Canadian Blood Services
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Eye and Tissue Banking in Canada: A Leading Practices Workshop

Canadian and International Survey Responses: Part 4 – Specifications and Methodologies

The Planning Committee recommended the development of two surveys to inform the workshop, one for Canadian banks and one for international programs. Both surveys focused on identifying variance in practices among tissue and eye banks. This summary focuses on the areas of variation which will be discussed during this session; a full report of survey responses will be distributed after the workshop. The survey information will allow delegates to better understand Canadian and international practices, and will help shape future workshops facilitated by Canadian Blood Services.

Respondents - Canadian Survey

The first 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 are not attending the workshop and therefore did not submit surveys).

Table 1: Canadian Eye and Tissue Banks

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*

The geographical distribution of survey respondents was:

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

Respondents - International Survey

The second survey was distributed to 14 international tissue programs with whom Canadian Blood Services has previously consulted; 11 programs responded.

Table 2: International Eye and Tissue Programs

Tissue Type	Description	No. of Responses
Multi-Tissue Banks	Programs which recover two or more distinct tissue types from deceased donors (musculoskeletal, cardiovascular, skin or ocular). These programs may also recover surgical bone.	4
Eye Banks	Programs which recover only ocular tissue	7
Total		**11**

- *One of the four multi-tissue programs recovers ocular tissue*
- *All four of the multi-tissue programs recover surgical bone*

The responses to the international survey included:

- United States (two programs);
- Australia (two programs);
- Germany;
- Netherlands;
- United Kingdom;
- Italy;
- Denmark;
- India; and
- Scotland.

The results of the international survey provide a sampling of practices around the world, not a comprehensive data set from all eye and tissue banks.

A. Eye and Tissue Donor Specifications

1. Donor Age

STRUCTURAL BONE GRAFTS

Canadian Banks		International Programs	
Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
15	65	17	45 F, 50 M
15 F, 16 M	80	17	50
18	75	18	50
18	75	18	65
18	60		
16	50		
20	50		
16	55 F, 60 M		

Adjacent values are the age range for individual banks

Among Canadian banks:

- Minimum age range: 15 to 20 years;
- Maximum age range: 50 to 80 years;
- 3 banks had identical age ranges for both their structural and non-structural donors.
- The range of minimum donor ages is always much smaller (5 years) than the range of maximum donor ages (30 years);
- Two banks distinguish between male and female donor ages – one for the minimum age (1 year apart) and one for the maximum age (5 years apart). Female data is always the lower; and
- An older minimum age does not necessarily mean an older maximum age:
    - Banks with the same minimum age (15 or 16) have maximum ages that are 15 to 30 years apart (50 to 80)
    - The bank with the lowest minimum age (15) also has the highest maximum age (80).

Among international programs:

- Minimum age range: 17 or 18 years;
- Maximum age range: 45 to 65 years;
- The range of minimum donor ages is much smaller (1 year) than the range of maximum donor ages (20 years); and
- One program has the lowest female donor age among both Canadian and international respondents, and the highest maximum age in any of the international programs is 15 years younger than the highest maximum age at one Canadian bank.

NON-STRUCTURAL BONE GRAFTS

Canadian Banks		International Programs	
Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
16	80	17	55
15F, 16M	80	17	None
15	70	17	None
18	80	18	65
18	75		
18	75		
16	50		
14	100		
16	70		

Adjacent values are the age range for individual banks

Among Canadian banks:

- Minimum age range: 14 to 18 years;
- Maximum age range: 50 to 100;
- The range of minimum donor ages is much smaller (4 years) than the range of maximum donor ages (50 years);
- One bank distinguishes male and female donors at the minimum age (1 year difference);
- An older minimum age does not necessarily mean an older maximum age
    - Banks with the same minimum age (15 or 16) have maximum ages that are 20 to 30 years apart (50 to 80).
    - The bank with the lowest minimum age (14) also has the highest maximum age (100).

Among international programs:

- Minimum age range: 17 or 18 years;
- Maximum age range: 55 to None; and
- The range of minimum donor ages is smaller (1 year) than the range of maximum donor ages (10 years).

SURGICAL BONE

Canadian Banks		International Programs	
Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
15F, 16M	None	17	None
None	80	18	None
16	None	None	None
18	75	None	None
None	None		
16	85		
18	None		
14	100		
20	None		
None	75		

Adjacent values are the age range for individual banks

Among Canadian banks:

- Minimum age range: None to 20;
- Maximum age range: 75 to no maximum;
- The range of minimum donor ages is much smaller (6 years) than the range of maximum donor ages (75 – 100 / no limit);
- One bank has no donor age limits at all; and
- There is no pattern of minimum to maximum age ratios.

Among international programs:

- Minimum age range: None to 18;
- Maximum age range: No maximum ages; and
- Two programs have no donor age limits at all.

TENDONS

	Canadian Banks		International Programs	
	Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
Male	16	60	17	55
	16	60	17	60
	15	60	17	60
	18	75	18	55
	18	75		
	18	55		
	16	50		
	14	60		
	16	65		
Female	15	60	17	55
	15	60	17	60
	15	60	17	60
	18	70	18	55
	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.

Among Canadian banks:

- Minimum age range, males: 14 to 18 years, Females: 14 to 18 years;
- Maximum age range, males: 50 to 75 years, Females: 50 to 75 years;

- For both genders, the range of minimum donor ages is much smaller (4 years) than the range of maximum donor ages (25 years);

- Although the overall minimum and maximum age ranges are the same for both genders, four banks accept female donors at lower ages than males:

    - Two banks distinguish at the minimum age (1 year difference)

    - Two banks distinguish at the maximum age (5 year difference); and

- An older minimum age does not necessarily mean an older maximum age; banks with the same minimum age (16) have maximum ages that are 10 to 15 years apart (50 to 65).

Among international programs:

- Minimum age range: 17 to 18 years;
- Maximum age range: 55 to 60 years; and
- The range of minimum donor ages is smaller (1 year) than the range of maximum donor ages (5 years).

CARDIOVASCULAR TISSUE

Canadian Banks			International Programs		
Minimum Age	**Minimum Weight**	**Maximum Age**	**Minimum Age**	**Minimum Weight**	**Maximum Age**
-	2.7 kg	55	-	1.5 kg	65
-	2.7 kg	55	32 weeks gestation	-	65
-	2.7 kg	60	3 months	-	55 for aortic 60 for pericardium 65 for pulmonary
Full term	2.7 kg	60	full term birth + 1 month	2.5 kg	60 M, 65 F
Full term		60			
Full term		60			
37 weeks gestation	2.7 kg	60			

Adjacent values are the age range for individual banks

Among Canadian banks:

- Five of the seven banks link weight to donor suitability:
  - Three banks do not identify a minimum age, instead a minimum weight is used; and
  - Two banks require both a minimum age and a minimum weight.
- There is no pattern of minimum age / weight to maximum age ratios.

Among international programs:

- Two of the four programs link weight to donor suitability but one accepts a much lower weight than the other, and it is lower than that of all applicable Canadian banks.

SKIN

Canadian Banks		International Programs	
Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
16	65	17	70
15F, 16M	65	17	80
15	70	None	None
18	75	Based on donor weight but weight limits not given	
14	100		
15	80		

Adjacent values are the age range for individual banks

Among Canadian banks:

- Minimum age range: 14 to 18 years;
- Maximum age range: 65 to 100 years; and
- The range of minimum donor ages is much smaller (4 years) than the range of maximum donor ages (35 years).
- An older minimum age does not necessarily mean an older maximum age
    - Banks with the same minimum age (15 or 16) have maximum ages that are 5 to 15 years apart (65 to 80); and
    - The bank with the lowest minimum age (14) also has the highest maximum age (100).

Among international programs:

- Minimum age range: None to 14 years;
- Maximum age range: 80 to no maximum; and
- One program has no age limits but bases donor suitability on weight instead.

OCULAR

Canadian Banks		International Programs	
Minimum Age	**Maximum Age**	**Minimum Age**	**Maximum Age**
18 months	70	17	85
18 months	70	4	74
2	85	18	None
2	75 for corneas, None for whole eyes	2	75
2	None	2	90
3	70	2	75
2	80	None	None
2	80	None	None
2	75		

Adjacent values are the age range for individual banks

Among Canadian banks:

- Minimum age range: 18 months to 3 years;
- Maximum age range: 70 to no maximum;
- The range of minimum donor ages is much smaller (6 months) than the range of maximum donor ages (15 years, not including the 'no maximum age');
- One bank distinguishes maximum donor age based on the whether the cornea or whole eye is being donated; and
- One bank has no maximum donor age.

Among international programs:

- Minimum age range: None to 18 years;
- Maximum age range: 74 to no maximum;
- Two programs have minimum ages which are much higher (15 to 16 years older) than all Canadian banks;
- To programs have no minimum age and three programs have no maximum age; and
- One bank distinguishes donor age limits based on the whether the cornea, sclera or whole eye is being donated.

2. ‘Grey Areas’ Within Non-Mandatory Exclusion Criteria

Canadian banks were asked to identify the two non-mandatory donor exclusion criteria which present the greatest challenges when Medical Directors are making decisions about whether to accept or reject a donor. There was significant variation in the responses to this question; below are the two most cited of these criteria for each tissue type. Note that banks could choose to identify grey areas for both ‘tissues in general’ and specific tissue types.

For tissues in general (percentage of 18 respondents):

- Death from an unknown cause, Septicaemia (5 citations each; 27.8%); and
- Jaundice (4 citations, 22.2%).

For musculoskeletal tissue (percentage of 14 respondents):

- Steroid use, Clinically significant metabolic bone disease (5 citations each, 35.7%); and
- Osteoporosis (3 citations, 21.4%).

For cardiovascular tissue (percentage of 7 respondents):

- Bacterial endocarditis, Trauma to donor area (2 citations each; 28.6%).

For skin (percentage of 7 respondents):

- Poor quality skin (3 citations, 42.9%); and
- Extensive skin lesions (2 citations, 28.6%).

For ocular tissue (9 respondents), each bank cited unique criteria (some of these were cited by the same bank):

- Slit lamp and specular microscopy findings;
- Intubation longer than 7 days or positive sputum;
- Cancer therapy (radiation, chemotherapy);
- Neurological disorders (MS, Parkinsons's);
- Severe systemic connective tissue disease - challenge to define 'severe';
- Primary brain tumour;
- Down's Syndrome;
- Drowning; and
- Travel outside of Canada.

3. Donor Testing (Canadian banks only)

	Number of Banks			
Test	**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
WNV	8	1	8	3

Additional tests:

Test	Number of Banks	Describe Application of Testing
HTLV-I/II	16	14 – All donors 2 – Amnion donors
EBV	0	
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	• HSV I/II for amnion donors • total protein, albumin and Duffy A&B for all donors • pathological examination of musculoskeletal chips
No Additional Tests	1	

B. Reduction of Bioburden at Recovery

The responses to several of the questions relating to minimisation of bioburden at the time of tissue recovery did not reveal significant variation for some practices in Canadian banks. These include the maximum acceptable time from death to recovery (whether or not the body is refrigerated), whether documented standard operating procedures are in place for evaluating and preparing recovery sites, and what items are checked in the processes of evaluating and preparing recovery sites.

Significant variation in practices among Canadian banks was reported in relation to the types of samples taken for microbiological testing and the use of antibiotics at the time of recovery.

Samples taken for microbiological testing

Musculoskeletal Sample Type	# Canadian Banks (14 respondents)	# International Programs (4 respondents)
Chip	6 (43%)	2 (50%)
Swab	7 (50%)	2 (50%)
Chip and Swab	1 (7%)	0

Among the 14 Canadian banks which recover musculoskeletal tissue, four recover only from living donors, four recover only from deceased donors, and six recover from both living and deceased donors.

Cardiovascular Sample Type	# Canadian Banks (7 respondents)	# International Programs (4 respondents)
Aliquot of Transport Solution	2 (29%)	0
Swab	1 (14%)	0
Aliquot of Transport Solution Plus a Tissue Sample	2 (29%)	2 (50%)
Aliquot of Transport Solution Plus a Swab	0	1 (25%)
Tissue Sample Plus a Swab	0	1 (25%)
None*	3 (43%)	0

**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.*

Seven Canadian banks and four international programs recover cardiovascular tissue. Practices relating to the subtypes of this tissue were not investigated in either survey.

Skin Sample Type	# Canadian Banks (7 respondents)	# International Programs (4 respondents)
Biopsy	5 (72%)	2 (50%)
Swab	1 (14%)	0
None*	1 (14%)	2 (50%)

**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.*

Antibiotics Applied to Tissue at Time of Recovery

Tissue Type	# Canadian Banks (15 respondents)	# International Programs (4 respondents)
Musculoskeletal	3 (both living and cadaveric donors)	1 (both living and cadaveric donors)
Cardiovascular	0	1 (only if the tissue will be in transit for longer than 2 hours)
Skin	4	1
None	9	1

This question did not apply to ocular-only banks; proportions are based on the number of banks which recover each tissue type

Eight out of 15 Canadian banks and three out of four international programs do not apply antibiotics to any tissue at the time of recovery.

C. Corneal Recovery Practices and Corneal Tissue Specifications

Little or no variation was revealed in relation to several of the questions, including the application of povidone to eye at some point between death and preservation, the use of draping for ocular-only recoveries, and the timing of ocular tissue recovery with a multi-tissue donor. However, there is a lack of documented standard operating procedures (SOPs) for evaluating the suitability of recovery sites (6 of 9 banks do not have one) and there is variation in recovery techniques (enucleation versus in situ) and in the determination of the expiry date for corneas.

The survey results indicate that all banks in Canada which recover ocular tissue use organ culture for temporary storage during transport for processing. However, four international programs use organ culture while three use hypothermic storage and one uses McCarey-Kaufman medium at 4 °C.

Below are data relating to the questions which revealed the greatest amount of variation in relation to this topic.

Method of Corneal Recovery

	Canadian Banks		International Programs	
	In situ	**Enucleation**	***In situ***	**Enucleation**
None	2	1	4	2
Less than 25%	4	2	0	2
More than 75%	2	4	2	0
All	1	2	2	4

- 7/9 (78%) Canadian banks carry out *in situ* excision;
- 8/9 (89%) Canadian banks enucleate;
- 6/9 (67%) Canadian banks do both types of recoveries;
- 2/8 (25%) of international programs do both types of recovery; and
- 4/8 (50%) of international programs enucleate only.

Application of Antibiotics to Whole Globes

- 5/8 (62.5%) Canadian banks irrigate whole globes with antibiotic solution.

Note that international programs were not asked this question. One Canadian bank does not enucleate.

% of Corneas for Endothelial Keratoplasty Pre-Cut By Banks

	Canadian Banks	International Programs
None	6	3
Less than 25%	-	1
25-50%	-	1
50-75%	-	1
More than 75%	1	1
All	2	1

- 3/9 (33%) of Canadian banks pre-cut corneas; and
- 5/8 (62.5%) of international programs pre-cut corneas, but only one does pre-cuts of all corneas.

Minimum endothelial cell count

mm^2	Canadian Banks		International Programs	
	EK	**PK**	**EK**	**PK**
1500 - 2000	1	-	-	-
2000	5	7	4	4
2100	1	1	-	-
2200	2	1	-	2
2300	-	-	1	1
2500	-	-	2	1

EK = endothelial keratoplasty; PK = penetrating keratoplasty

One international program does not provide ocular tissue for EK

- Among both Canadian banks and international programs, 2000 mm^2 is the most common minimum endothelial cell count for both EK and PK.

Starting Point for Calculation of Expiry Date for Corneas

	Canadian Banks	International Programs
Time of Death	4	5
Time of Enucleation / In Situ Excision	2	1
Where Enucleated: Time of Preservation in the Lab	3	2

- All Canadian banks which identify the time of death as the starting point for calculating corneal expiry dates carry out enucleation; and
- 3/5 (60%) of international programs which identify the time of death as the starting point for calculating corneal expiry dates carry out enucleation.

Maximum Storage Period for Corneas

Days	Canadian Banks		International Programs	
	EK	PK	EK	PK
4	-	-	1	1
7	-	-	1	1
8	1	-	-	-
9	-	1	-	-
10	1	1	-	-
14	7	7	2	2
28	-	-	1	2
31	-	-	1	1
49	-	-	1	1

EK = endothelial keratoplasty; PK = penetrating keratoplasty

One international program does not produce ocular tissue for EK

- 7/9 (78%) of Canadian banks have a maximum storage period for corneas of 14 days whether they will be used for EK or PK. This is also the practice for 2/8 (25%) international programs;
- All banks have the same maximum storage period for corneas used for EK and PK except one Canadian banks which stores 8 days for EK and 9 days for PK; and
- Two international programs store corneal tissue for shorter time periods than Canadian banks, and two store for longer than Canadian banks.