Canadian Blood Services
it's in you to give

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

International 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. To inform workshop discussions, two surveys were developed in order to learn about current eye and tissue banking practices internationally: one for tissue programs (which may include ocular) and one for ocular-only programs; both surveys focused on identifying variance in practices among tissue and eye banks.

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 both surveys. The results of the international survey provide a sampling of practices around the world, and are not intended to represent a comprehensive data set from international eye and tissue banks.

Respondents

Surveys were distributed to 14 international tissue and ocular programs with whom Canadian Blood Services has previously consulted; 12 programs responded.

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	8
Total		**12**

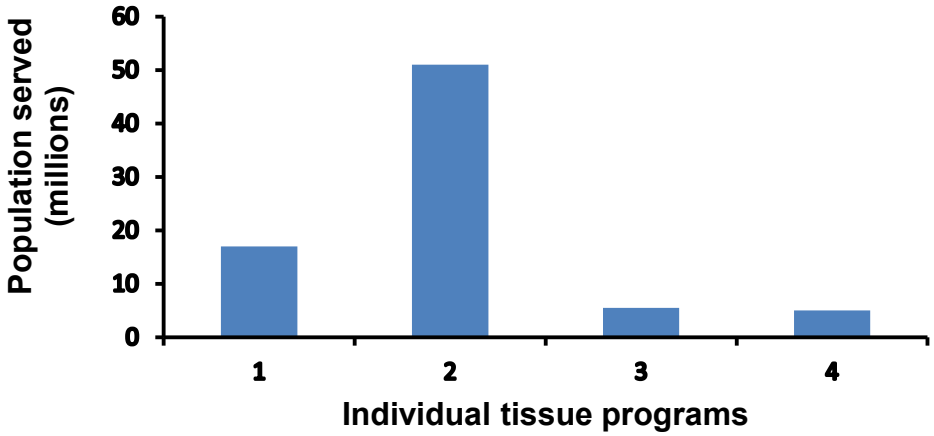
- *One of the four multi-tissue programs recovers ocular tissue*
- *All four of the multi-tissue programs recover surgical bone*

The responses to the international survey were from programs located in:

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

Multi-tissue programs

1. *What is the approximate population of the area from which your program recovers tissue (including ocular) donors?*

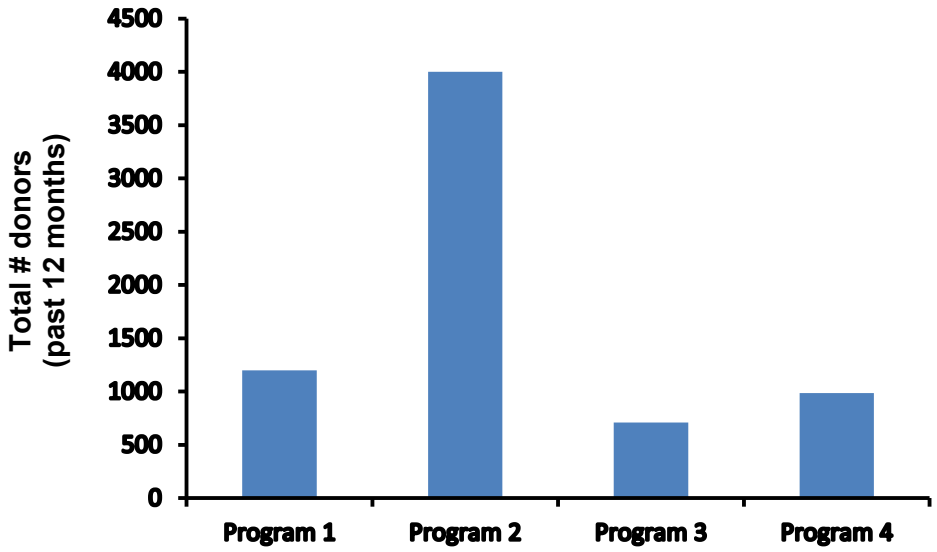


2. *What types of tissues do you recover?*

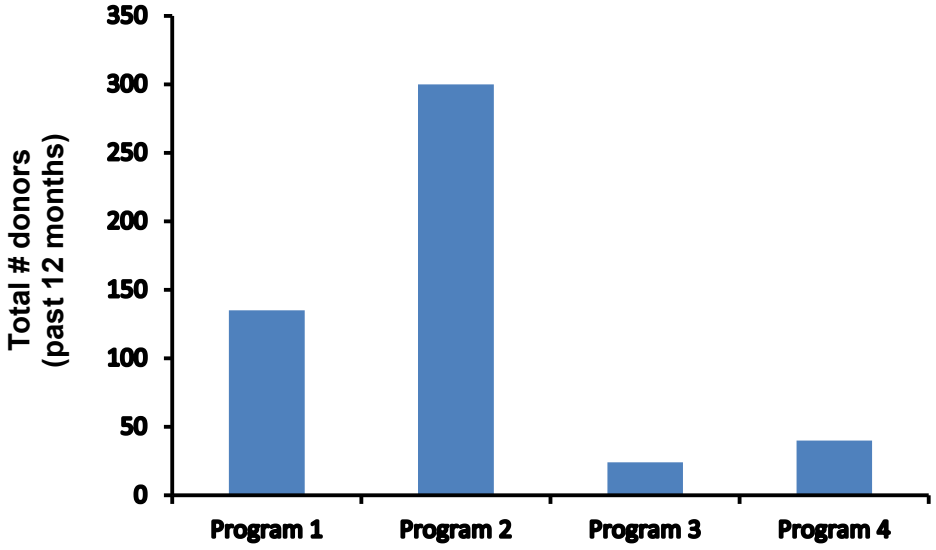
Program 1: Musculoskeletal (deceased and living), cardiovascular, skin, ocular
Program 2: Musculoskeletal (deceased and living), cardiovascular, skin
Program 3: Musculoskeletal (deceased and living), cardiovascular, skin
Program 4: Musculoskeletal (deceased and living), cardiovascular, skin

3. *Please provide an estimate of the total number of donors where the following tissue types were recovered in the past 12 months. For multi tissue donors, provide the number of donors in <u>each</u> category of tissue that was recovered.*

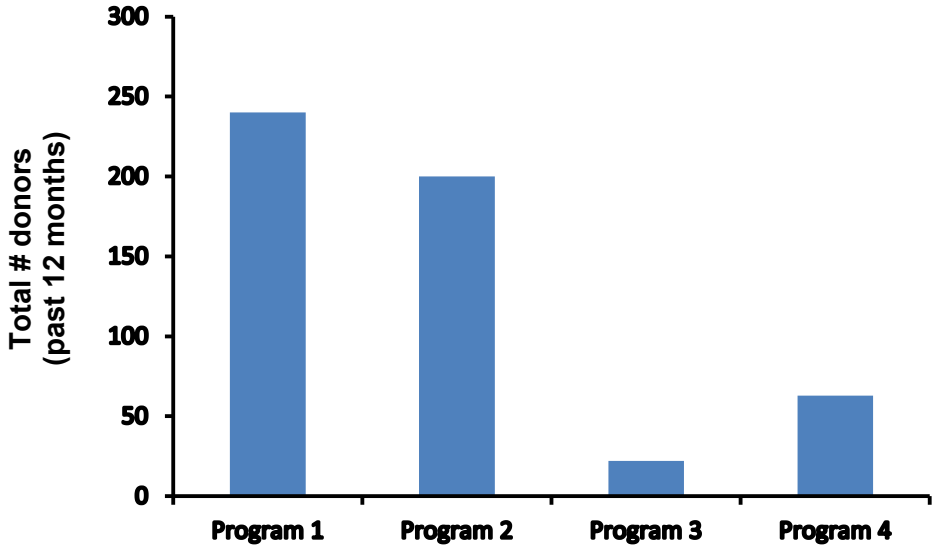
Musculoskeletal, living donors



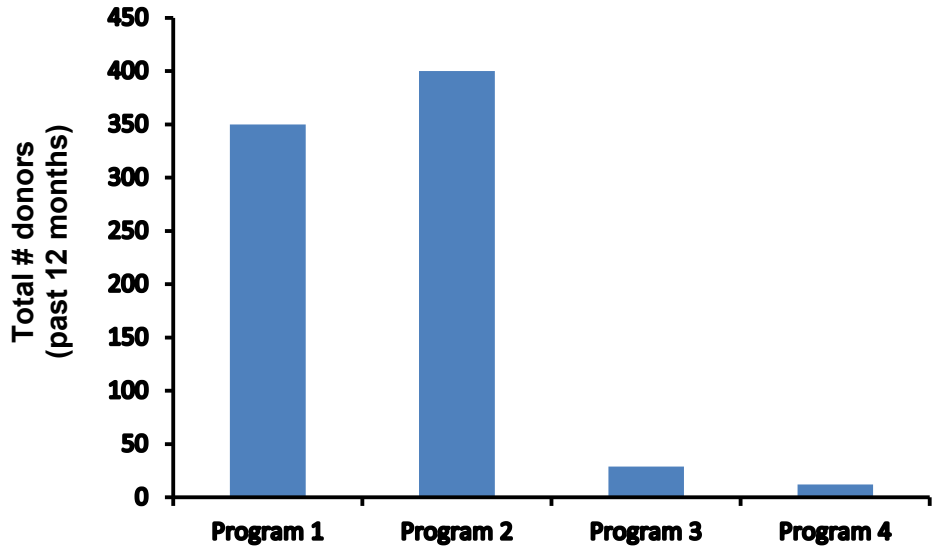
Musculoskeletal, deceased donors



Cardiovascular tissue

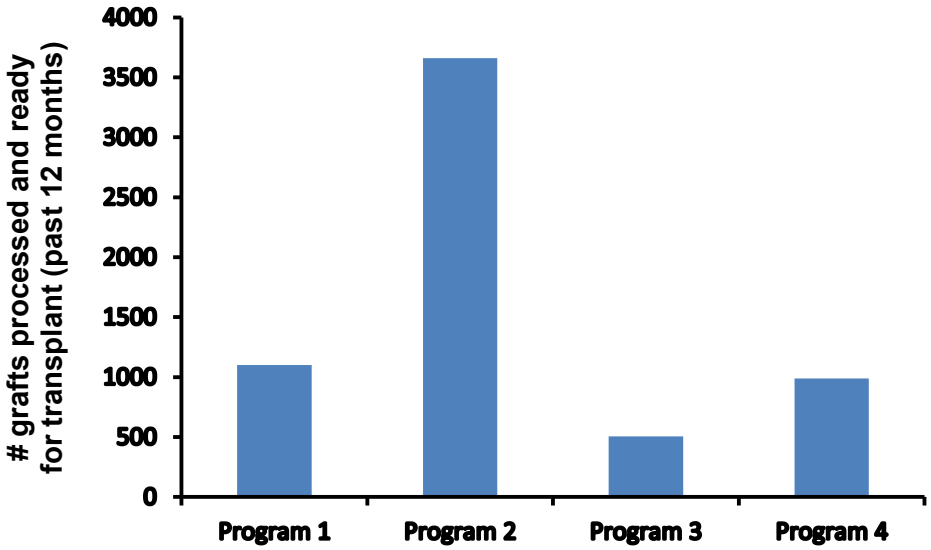


Skin

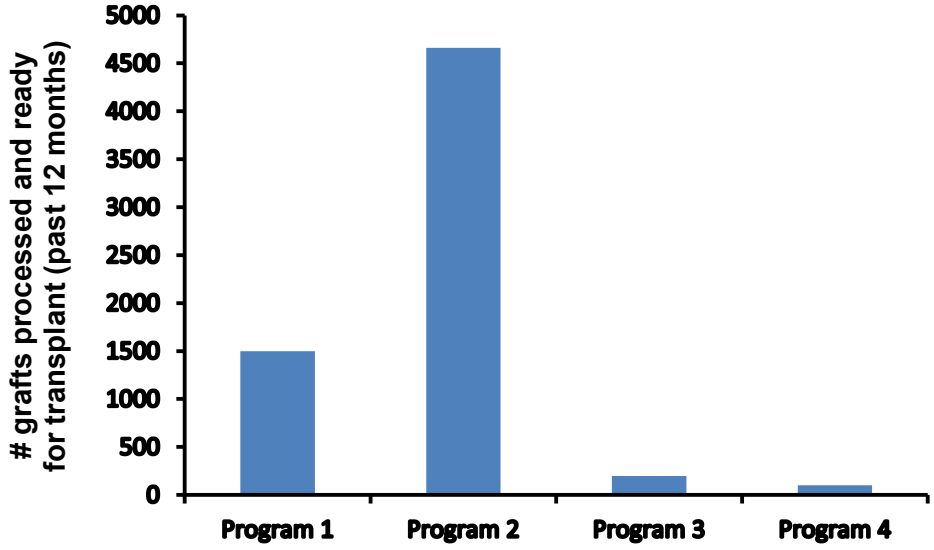


4. *Please provide an estimate of the total number of grafts of each tissue type that were processed and ready for use for transplantation (including those stored for future use for transplant) in the past 12 months.*

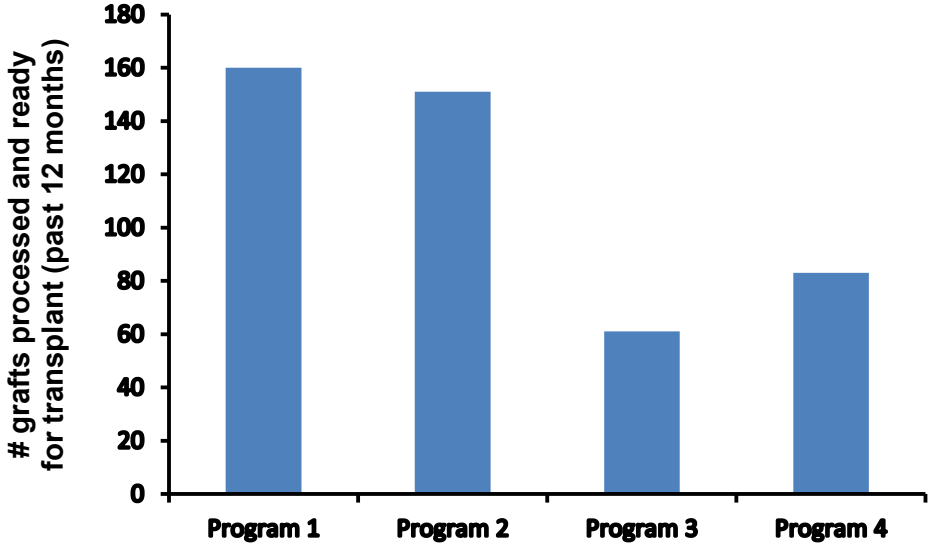
Musculoskeletal, living donors



Musculoskeletal, deceased donors

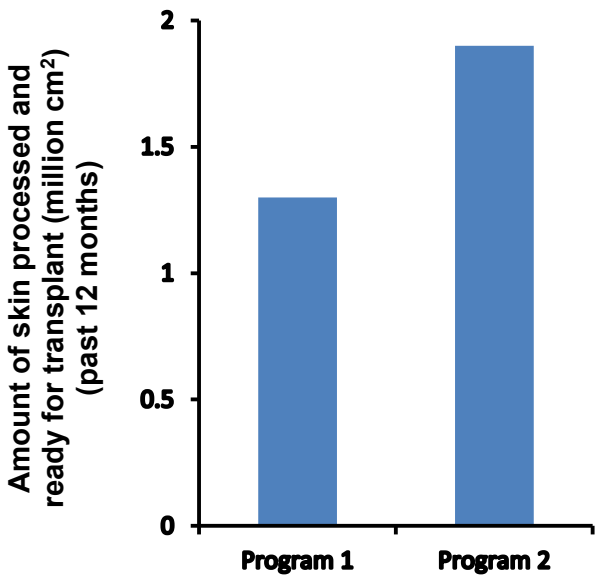


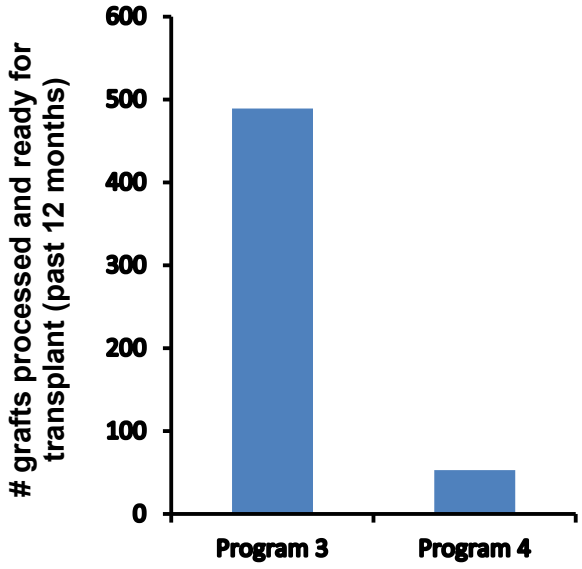
Cardiovascular tissue



Skin

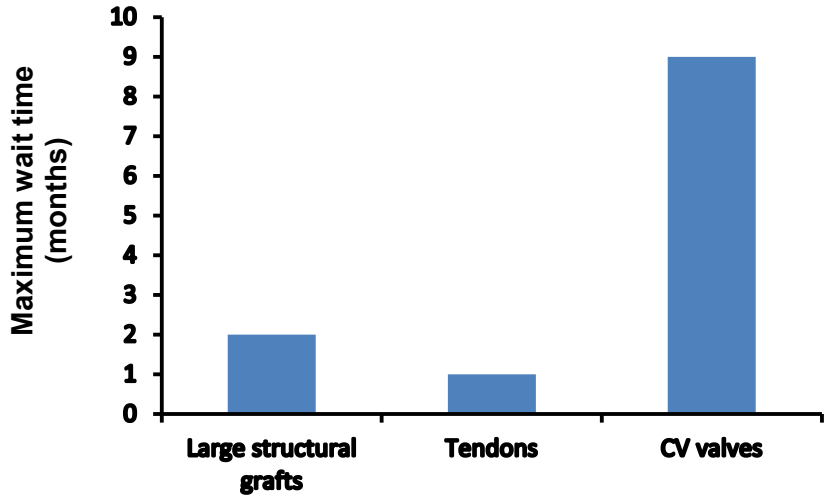
In response to this question, two programs provided the total amount of skin and two programs provided the total number of grafts.





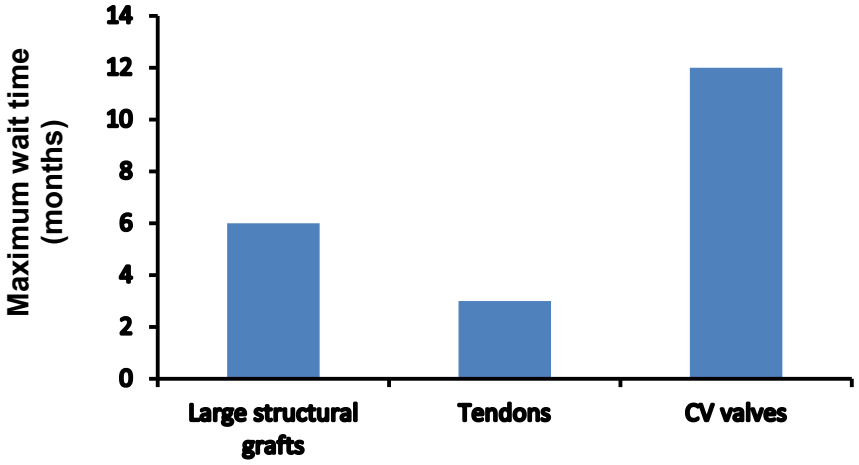
5. *Please indicate the allografts where the demand for the graft type exceeds your program's capacity to supply that type of graft. If the demand exceeds supply, indicate the wait time.*

Program 1:



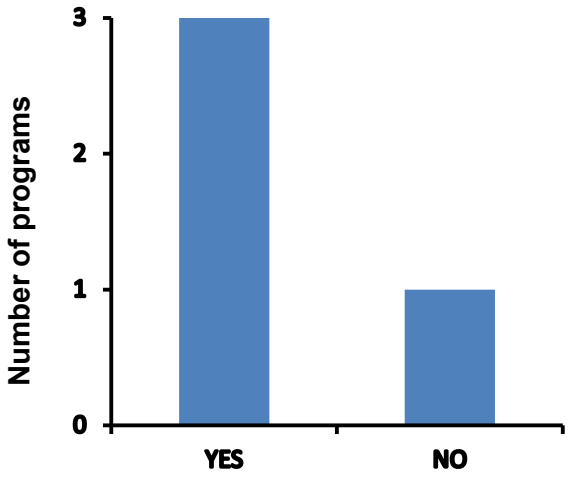
Program 2: Demand does not exceed supply for any type of graft.

Program 3:



Program 4 indicated that demand for large structural grafts exceeds supply but did not provide a wait time for this type of graft.

6. *Does your program regularly estimate future demand for each allograft type (i.e. do you perform demand forecasting)?*



7. *Regarding supply and demand planning, please describe the challenges your program has identified in ensuring that the supply of tissues meets demand. Please describe initiatives that have been introduced (or are planned) to overcome these challenges.*

Challenge	Solution
Managing the balance between scarcity and overproduction	• Adjust donor age ranges • Engage donor co-ordinators so they are aware of what tissue is needed and what isn't
Finding a supplier for menisci	• Encourage a network for banks to share allografts
Low quality heart valve donors	• Establish better donor criteria
Low quality tendons	• Improve the recovery procedure
Low donation rates	• Improve donation from non-acute cases (i.e. medical examiner / coroner) • Ensure banks timely access to death notifications (e.g. from hospitals, ambulatory services) • Require all deaths to be referred • National donation campaign • Train more staff to identify donors, take consent, recover
Accurately forecasting demand	• Regularly engage clinicians

8. *Describe the two main issues that impact your tissue program's performance. What are your current plans or initiatives for improving performance? What are the greatest barriers to achieving them?*

Factor affecting performance	Solution	Barrier
Low donation rates / inadequate donors	• Centralised death notification system • Train doctors and nurses to increase awareness	Lack of funding
Contamination	• Improve procedures	Lack of funding
Lack of funding (cited by a program which operates on cost-recovery)	-	Bureaucracy
Difficulties with the on-call system for staff (for out of hours cases)	• Review to make all processes lean, and reorganisation	Time
Small teams mean staff must be trained across tasks; all tasks require a high skill level so this it is difficult for all staff to maintain all skills	• Review to make all processes lean, and reorganisation	Time
*	• Rationalisation of surgical bone program to improve efficiency	Time
*	• Education for end users	Time
*	• Introduction of new products	Time

*One program did not cite any factors which negatively impact its performance, but identified three initiatives for continuing to improve performance

9. *In the region where your program is located, what proportion of organ donors are also tissue and/or ocular donors?*

Program	Proportion of organs donors which are also tissue donors
1	< 25%
2	50-75%
3	This information is not known
4	25-50%

10. *Please indicate if your country has national standardized practices (in addition to regulatory requirements) relating to the following:*

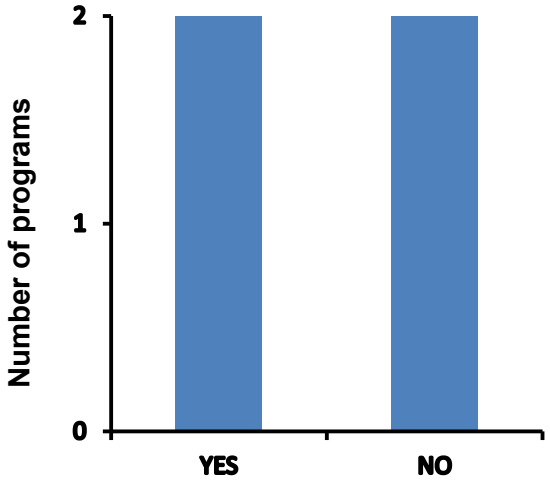
Practice	Number of programs
Donor identification and referral	2
Recovery activities	2
Processing activities	1
Distribution activities	1

Note: One program does not operate under any national standardized practices

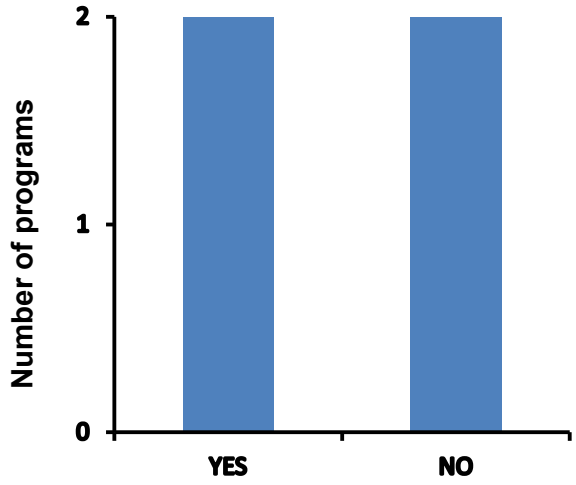
11. *Approximately what per cent of your overall number of deceased donors in the past 12 months were referred from your medical examiner / coroner service? "Deceased tissue donors" refers to actual donors where tissue was recovered.*

Percentage of deceased donors referred from ME/C cases (past 12 months)	Number of programs
None	1
< 5%	1
5-10%	0
10-15%	0
15-20%	1
>20%	1

12. *Are there standardized practices used by the medical examiner / coroner service to identify and refer deceased donors to your program?*



13. *Does your program actively work with or provide educational support to funeral professionals?*



14. *Briefly describe what benefits or challenges mandatory referral, or the lack of mandatory referral, poses for your program.*

None of the tissue programs operate in regions where death referral is mandatory. One program indicated that mandatory referral may lead to disappointment for donor families if tissue is not needed or recovery is not feasible for any reason (not uncommon in rural areas).

Three of the four programs work under alternate initiatives for ensuring that potential donor referrals are maximized:

- A national registry where wishes are recorded while individuals are living; physicians are required to consult the registry when a death occurs. If the wishes deceased are not in the registry, physicians are encouraged to approach the family for consent. In both cases, potential donors should be reported to a national coordinating centre.
- Legislation allows the tissue bank access to any information required to assess donor suitability. Additionally, the bank has access to the coroner's records and is able to check deaths at any time.
- The tissue bank works with "designated requesters" and monitors their activities.

15. *Please provide your acceptable age ranges for the following types of donors. For cardiovascular tissue, include your minimum weight requirement.*

Structural bone grafts

Minimum age	Maximum age
17	45 F, 50 M
17	50
18	50
18	65

Non-structural bone grafts

Minimum age	Maximum age
17	55
17	None
17	None
18	65

Surgical bone

Minimum age	Maximum age
17	None
18	None
None	None
None	None

Tendons

	Minimum age	Maximum age
Male	17	55
	17	60
	17	60
	18	55
Female	17	55
	17	60
	17	60
	18	55

Cardiovascular tissue

Minimum age	Minimum weight	Maximum age
-	1.5 kg	65
32 weeks gestation	-	65
3 months	-	55 for aortic; 60 for pericardium; 65 for pulmonary
full term birth + 1 month	2.5 kg	60 , 65 F

Skin

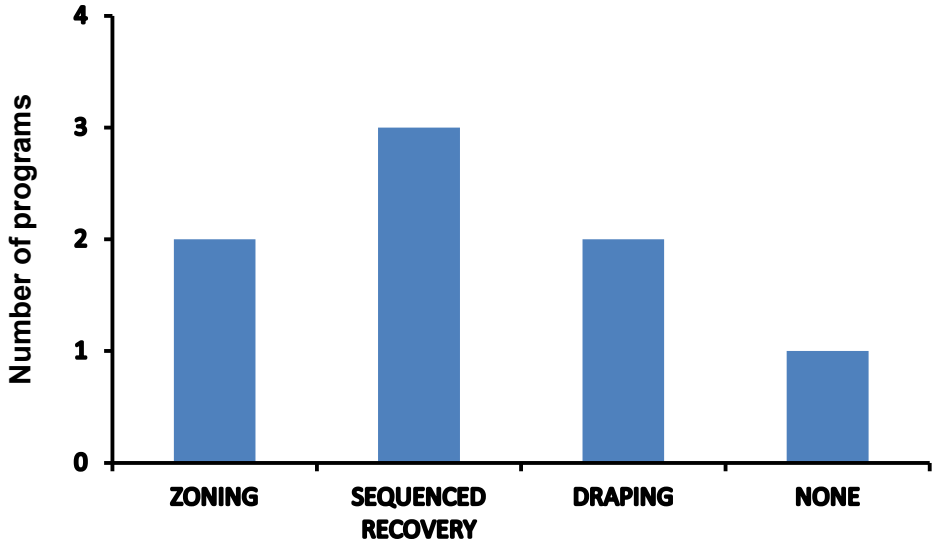
Minimum Age	Maximum Age
17	70
17	80
None	None
For one program, skin donor age is based on donor weight but weight limits were not provided.	

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

All four programs have the same time limits following death for tissue recovery to take place, for all tissue types with the exception of Program 2, which has a variance for cardiovascular tissue.

Program	Body cooled within designated time: time limit to recover tissue		Body not cooled within designated time: time limit to recover tissue	
1	Cooled within 6 hours: Recovery within 24 hours		Cooled after 6 hours: Recovery within 12 hours	
2	**Musculoskeletal and Skin**	Cooled within 6 hours: Recovery within 48 hours	**Musculoskeletal and Skin**	Cooled after 6 hours: Recovery within 12 hours
	Cardiovascular	Cooled within 6 hours: Recovery within 48 hours	**Cardiovascular**	Cooled after 6 hours: Recovery within 6 hours
3	Cooled within 12 hours: Recovery within 24 hours		Cooled after 12 hours: Recovery within 12 hours	
4	Cooled within 12 hours: Recovery within 48 hours		Cooled after 12 hours: Recovery within 12 hours	

17. *Select the practices you employ during musculoskeletal/cardiac /skin tissue recovery.*



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

Musculoskeletal sample type	Number of programs
Chip	2
Swab	2
Chip and Swab	0

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

Skin sample type	Number of programs
Biopsy	2
Swab	0
None*	2

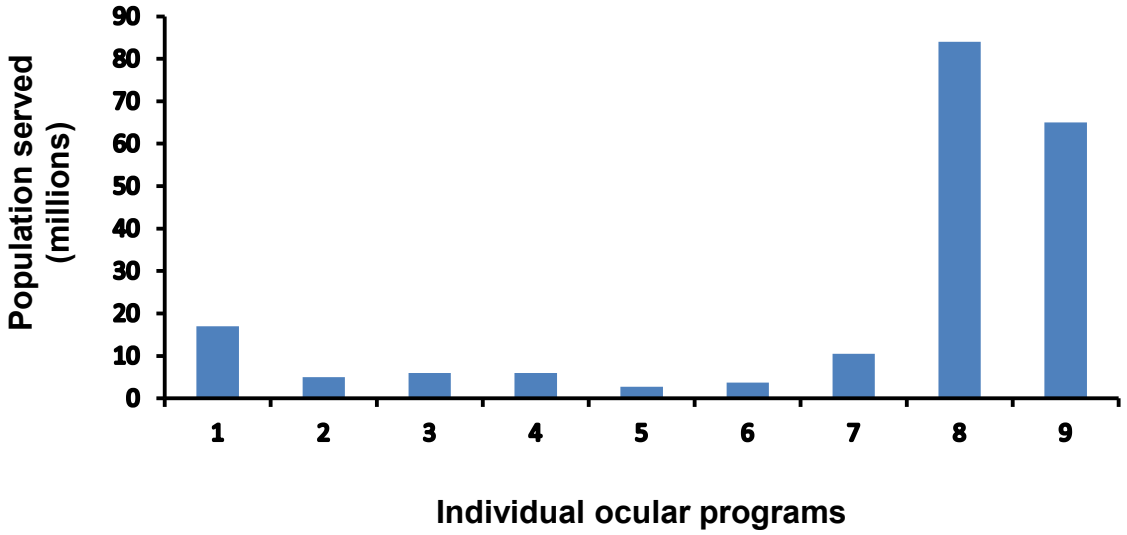
*No samples taken for microbiology at the time of recovery does not necessarily mean this is not practiced; the sampling may be done at the time of processing.

19. *For each tissue type, indicate whether you add antibiotics to your transport solution/media at the time of recovery.*

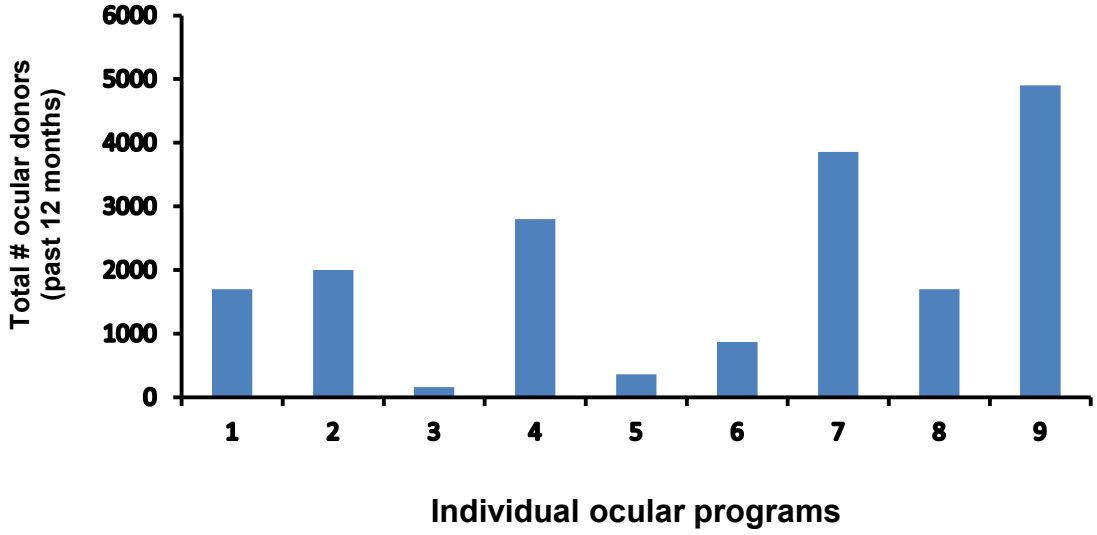
Tissue type	Number of programs
Musculoskeletal	1 (both living and cadaveric donors)
Cardiovascular	1 (only if the tissue will be in transit for longer than 2 hours)
Skin	1
None	1

Ocular programs

1. *What is the approximate population of the area from which your program recovers ocular donors?*



2. *Please provide an estimate of the total number of donors where ocular tissue was recovered in the past 12 months.*



3. *In the region where your program is located, what proportion of organ donors are also ocular donors?*

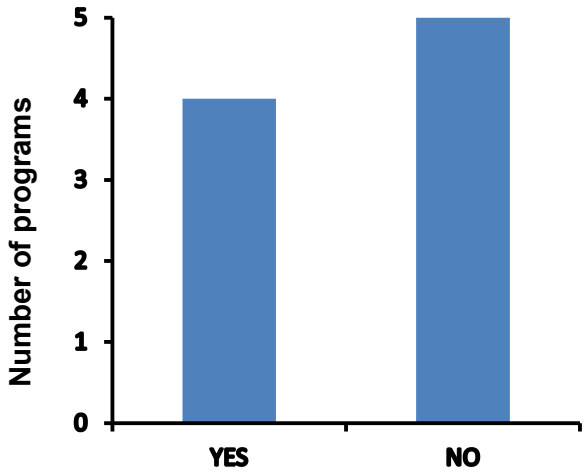
Percentage of organ donors who are also ocular donors	Number of programs
< 25%	6
25-50%	2
100%	1

4. *Please provide an estimate of the total number of ocular grafts that were processed and ready for use for transplantation (including those stored for future use for transplant) in the past 12 months.*

	Type of ocular tissue		
Program	**Corneas**	**Whole sclera**	**Sclera segments**
1	1800	200	200
2	4000	150	-
3	300	-	-
4	3000	15	300
5	584	60	-
6	2103	46	-
7*	5233	62	110
8	2000	-	-
9	4037	-	-

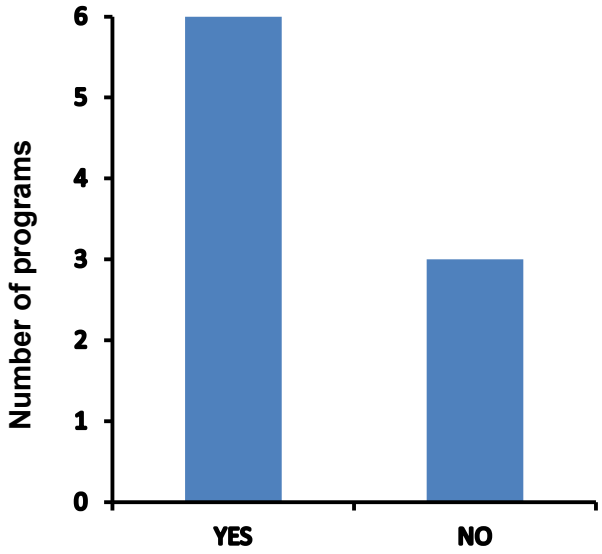
*This program also recovers ocular tissue for glaucoma surgery and patch grafts (glycerine-preserved corneas not included in these counts)

5. *Does the demand for corneas exceed your program's capacity to supply them? If the demand exceeds supply, indicate the wait time.*



Only one of the programs where demand for corneas exceeds supply provided their wait time, which is a maximum of six months.

6. *Does your program regularly estimate future demand for each allograft type (i.e. do you perform demand forecasting)?*



7. *Regarding supply and demand planning, please describe the challenges your program has identified in ensuring that the supply of tissues meets demand. Please describe initiatives that have been introduced (or are planned) to overcome these challenges.*

Challenge	Solution
Managing the balance between scarcity and overproduction	• Adjust donor age ranges
Obtaining reliable donor information	• Work with surgeons directly to obtain information
Lack of awareness about donation among hospital staff	• Train hospital staff • Place bank staff in the hospital to liaise with families
Requests from surgeons for tissue with particular traits (donor age, cell density)	• Work with surgeons to discuss the implications of making these requests – adequate tissue may be available but they are rejecting it
Poor quality tissue	• Improve quality practices including audits and training
Improperly screened donors	• Train individuals who screen and refer donors
Lack of supportive legislation	-
Low donation numbers	• Give all hospitals access to the same donor database
*	• Vigilant performance monitoring to ensure potential donation is maximized

*One program did not cite any challenges in ensuring supply meets demand, but described initiatives for ensuring it continues to meet non-local demand (this program supplies tissue to other regions, domestically and internationally)

8. *Describe the two main issues that impact your tissue program's performance. What are your current plans or initiatives for improving performance? What are the greatest barriers to achieving them?*

Factor affecting performance	Solution	Barrier
Low donation rates / inadequate donors	• Centralised death notification system • Train doctors and nurses to increase awareness • Donor campaign	• Lack of funding • Lack of legislation
Contamination	• Improve procedures	Lack of funding
Not enough staff	• Reorganise the program • Train more staff	Lack of funding
Lack of awareness about donation among healthcare professionals	• Train staff • Involve bank staff at hospital	Time
Establishing recovery sites	-	-
Bottlenecks created due to staff specialization in skills / tasks	• Cross-train staff on multiple skills / tasks • Use tracking and trending	Cost, time, identifying what needs to be tracked
Difficulty placing tissue outside of the local region	• Amalgamate banks	Bureaucracy
Accessing up to date donor information	• Improved donor database	Time
Inadequate facilities	• Improved or new facilities	Cost
Poor quality donor blood samples	• Quality initiatives	-

9. *Please indicate if your country has national standardized practices (in addition to regulatory requirements) relating to the following:*

Practice	Number of programs
Donor identification and referral	9
Recovery activities	6
Processing activities	5
Distribution activities	5

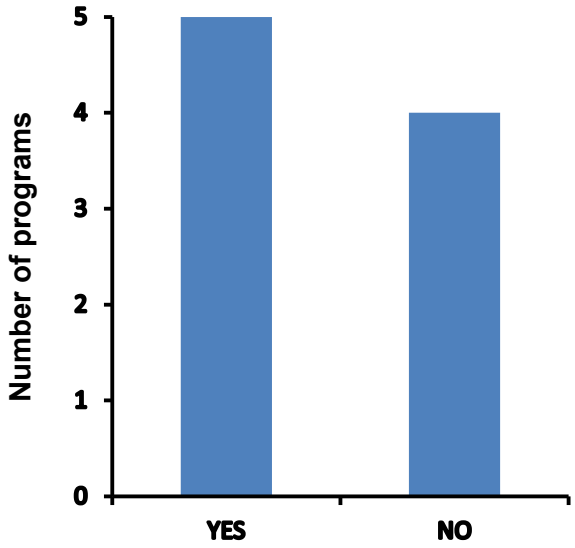
10. *Approximately what percent of your overall number of deceased donors in the past 12 months were referred from your medical examiner or coroner service? "Deceased donors" refers to actual donors where tissue was recovered.*

Percentage of deceased donors referred from ME/C cases (past 12 months)	Number of programs
None	6
< 5%	2
5-10%	1
10-15%	0
15-20%	0
>20%	0

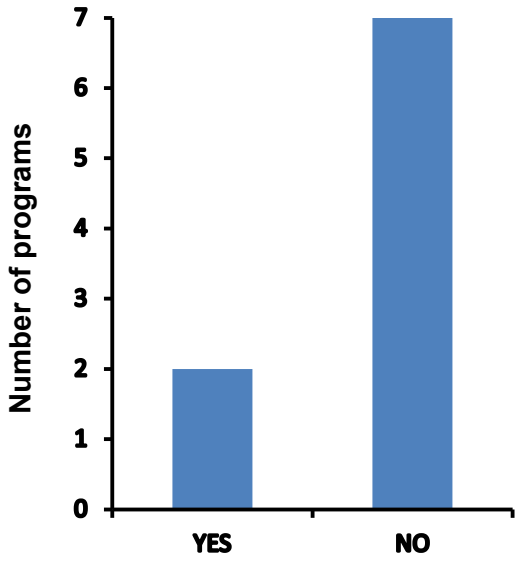
11. *Are there standardized practices used by the medical examiner / coroner service to identify and refer ocular donors to your program?*

There are no programs which have standardized practices with their medical examiner / coroner service.

12. *Does your program actively work with or provide educational support to funeral professionals?*



13. *Is it mandatory (a legal requirement) to refer every death for organ and tissue donation in your country or region*?



14. *Briefly describe what benefits or challenges mandatory referral, or the lack of mandatory referral, poses for your program.*

Two programs work under mandatory referral legislation; one commented that it takes a lot of resources to ensure compliance. Both commented that mandatory referral legislation has increased donation.

Two programs indicated that they work under alternate initiatives for ensuring that potential donor referrals are maximized:

- A national registry where wishes are recorded while individuals are living; physicians are required to consult the registry when a death occurs. If the wishes deceased are not in the registry, physicians are encouraged to approach the family for consent. In both cases, potential donors should be reported to a national coordinating center.
- Agreements for automatic referral of all deaths from all local hospitals.

15. *Please provide your acceptable age ranges for ocular donors.*

Minimum age	Maximum age
2	75
Corneas and whole globes: 2 Sclera: 14	All ocular tissue: 75
2	90
4	74
6	None
17	85
18	None
None	None
None	None

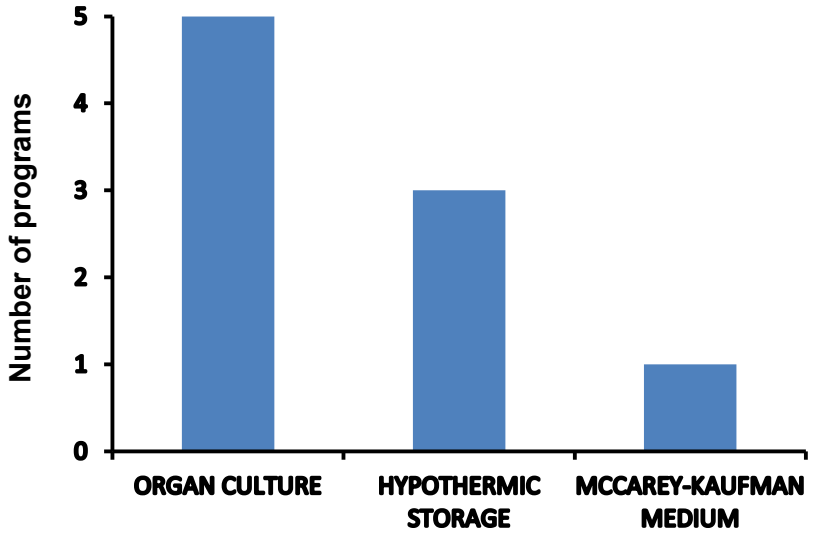
Adjacent values are the age range for individual programs

16. *What is your minimum acceptable endothelial cell count (per square millimetre) for grafts being used for Penetrating Keratoplasty (PK) and Endothelial Keratoplasty (EK?)*

mm^2	Number of programs	
	EK	PK
1500 - 2000	-	-
2000	4	5
2100	-	-
2200	-	2
2300	2	1
2500	2	1

Note: One program does not provide ocular tissue for EK

17. *Do you store corneas under organ culture or hypothermic conditions?*



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

	Number of programs
Time of death	5
Time of enucleation / *In Situ* excision	2
Where enucleated: time of preservation	2

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

Days	Number of programs	
	EK	PK
4	1	1
7	1	1
14	2	2
28	1	2
30	1	1
31	1	1
49	1	1

Note: One program does not produce tissue for EK

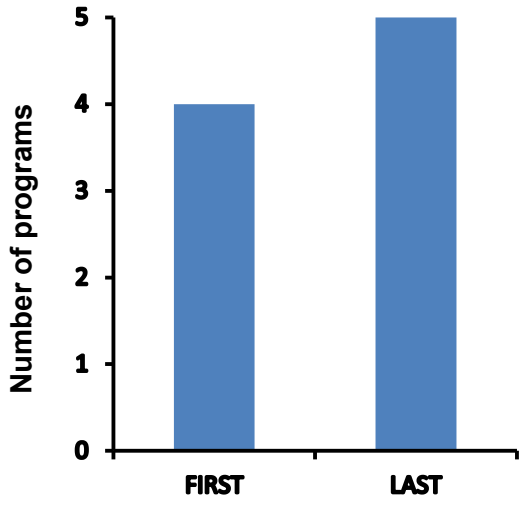
20. *Of the total EK corneal transplants performed in your region, in what per cent of cases does the eye bank perform the cutting procedure?*

Per cent cut in bank	Number of programs
None	4
Less than 25%	1
25-50%	1
50-75%	1
More than 75%	1
All	1

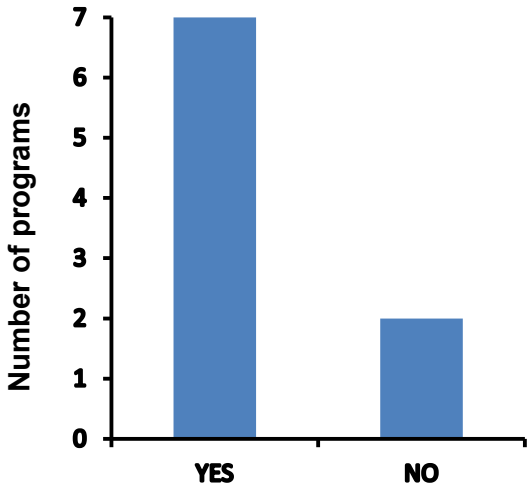
21. *Please estimate your program's percentage of each type of ocular recovery:*

	Number of programs	
	In situ	**Enucleation**
None	4	3
Less than 25%	0	2
More than 75%	2	0
All	3	4

22. *If an ocular donor is also donating other tissues types, at what stage would the ocular tissue be recovered?*



23. *Do you expose eyes to povidone iodine at any point between the time of donor death and tissue preservation (i.e. at any time prior to corneal recovery)?*



24. *Do you using draping during recovery of ocular tissue, if only ocular tissue is being recovered?*