adequate space
- Adequate lighting
- Suitable plumbing /drainage
- No standing fluids or contaminated waste present
- Confirmation that access to the site can be limited during recovery
- Adequate air flow system
- Surfaces are suitable for cleaning
- Site is in good repair
- Cleaning / disinfection of site prior to recovery

3.2 Select the practices you employ during tissue recovery.

Note: This question did not apply to banks which do not have staff that recover tissue, or to standalone surgical bone banks; total number of respondents was 11.



3.3 For each tissue type, indicate the samples used for microbiological testing of recovered tissue.

Musculoskeletal sample type	Number of banks
Chip	6
Swab	7
Chip and Swab	1

Cardiovascular sample type	Number of banks
Aliquot of Transport Solution	2
Swab	1
Aliquot of Transport Solution + Tissue Sample	2
Aliquot of Transport Solution + Swab	0
Tissue Sample + Swab	0
None*	3

*No samples taken for microbiology at the time of recovery does not necessarily mean this is not practiced; the sampling may be done at the time of processing.

Skin sample type	Number of banks
Biopsy	5 (72%)
Swab	1 (14%)
None*	1 (14%)

*No samples taken for microbiology at the time of recovery does not necessarily mean this is not practiced; the sampling may be done at the time of processing.

3.4 *For each tissue type, indicate if tissues are treated with antibiotics at the time of recovery either by washing with an antibiotic solution or transporting in solution/media containing antibiotics.*

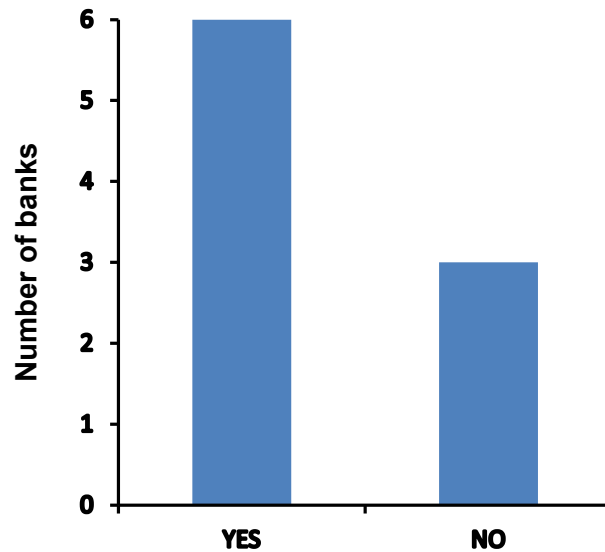
Nine banks do not treat any tissues with antibiotics at the time of recovery.

Tissue type	Number of banks
Musculoskeletal	3 (both living and cadaveric donors for all banks)
Cardiovascular	0
Skin	4

4. Corneal tissue recovery practices

4.1 *Do you have a documented standard operating procedure (SOP) for evaluating the suitability of sites for ocular recovery, including preparation of sites?*

Note: This question did not apply to banks which do not have staff that carry out recovery activities, those which do not handle ocular tissue, or to standalone surgical bone banks.



4.1.1 *If you answered “Yes” to Question 4.1, do you have a standard checklist to document the evaluation/preparation of the ocular recovery site?*

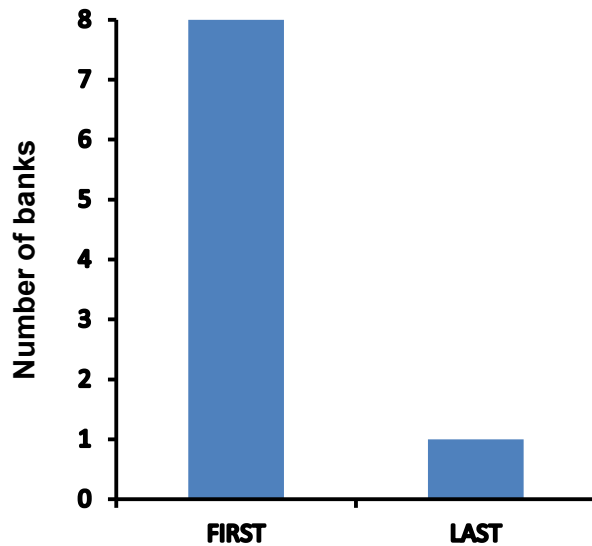
Four banks do not have an SOP as described in Question 4.1. Of the six banks with an SOP, two include a checklist which covers the following items:

- Adequate space
- Adequate lighting
- Suitable plumbing /drainage
- No standing fluids or contaminated waste present
- Confirmation that access to the site can be limited during recovery
- Adequate air flow system
- Surfaces are suitable for cleaning
- Site is in good repair
- Cleaning / disinfection of site prior to recovery

4.2 Indicate your percentage of each type of corneal recovery.

	Number of banks	
	<i>In situ</i>	Enucleation
None	2	1
Less than 25%	4	2
More than 75%	2	4
All	1	2

4.3 If an ocular donor is also donating other tissue types, at what stage would the ocular tissue be recovered?



4.4 Do you use draping during recovery of ocular tissue from ocular-only donors?

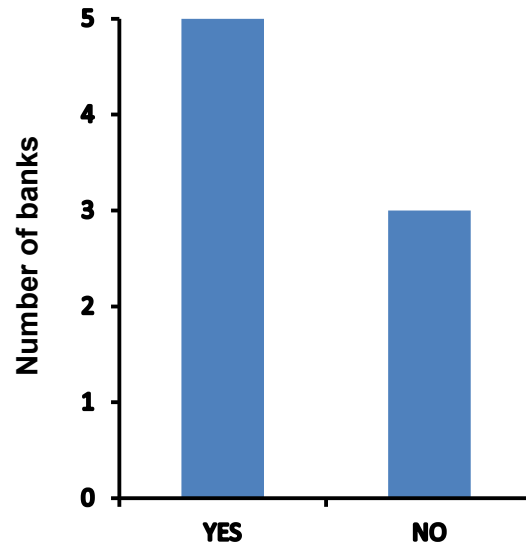
All banks use draping even when only ocular tissue is being recovered.

4.5 Do you expose eyes to povidone iodine at any point between the time of donor death and tissue preservation?

All banks expose ocular tissue to povidone at some point between death and preservation.

4.6 *For eye banks that carry out enucleation: following recovery of whole globes, do you irrigate eyes with antibiotic solution?*

Eight banks carry out enucleation:



5. Corneal tissue specifications

5.1 What is the minimum acceptable endothelial cell count (per square millimetre) for corneal tissue intended for transplant?

mm ²	Number of banks	
	EK	PK
1500 - 2000	1	-
2000	5	7
2100	1	1
2200	2	1
2300	-	-
2500	-	-

EK = endothelial keratoplasty; PK = penetrating keratoplasty

5.2 What is used as the starting point when calculating the expiry date of corneas intended for transplant?

Starting point for calculation of expiry date	Number of banks
Time of death	4
Time of enucleation / <i>In Situ</i> excision	2
Where enucleated: time of preservation	3

5.3 What is the maximum storage time (in days) of corneal grafts intended for transplant?

Days	Canadian Banks	
	EK	PK
8	1	-
9	-	1
10	1	1
14	7	7

EK = endothelial keratoplasty; PK = penetrating keratoplasty

5.4 *If grafts will be used for EK, indicate the per cent that are pre-cut in the eye bank.*

Percent pre-cut in bank	Number of banks
None	6
Less than 25%	-
25-50%	-
50-75%	-
More than 75%	1
All	2