



Canadian Blood Services
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Demand for Ocular Tissue in Canada - Final Report

January 2010

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Executive Summary

In 2009, Canadian Blood Services prepared and distributed the National Survey for Demand of Ocular Tissue. The goal of the survey was to obtain information on the demand for ocular tissue allografts and on importation practices in Canada. A total of seven programs involved with recovery, processing and distribution of ocular tissue completed the survey. The findings from the survey capture the demand and usage of ocular tissue in all Canadian provinces with the exception of Quebec.

The seven respondents reported an average corneal transplant waiting list length of 335 patients with a total of 2348 people waiting nationwide, excluding those waiting in Quebec. The length of the waiting list for each jurisdiction can be approximately correlated to the size of the population served by each program. The estimated average wait times for corneal transplantation ranged from 7 months up to 36 months. The number of ophthalmologists performing corneal transplants varies significantly from one program's jurisdiction to another, but is positively correlated to the population served. Survey respondents reported a total of 61 ophthalmologists performing transplants.

The seven programs indicated that they supported a total of 1969 corneal transplants. None of the programs reported having imported ocular tissues from foreign sources. However, the responses indicated that there is some movement of ocular tissue between regions and provinces. The programs noted that imported corneal tissue grafts, sourced from external Canadian ocular programs were used in 256 corneal transplants, representing 13% of the total number of transplants. When asked about the anticipated change in demand for different types of ocular tissue and procedures in the next 2-5 years, programs clearly indicated that there would be a significant increase in the number corneas used in partial thickness corneal transplant procedures.

The majority (5 of 7) of the ocular programs noted that they determine the suppliers of imported ocular tissue on behalf of the ophthalmologists. It is important to note that there is currently no transfer of funds between ocular programs for corneas. However, some programs do recover costs for sclera and amniotic membrane allografts. For programs that purchase these allografts, the costs of the allografts purchased are covered by the Department of Ophthalmology's budget, the operating room budget or the ocular program's budget.

Background

The purpose of the National Survey for Demand of Ocular Tissue was to quantify the distribution of ocular tissue and to provide information on both the availability of ocular tissue and Canadian importation practices. Eye banks and tissue programs involved with the distribution of ocular tissue were asked to provide activity data from the 2008 calendar or fiscal year. The scope of this survey included ocular tissue and other tissue used by ophthalmologists including corneas, sclera and amniotic membrane. The two eye banks that operate in Quebec (Banque d'yeux du Quebec and Banque d'yeux Nationale Inc.) were not included within the scope of the survey work.

Purpose

The purpose of this report is to provide key data and findings from the results of the National Survey for Demand of Ocular Tissue that will inform discussions about future system design. Additional information from the Canadian Blood Services 2009 environmental scan activities of the Canadian tissue banking community is provided where it provides context for the interpretation of survey results.

Overview

In August 2009 the survey was sent to eye banks and tissue programs involved with the recovery, processing and distribution of ocular tissue. The respondents completed either an online or hard copy version of the survey, or provided responses to the survey questions via a phone interview with a CBS representative. The seven respondents to the survey included:

- Eye Bank of British Columbia
- Lions Eye Bank – Alberta Health Services (Calgary)
- Comprehensive Tissue Centre (Edmonton)
- Lions Eye Bank of Saskatchewan
- Lions Eye Bank of Manitoba & NW Ontario
- Eye Bank of Canada (Ontario Division)
- Regional Tissue Bank (Halifax)

All programs provided data from the 2008 calendar year with the exception of one program that provided 2008 fiscal year data. The New Brunswick Eye and Tissue Bank did not participate in the survey because they do not provide ocular tissue to local ophthalmologists and are not involved with importing ocular tissue into their region. The Regional Tissue Bank in Halifax serves patients from Nova Scotia, New Brunswick, Prince Edward Island, as well as those from the city of St. John's, Newfoundland and routinely imports ocular tissue from New Brunswick. The use of ocular tissue that was recovered and processed in New Brunswick is captured in the survey responses of programs that import ocular tissue grafts from New Brunswick. Additional information was obtained in a phone interview with Eastern Health's Organ Procurement and Exchange program on the distribution of ocular tissue within Newfoundland. It was determined that the number of ocular tissue grafts distributed within Newfoundland is small and that these ocular tissues would not be included in this report. In accordance with the confidentiality commitment noted in the survey, the responses of individual programs are not identified within this report.

Limitations

There are several limitations related to the information contained in this report and the methods used to derive this information:

- Key project stakeholders and representatives from the tissue bank community evaluated the pilot survey prior to finalization. Enhancements were made to the final design and content of the surveys; however, all respondents may not have interpreted each question consistently.
- The data provided by the respondents is subject to any pre-existing limitations or errors in their own record keeping systems/processes.
- In certain cases respondents provided estimates, as the specific data requested was not available. The accuracy of the estimates provided may vary.

- In some cases questions were left blank as the data was not available and could not reasonably be estimated.

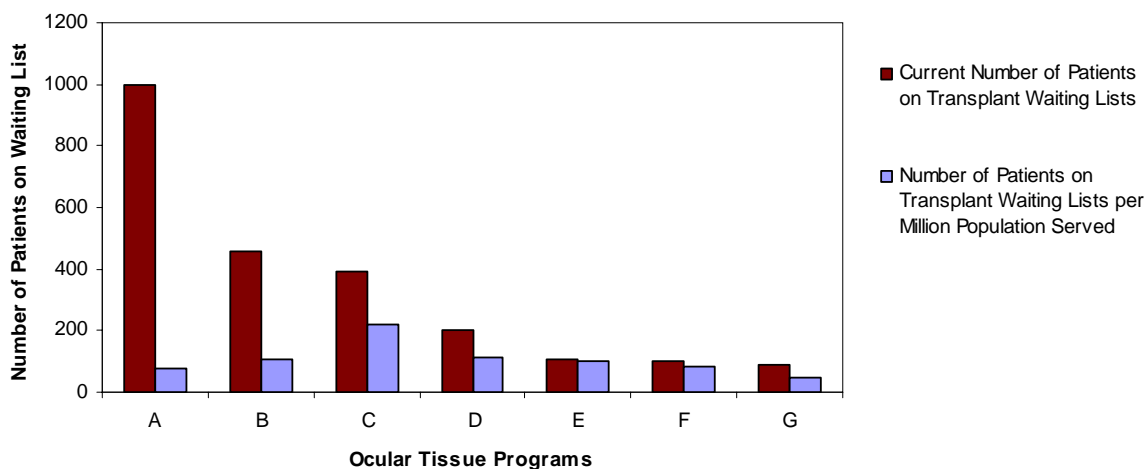
Waiting Lists for Cornea Transplants

This section of the survey provided data about the number of patients on cornea transplantation wait lists, the average time on those waiting lists, and examined the role the ocular tissue banks play in wait list management.

Number of Patients on the Waiting List

The seven respondents reported an average waiting list length of 335 patients (median: 200). The total number of people reportedly waiting nationwide was 2348. It is important to note that the majority of banks do not maintain waiting lists and the numbers provided within the survey would be estimates based on lists obtained from surgeons. In addition, this data is a “point-in-time” snapshot of the length of the waiting lists from each program. The length of the waiting list for each jurisdiction can be approximately correlated to the size of the population served by each program (See Figure 1). Some estimates were made for population served, due to the regional nature of the programs. See Appendix A for details.

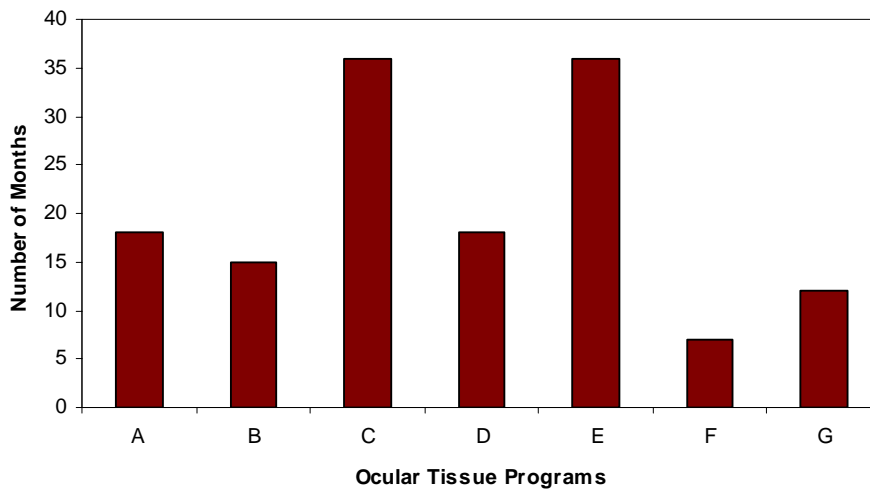
Figure 1: Cornea Transplant Waiting Lists



Average Time Spent on Waiting Lists

The average wait times for corneal transplants provided by the seven respondents ranged from 7 months up to 36 months. As noted above, the numbers provided by the eye programs are estimates as the programs do not always maintain detailed data on the actual wait time of each patient. Surgeons will allocate the corneas to patients based on clinical need, and as such, the actual time each patient will spend on a wait list can vary substantially.

Figure 2: Average Time Spent on Waiting Lists (Months)



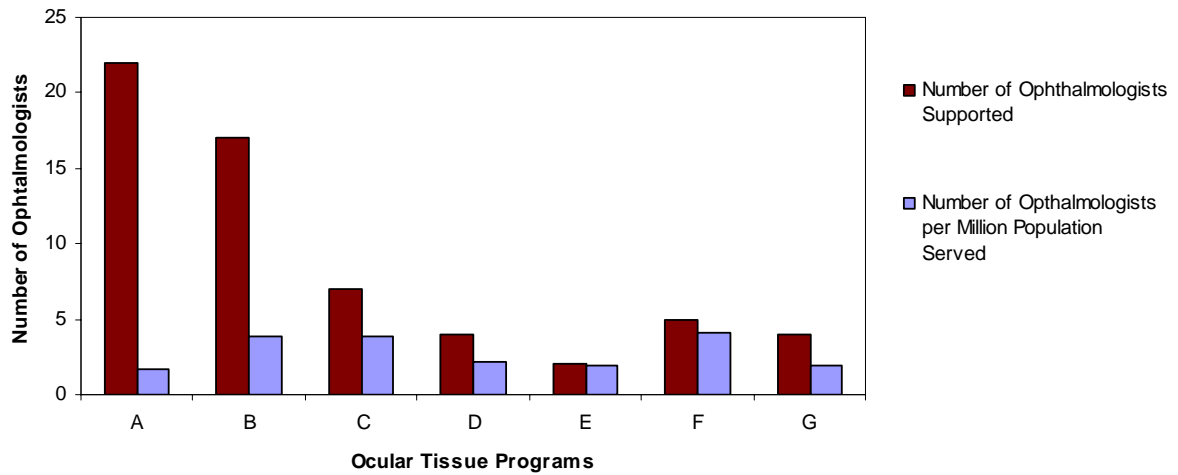
Management of Waiting Lists:

Three of the seven respondents noted that they are involved with the management of waiting lists for corneal transplants. The specific wait list management activities performed by these three programs vary. One program assigns a priority to each request for a cornea based on information provided by the ophthalmologists while another allocates corneas to operating room time slots and leaves it up to the ophthalmologist to determine the patient that will fill the slot. The third program allocates corneas to ophthalmologists proportionally based on the number of patients on each individual ophthalmologist's waiting list. The remaining four programs indicated that wait lists are maintained by transplanting ophthalmologists.

Number of Ophthalmologists Performing Transplants:

Respondents were asked how many ophthalmologists performing transplants they support with their programs. Follow-up with the respondents indicated that this question was interpreted to mean corneal transplants. The number of ophthalmologists performing transplants varies significantly from one program's jurisdiction to another, but is positively correlated to the population served. Survey respondents reported a total of 61 ophthalmologists performing transplants.

Figure 3: Number of Ophthalmologists Supported by Each Program



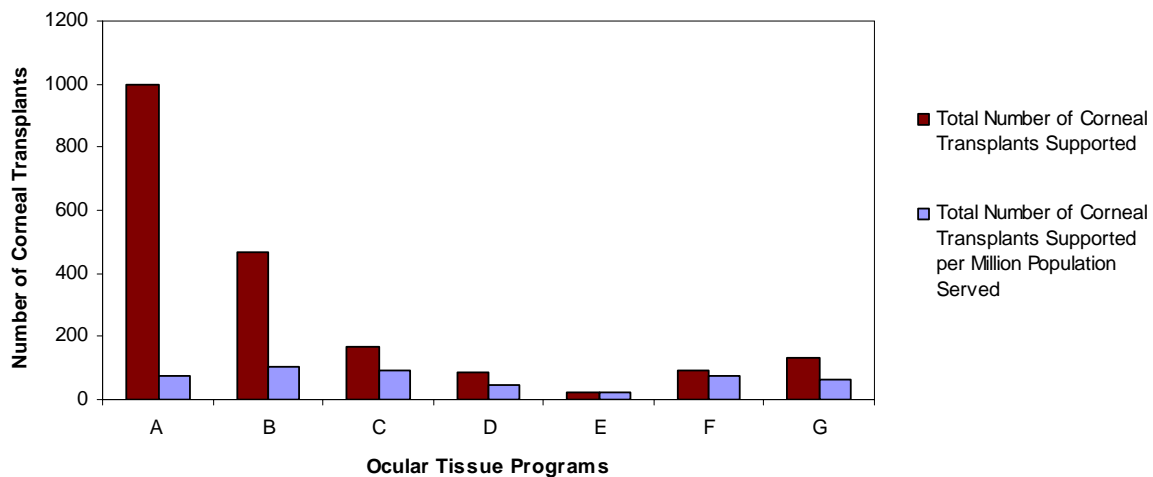
Corneal Transplants and the Importation of Ocular Tissue

This section of the survey provided data about the number of corneal transplants, and the extent to which ocular tissue programs import corneas from other programs.

Number of Corneal Transplants

Survey respondents reported that they supported a total number of 1969 corneal transplants.

Figure 4: Total Number of Corneal Transplants Supported by Each Program



Importation of Ocular Tissue from International Sources

None of the respondents reported having imported any ocular tissues from foreign sources.

Importation of Ocular Tissue from Canadian Sources

In the context of this report, importation from a Canadian source means corneas imported from another ocular tissue program in the same province (where they may exist), or from an ocular tissue program in another province.

The extent to which programs are involved in importing tissue for surgeons varies by program. In some regions, the surgeons will order directly from ocular tissue programs outside their region with the local ocular tissue program providing logistical support. In other regions, ocular tissue programs will receive offers of cornea tissue from external ocular programs and are more involved with allocating the tissue.

Overall, imported tissue is used in only a small percentage of the total number of corneal transplants. The survey respondents and program contacts reported that imported corneas were used in 256 of 1969 (13%) cornea transplants. Of the 256 corneas that were imported, 225 (88%) were imported by three ocular tissue programs.

The survey respondents reported a total of 50 sclera allografts and 31 amniotic membrane allografts that were imported. It is important to note that the ocular programs surveyed do not always manage the distribution of sclera or amniotic membrane. Thus, the overall demand for sclera and amniotic membrane allografts have not been captured within this report.

Availability of Ocular Tissue and Import Practices

This section of the survey provided information about future trends in ocular tissue grafts, general availability of ocular tissue, how an external ocular tissue supplier is selected when product must be imported, and how external purchases are funded.

Demand for Grafts

Respondents were asked to indicate the expected change in demand for grafts (ocular tissue and related grafts) in the next 2-5 years. Although the responses across the banks were quite variable, the following observations can be made:

- Most ocular programs anticipate an increase in the number of partial thickness corneal transplant procedures. Four programs indicated that they expected the number of endothelial keratoplasty procedures to increase over 25% in the next 2-5 years and one program expected an increase of up to 25%.
- Three of the seven programs indicated that they anticipate an increase in demand for sclera.
- Four of the seven programs indicated that they anticipate an increase in the demand for amniotic membrane.

Availability of Ocular Tissue from Suppliers

Respondents were asked to rate the availability of the various ocular tissue grafts from suppliers. The respondents did not rate the availability of ocular tissue from foreign suppliers as they did not import ocular tissue from foreign suppliers. When rating the availability of ocular tissue from Canadian suppliers, there was high variability in the responses, without general agreement. This variability may be due in part to the small number of ocular tissue grafts imported by certain banks.

Selection of Ocular Tissue Suppliers

The "Safety of Human Cells, Tissues and Organs for Transplantation Regulations" (CTO Regulations) require that all tissues that are imported are sourced from suppliers who are on Health Canada's list of CTO registered establishments. Respondents were also asked to rate the importance of various other factors in choosing tissue suppliers. The factors listed in the survey were:

- Price;
- assurance of safety of products;
- quality of products;
- availability of required products;
- speed of delivery;
- Eye Bank Association of America (EBAA) accreditation, and;
- Canadian source.

The majority of program rated all factors, with the exception of price as being "important" , "very important" or "extremely important". The majority of programs noted that price was not applicable as a factor due to the fact that Canadian programs importing tissue do not currently reimburse the ocular program supplying the corneas. Price would likely be a more important factor if ocular tissues were imported from foreign sources.

Respondents were asked to define the process for selecting an external supplier of ocular tissue. The majority (5 of 7) of ocular programs noted that they determine the suppliers of imported ocular tissue, while one program noted that the ophthalmologists identify the registered programs they will obtain ocular tissue from and that the program's role is only to help with the logistics of obtaining the ocular tissue. Another program noted that they only import ocular tissue for emergency surgeries and when there is a surplus of tissue in other Canadian eye banks.

Budget for Purchasing Ocular Tissue

It is important to note that there is currently no transfer of funds between ocular programs for corneas provided. However, there is some cost recovery occurring for sclera and amniotic membrane grafts that are distributed. Three of the seven programs indicated that there was no transfer of funds for ocular tissue grafts they had imported. Two programs indicated that ocular allografts were purchased under the Department of Ophthalmology's budget. One program noted that ocular allografts were purchased within the operating room's budget while one program noted that allografts were purchased under the eye bank's budget.

Appendix A – Population Data

For the purpose of calculating data per million population (PMP), the population served by each of the ocular tissue programs was estimated as indicated in the table below.

Region	Ocular Program	Population ¹ (thousands)
British Columbia	Eye Bank of British Columbia	4383
Alberta – Calgary Region	Lions Eye Bank – Alberta Health Services (Calgary)	1800 ²
Alberta – Edmonton Region	Comprehensive Tissue Centre (Edmonton)	1800 ²
Saskatchewan	Lions Eye Bank of Saskatchewan	1016
Manitoba	Lions Eye Bank of Manitoba & NW Ontario	1208
Ontario	Eye Bank of Canada (Ontario Division)	12936
Atlantic	Regional Tissue Bank (Halifax)	2008 ³

¹ 2008 Population Data Source: Statistics Canada, Population by year, province and territory
<http://www40.statcan.gc.ca/01/cst01/demo02a-eng.htm?sdi=population> 2010-01-10

² The population served by the Comprehensive Tissue Centre (Edmonton) was estimated to be 1.8 million, approximately half of the total population of Alberta. The population served by the Lions Eye Bank – Alberta Health Services (Calgary) was also estimated to be 1.8 million.

³ The Regional Tissue Bank in Halifax serves patients from Nova Scotia, New Brunswick, Prince Edward Island, as well as those from the city of St. John's, Newfoundland, giving a total population of about 2.0 million.

Appendix B – National Survey for Demand of Ocular Tissue



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National Survey for Demand of Ocular Tissue

Canadian Blood Services

August 2009

1.0 General Information and Introduction

1.1 General Information

*Name of Eye Bank:

*Eye Bank Director:

*Geographical Area Serviced by Eye Bank:

*Individual Completing the Survey:

1.2 Introduction

This survey includes questions related to ocular tissue distribution activity, availability of ocular tissue and import practices.

Required entries are noted with a *.

All questions in the survey focus on tissue usage during the 2008 calendar year. If your data is collated by fiscal year, please provide data for the most recent fiscal year collated and indicate the year:

Throughout this survey, the following breakdown for ocular tissues will be used:

Ocular tissue category
Whole Eye
Corneas for Penetrating Keratoplasty (PK)
Corneas for Lamellar Keratoplasty (LK)
Corneas for Endothelial Keratoplasty (EK)
Sclera
Amniotic Membrane
Research Tissue

2.0 Distribution of Ocular Tissue

2.1 *Does your eye bank maintain cornea transplant waiting lists for the jurisdiction you serve?

Yes

No

If No, who maintains the waiting lists?

2.2 *What is the current number of patients on your cornea transplant waiting lists for the jurisdiction you serve?

Total Patients:

2.3 *What is the average waiting time for a cornea transplant in the jurisdiction you serve?

2.4 *How many ophthalmologists (performing transplants) does your program support?

Total :

2.5 *How many cornea transplants did your program support in 2008?

Total :

2.6 *In the following section, please indicate the number of grafts your eye bank imported from Canadian and/or foreign eye banks in 2008 and indicate the distributing bank(s). If a graft type was not imported, enter "0".

2.6.1 Number of Grafts imported from Canadian Eye Banks

*Corneas PK

*Corneas LK

*Corneas EK

*Sclera

*Amniotic Membrane

*Research Tissue

2.6.2 Select the names of Canadian eye banks you routinely import tissue from.

Eye Bank of British Columbia
 Comprehensive Tissue Centre

Eye Bank of Canada - Ontario Division
 Banque d'Yeux Nationale Inc.



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- | | |
|--|--|
| <input type="checkbox"/> Lions Eye Bank - Alberta | <input type="checkbox"/> Banque d'Yeux du Québec |
| <input type="checkbox"/> Lions Eye Bank of Saskatchewan | <input type="checkbox"/> Regional Tissue Bank |
| <input type="checkbox"/> Lions Eye Bank of Manitoba and
Northwest Ontario | <input type="checkbox"/> New Brunswick Eye and Tissue Bank |

2.6.3 Number of Grafts imported from Foreign Eye Banks

- *Corneas PK
- *Corneas LK
- *Corneas EK
- *Sclera
- *Amniotic Membrane
- *Research Tissue

2.6.4 Select the names of foreign eye banks you routinely import tissue from.

- | | |
|---|--|
| <input type="checkbox"/> Alabama Eye Bank | <input type="checkbox"/> Lions Medical Eye Bank & Research
Center of Eastern Virginia, Inc. |
| <input type="checkbox"/> Heartland Lions Eye Bank | <input type="checkbox"/> North Carolina Eye Bank, Inc. |
| <input type="checkbox"/> Heartland Lions Eye Bank, Kansas City | <input type="checkbox"/> Midwest Eye-Banks |
| <input type="checkbox"/> Indiana Lions Eye & Tissue Transplant
Bank | <input type="checkbox"/> Minnesota Lions Eye Bank |
| <input type="checkbox"/> Indiana Lions Eye & Tissue Transplant
Bank | <input type="checkbox"/> Rochester Eye & Human Parts Bank |
| <input type="checkbox"/> Iowa Lions Eye Bank | <input type="checkbox"/> Rocky Mountain Lions Eye Bank |
| <input type="checkbox"/> LifePoint, Inc. | <input type="checkbox"/> San Diego Eye Bank |
| <input type="checkbox"/> Lions Eye Bank of Lexington-Vision Share | <input type="checkbox"/> SightLife |
| <input type="checkbox"/> Lions Eye Bank of Oregon | <input type="checkbox"/> The National Eye Bank Center /Tissue
Banks International |
| <input type="checkbox"/> Lions Eye Institute for Transplant &
Research, Inc. | <input type="checkbox"/> Utah Lions Eye Bank |
| <input type="checkbox"/> Other - Please specify | |



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2.7 *Given your current practice and demand for services, indicate the expected change in demand for grafts in the next 2-5 years. Your best estimate is appreciated.

	Decrease more than 25%	Decrease between 1 and 25%	No Change	Increase between 1 and 25%	Increase more than 25%	Not applicable
Corneas PK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Corneas LK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Corneas EK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sclera	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amniotic Membrane	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Research Tissue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Artificial Corneas e.g. AlphaCor™	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.0 Availability of Ocular Tissue and Import Practices

3.1 *Please rate the availability of the following ocular tissue from Canadian suppliers.

	Always difficult to obtain	Often difficult to obtain	Average availability	Good availability	Very Good availability	Not applicable
Corneas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sclera	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amniotic Membrane	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Research Tissue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.2 *Please rate the availability of the following ocular tissue from foreign suppliers.

	Always difficult to obtain	Often difficult to obtain	Average availability	Good availability	Very Good availability	Not applicable
Corneas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sclera	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amniotic Membrane	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Research Tissue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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3.3 *What factors are considered in the selection of ocular tissue suppliers? Please indicate the relative degree of importance of each factor.

	Not important	Somewhat important	Important	Very important	Extremely important	Not applicable
Price	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Assurance of safety of products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Availability of required products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speed of delivery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Eye Bank Association of America (EBAA) Accreditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Canadian Source	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If Other, please specify:

3.4 *Within your facility, what is the process for selection of external ocular tissue suppliers?

Formal competitive purchasing procedures to determine ocular tissue suppliers (Request for Quotation, Request for Tender, Request for Proposal used)

Single source selection of ocular tissue suppliers (Eye bank determines tissue suppliers)

Other (please describe)

3.5 *Under whose budget is funding identified for purchasing ocular allografts?

Department of Surgery

Department of Ophthalmology

Operating Room

Eye Bank

Other (please specify):

Not Applicable – No funds transferred.



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- 3.6** Please provide your actual or estimated total annual expenditure for purchased ocular grafts, (if applicable).

Actual annual expenditure:

Estimated annual expenditure:

- 3.7** If available, please provide the breakdown of the total annual expenditure for purchased ocular grafts by graft type.

Cornea:

Sclera:

Amniotic Membrane:

**Thank you for taking the time to answer this survey.
Your answers will remain confidential.**

For further information, please contact:

Deloitte Project Consultant

Patti Telford Tel: 604.601.3466 Email: patelford@deloitte.ca

Canadian Blood Services

Paul Derksen Tel: 416.313.3298 Email: paul.derksen@blood.ca