

# Cornea Donation and Transplantation:

## A National Consensus Forum for Improving Access in Canada

February 9-10, 2020



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Most importantly, we sincerely acknowledge the generosity of cornea donors, their families and loved ones, who give selflessly to provide sight to transplant recipients and offer hope to recipients who are waiting across the country.

## Disclosures

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## Patient and family perspectives

Donor families and transplant recipients signify the beginning and the end of the donation and transplantation process. Yet, it is imperative that these two groups remain an essential focus of all professionals involved in this continuum. The centrality of donor families and transplant recipients both framed and influenced the development of this national consultation.

Donor family members who participated in the event shared their gratitude that something as meaningful as restoring sight for another person could result from the tragedy of losing a loved one. They ask those reading this report to remember the human stories behind the donated tissue and to maximize the benefits of these precious gifts.

Transplant recipients acknowledged their sincere thanks and admiration for the selfless gift that the donor and their family gave them; not only restored vision, but restored quality of life. Those facing loss of vision are also facing a loss of independence and a loss of life as they know it. The gift of sight is truly life-preserving. Transplant recipients ask those reading this report to remember that the need is real; there are many waiting recipients across the country.

By participating in the development of this national consultation, both donor families and transplant recipients gained an appreciation for the depth of resources involved in the donation and transplantation system.

Grateful for the opportunity to participate in this process, there is hope that donation and transplantation will further become an integral part of Canadian culture; that we will continue to push boundaries and find innovative ways to ensure the cornea donation and transplantation system is equitable and accessible to all Canadians.



In this photo: Denice Klavano (donor family), Susan Harason (cornea recipient), Kathleen Tabinga (donor family), Shirley Sinclair (cornea recipient), Dr. Paul Postuma (cornea recipient)

## Executive summary

The guidance stemming from this national consultation is transformational and acting on the recommendations will improve access to cornea donation and transplantation in Canada.

For the last decade the increasingly long waiting lists for cornea transplantation have consistently gained media and government attention. Wait times are often measured in years as opposed to months, meaning the rates of access to cornea transplantation in Canada are on par with, or lower than, the rates seen in some developing countries.<sup>1</sup> Yet, despite all the attention the number of corneas transplanted in Canada has remained unchanged for the last six years and no focused and coordinated efforts have been expended to improve this system.<sup>2</sup>

On Feb. 9 and 10, 2020, eye and tissue bank representatives, health authority and hospital leadership, transplant ophthalmologists, organ donation organizations, transplant recipients, donor families and several national organizations – including the Canadian Ophthalmological Society, the Canadian National Institute for the Blind, the Canadian Donation and Transplantation Research Program, the Canadian Standards Association – Ocular Technical Committee, Canadian Blood Services, and the Donation Physician Network, came together to identify opportunities and solutions and in doing so, put forth the ultimate recommendation:

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*To create a Canadian cornea donation and transplantation system that is self-sufficient and eliminates corneal transplant waiting lists within five years.*

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The community of experts assembled understood the challenges that undertaking system-level improvement presents; however, they believe the recommendations identified in this guidance are specific, realistic, time-based, and largely attainable and that implementation of the recommendations will lead to transformative change. Respecting the resource limitations of the current system, there are opportunities to optimize existing programs and infrastructure and execute strategies at the provincial level that will ultimately demonstrate national system improvement.

The engagement, excitement and momentum generated from this consultation is palpable. The energy and recommendations from the community will provide guidance to the provinces, governments, health-care organizations, health-care professionals, researchers, transplant recipients, and donor families who want to work together to achieve this bold vision.

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<sup>1</sup> Global Alliance of Eye Bank Associations (2020).

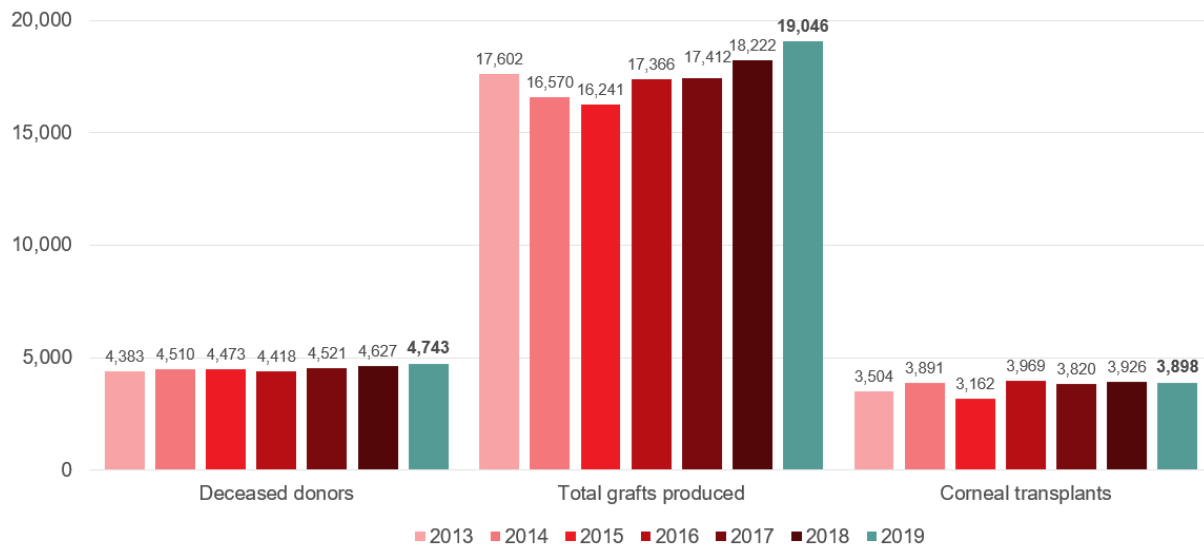
<https://www.gaeba.org/#:~:text=As%20a%20not%2Dfor%2Dprofit,and%20international%20recommended%20Standards%20of>

<sup>2</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

## Current context

The provincial demand for corneas for transplantation is increasing and will continue to increase due to an aging population and refined surgical techniques that allow for better outcomes, wider indications for surgery, as well as shorter surgical times and faster recoveries. Unfortunately, despite the increasing demand there has been no significant change in the supply of corneas in Canada over the last six years.<sup>3</sup>

### Canadian tissue donation, graft production and corneal transplants



National communication and advisory forums for the organ donation and transplantation community have advanced coordinated strategies to improve system performance, resulting in a 38% increase in organ donation in Canada over the last five years<sup>4</sup>. Without these nationally coordinated strategies and communication forums, the Canadian eye and tissue donation community has only seen a 5% increase in tissue donation over the same period<sup>5</sup>; despite the fact the number of potential cornea donors far exceeds the number of potential organ donors.<sup>6</sup>

In Canada, the cornea transplant rate varies by province from 36 to 126 per million population<sup>7</sup>, while wait times for a non-urgent cornea transplant estimates range from one month to more than two years. However, unlike the waitlists for organ transplants in Canada, there is little to no quantitative data or visibility to the actual number of patients waiting for cornea transplants or their actual wait times. There

<sup>3</sup> Canadian Blood Services. Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>4</sup> Canadian Blood Services 2020, Organ and Tissue Donation and Transplantation System Progress Report – 2018 Update

<sup>5</sup> Canadian Blood Services 2020. Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>6</sup> Canadian Blood Services 2020. Estimating Potential Tissue Donors in Canada 2014. <https://profedu.blood.ca/sites/msi/files/Estimating-potential-tissue-donors-in-Canada-from-2005-2008-An-update-based-on-acute-care-hospital-admissions-data-January.pdf>

<sup>7</sup> Canadian Blood Services 2020, Canadian Eye and Tissue Bank Committee Report: Canadian Eye and Tissue Banking Statistics 2018

is no standardized process to document or monitor access and waiting lists. Without this essential information provinces cannot appropriately plan for, or manage, demand and equitable access.

Though a small number of provinces have excess cornea supply, interprovincial sharing is infrequent. Over the last decade most provinces have, at some point, purchased corneas from the United States to mitigate their wait list challenges<sup>8</sup>. While cost recovery is in place in the Canadian tissue system, cost recovery for cornea tissue is not in place for Canadian eye banks. With no ability to recover the costs associated with tissue recovery, processing and distribution, eye banks with the capability to increase production to share interprovincially feel restricted to do so as they are not funded to provide tissue to other provinces. The resistance to cost recovery for ocular tissue seems to be related more so to historical practice than any regulatory barrier. A 2020 review of all provincial legislation identifies no regulatory barriers to cost recovery.<sup>9</sup>

Eye banks, organ donation organizations and transplant ophthalmologists identify a lack of eye bank funding as a primary barrier to increasing supply.<sup>10</sup> With appropriate operational resources, 44% of eye banks in Canada indicate that they could increase production within their current infrastructure to a surplus and provide tissue to other provinces.<sup>11</sup>

The past decade has seen significant technological advances in eye banking. While some eye banks evolved to undertake advanced processing practices, much of this work is still being performed in the operating room by ophthalmologists, using valuable operating room time for processing that could occur in the eye bank. More than 80% of transplant ophthalmologists believe eye banks should undertake this processing.<sup>12</sup> A lack of operating room time has been identified as a primary barrier to cornea transplantation; optimizing this time for transplantation instead of processing is essential.

Many Canadians in need of cornea transplantation to restore their vision and quality of life are disadvantaged by the gaps in the current system. Significant improvement to the ocular tissue donation and transplantation system is possible with coordinated efforts to enhance communication and optimize existing provincial infrastructure and resources.

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<sup>8</sup> Canadian Blood Services 2020. Direct communication Jim Mohr Senior Advisor, System Development, Organ and Tissue Donation and Transplantation.

<sup>9</sup> Canadian Blood Services 2020. Summary of Legislative Provisions Regarding the Sale of Tissue Meeting background document.

<sup>10</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

<sup>11</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

<sup>12</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

## Forum process

In March of 2019, Canadian Blood Services and the Canadian Ophthalmological Society partnered to engage the cornea donation and transplantation community to:

- determine gaps in the Canadian system;
- identify barriers and facilitators for change; and
- develop recommendations to improve access to, and equity in, cornea transplantation in Canada.

A planning committee was established to develop the meeting agenda and to prepare background materials. Meeting participants from a variety of backgrounds were invited to contribute to the two-day meeting held Feb. 9-10, 2020 in Toronto, including: transplant ophthalmologists, medical and administrative directors from provincial eye banks, donation organization administrators, donation physicians, donation coordinators, health authority representatives, transplant recipients, donor families, as well as experts in public awareness, professional education, bioethics and law. Formal representation from professional societies and organizations included: Canadian Ophthalmological Society, Canadian National Institute for the Blind, the Canadian Donation and Transplantation Research Program, the Canadian Standards Association – Ocular Technical Committee, Canadian Blood Services, and the Donation Physician Network. See Appendix 1 for the full list of participants. Consideration was given to ensure participants represented gender, cultural and geographic diversity.



In this photo: Forum Planning Committee



Significant effort was made to gather evidence that would prepare and inform meeting participants for reasoned and effective discussion and debate. Prior to and during their participation in the forum, participants reviewed information that would assist in evaluating the current Canadian system, including:

- a survey of Canadian eye banks,
- a survey of Canadian organ donation organizations,
- a survey of corneal transplant surgeons,
- an outline of the current provincial legal statutes and framework relating to valued consideration, cost recovery, donor identification and referral, and consent; and
- documents summing leading practice, literature and data analysis relating to corneal transplantation demand, access, supply, utilization, inter-provincial sharing and research.

The following presentations were delivered at the forum to inform and guide discussions:

## **Australia**

Australia has many similarities to Canada as they have publicly funded health care delivered provincially over a large geographical area. Australian eye banks focus on their jurisdiction but they have developed a national sharing approach to cornea donation and transplantation which improved access to cornea transplantation. The Australian experience and outcomes of a national approach to system improvement in cornea donation and transplantation was presented by Heather Machin, Project Officer to the Centre for Eye Research Australia, University of Melbourne. Key enablers of their success were identified and include:

- Collaborating with stakeholders.
- Interprovincial sharing.
- Adopting global best practices.
- Sharing standards and education tools.
- Assisting clinicians with their research.
- Contributing to Corneal Graft Registry.
- Ethical conduct.

Challenges were identified and include:

- Lack of eye donation and eye banking research.
- Innovating from within; Australia imports innovation.
- Succession planning; as a small community expertise, knowledge, and workload is held by a relatively small group which presents risks to both operations and to historic knowledge.

## **Quebec**

In nine years, Quebec transformed its cornea donation and transplant program from being dependent on cornea importation to becoming almost entirely self-sufficient. Quebec improved from importing 72% of its corneas with a waiting time of more than five years to importing only 9% of its corneas with a waiting time of less than three months. Etienne Fissette, Director, Human Tissue Operations, Héma-Québec presented their approach to system improvement and identified the following key enablers:

- Incorporation of eye and tissue within the mandate of Héma-Québec, the provincial blood agency, allows access to additional streams of expertise, resources and infrastructure.
- Detailing clear lines of roles and responsibilities in partnership agreements between Héma-Québec (referrals, screening, recovery, allocation and regulatory compliance) and two hospital-based eye banks (evaluation, processing and distribution).
- Centralizing the process and oversight for cornea importation including vendor qualification to Héma-Québec.
- Collaborated with international leader Sightlife to review cornea donor and cornea qualification criteria and to provide cornea recovery and evaluation training.
- Increased coordinator presence in hospitals, standardized donor identification and referral processes and improved communication and collaboration with the organ donation organization, with coroners and with paramedics.
- Increased focus to staff retention and skill development.
- Increased focus to continuous improvement with community engagement.

## **Ontario**

At 14.7 million, Ontario has the largest population in Canada. Provincial authority for organ and tissue donation has been legislated to the Trillium Gift of Life Network (TGLN) and the network reports directly to the Ministry of Health. Ontario's provincial, legislative and operational model is a functional partnership between TGLN and the Eye Bank of Canada (Ontario Division) in which TGLN manages all aspects of tissue donation, including referral, consent and recovery, and the Eye Bank manages cornea processing, evaluation and allocation. Christine Humphreys, Director, Eye Bank of Canada (Ontario Division), and Janet MacLean, Vice-President, Clinical Donation Services, Trillium Gift of Life Network presented the Ontario model. Key enablers of their success were identified and include:

### **TGLN**

- Required referral of all deaths and patients at high risk for imminent death.
- 96% compliance with required referral.
- 4.3 million registered donors (34% of Ontarians).
- TGLN provincial resource center is staffed 24/7 including dedicated tissue coordinators to receive and manage referrals.
- Tissue recovery coordinators based out of eight recovery pods across the province to provide coverage over a large area.

### **Eye Bank of Canada (Ontario Division)**

- Private not-for-profit organization directly funded by the Ministry of Health.
- Based out of an independent facility: the Kensington Eye Institute.
- 24/7 coverage to receive, process and distribute corneas.

### **Collaboration and shared responsibilities**

- A provincial approach to system improvement and oversight with the Ontario Vision Task Force reporting directly to the Ministry of Health and a Corneal Transplantation Working Group reporting to the Trillium Gift of Life Network.
- Business planning with target setting to align supply and demand; targets include consent rate and corneas for transplant.
- Professional education and staff training.

- Provincial oversight with public reporting of cornea waiting times.

Challenges were identified and include:

- Large geographical area (1.1 million square kilometers) makes the provision of recovery in all regions not feasible.
- Developing a cost-effective service delivery model.
- Staff recruitment and retention; significant training time requiring a unique and specific skill set.

## **New Brunswick**

In 2018 New Brunswick had the highest rate of cornea donation and release to transplantation in Canada when adjusted per million population. The key success factors of the New Brunswick Organ and Tissue Program's system and model were presented by Nadya Savoie, Administrative Director, New Brunswick Organ and Tissue Program and Debbie Jefferson, Quality Supervisor/Ocular Division Manager, New Brunswick Organ and Tissue Program. Key enablers of their success were identified and include:

- Required referral is mandated in the *Human Tissue Gift Act* and is facilitated by the Organ and Tissue Donation toll-free line.
- Full provincial cornea recovery capacity with trained eye bank technicians available to recover in all areas of the province.
- Comprehensive training program, which involves initial training and yearly recertification/competency processes.
- A small province geographically with hospitals in each region allowing accessibility to donation even in remote areas.
- Health-care professionals are part of the recovery team, they have experience with death and dying and dealing with families in crisis or grieving and have specific training in approaching families for donation which optimizes consent.
- Many of the eye bank technicians have been involved with the program for many years and have a breadth of experience.
- Utilization of hospital nursing supervisors in some regions to conduct initial donor screening and to approach the next-of-kin for consent reduces the workload on the on-call recovery staff.
- Changes to inclusion criteria for ocular donation, such as increasing the age criteria for donation (from  $\leq 70$  to  $\leq 75$  years of age) and increasing the death to preservation time (from 16 to 24 hours).

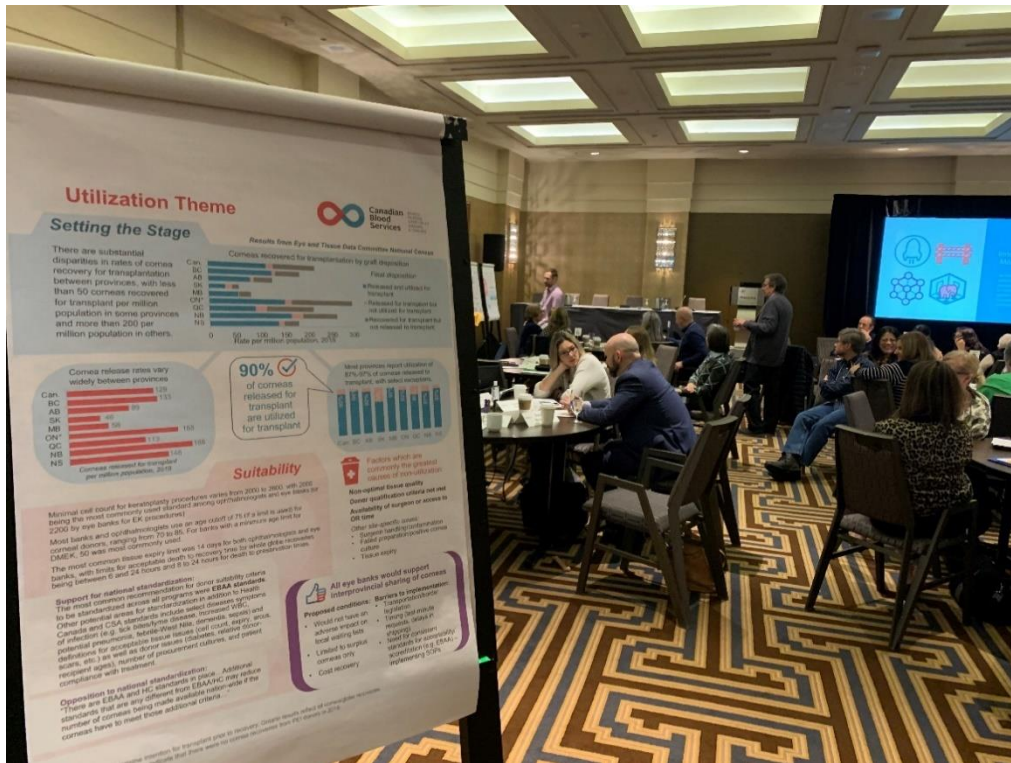
## **Donor Family and Transplant Recipient Experiences**

The donor family and transplant recipient experience were important emotion-filled reminders of the true impact of tissue and cornea donation and transplantation. Susan Harrison, Paul Postuma and Shirley Sinclair shared their experiences as cornea recipients, while Denice Klavano and Kathleen Tabinga reflected on their experiences as donor family members. The patient partners provided great insight throughout the entire meeting, in every breakout discussion and ensured all meeting discussions were patient-focused.

# World Cafés: Evidence Informs Guidance to Improve the Corneal Donation and Transplantation System

System gaps, improvement opportunities and challenges were identified using a World Café format, in which participants were divided into small multi-disciplinary, gender and geographically-balanced groups that rotated through six small table discussions.

Facilitated by a system leader, the World Café discussions identified system gaps, opportunities for improvement, and challenges related to demand, supply, access, utilization, interprovincial cornea sharing and cost recovery, and interprovincial knowledge sharing and research. To frame these discussions, participants were provided with a ‘think piece’ for each topic, comprised of a challenge statement, an infographic summarizing the key evidence collated from the surveys noted above, and a literature review summarizing both peer-reviewed and grey literature. The ‘think pieces’ are provided in Appendices 4 – 9.



## Demand

**Café lead: Dr. Sonia Yeung, Medical Director, Eye Bank of British Columbia**

The demand for corneas for transplantation is increasing annually in Canada. This may be attributable to an overall aging population, as well as to refined surgical techniques which allow for better outcomes, wider indications for surgery, and shorter surgical times and hospital stay.

*Demand* for cornea transplantation in Canada is defined as the number of people approved for and actively awaiting surgery. *Need* is defined as the number of people who would benefit from cornea transplantation. Need is higher than the estimate of demand as not all patients who would benefit from

a transplant are offered one. In our 2019 nationwide survey, 59% of transplant ophthalmologists and 75% of eye banks indicated that in addition to the current waiting lists (demand) there are patients not being referred for cornea transplantation due to their age, or the perception that there are not enough donors and the waiting lists are too long.<sup>13</sup>

A 2009 survey of Canadian eye banks reported wait times ranged from seven to 36 months for corneal transplantation.<sup>14</sup> A decade later, the results of our 2019 survey clearly demonstrate the challenge of meeting demand has still not been addressed. Of the transplant ophthalmologists surveyed, 33% estimate their non-urgent patients wait more than a year for cornea transplantation. One province reported that wait times for non-urgent patients are estimated to be two to three years.

The cornea donation and transplantation system will not be capable of aligning supply with demand until it has taken the steps to understand and quantify demand and waiting times for transplant.

### **System gaps**

- There is no robust way to accurately determine demand in Canada. Many of the surveyed eye banks report that current waiting lists may not be accurate, while others report having no visibility to current waiting lists, as these are managed by individual transplanting surgeons' offices.<sup>15</sup>
- National standardized comprehensive data is available for both cornea donations and corneal transplant surgeries.<sup>16</sup> However, there is no comprehensive data or established and standardized process to collect data about the number of patients waiting for cornea transplant or their waiting time. The only data available is estimates provided by surgeons and eye banks, which may be inaccurate and/or misleading. To determine if we are satisfying demand, we need an accurate measure of those actively awaiting cornea transplantation, in addition to the number of cornea donations and the number of cornea transplantation surgeries performed across Canada.
- Currently, there is no formal reporting of demand or waiting times. As well, eye banks are not required to set targets for supply, recovery and processing that align with demand. Without these measures for accountability, eye banks will not meet the needs of patients and surgeons.

### **Improvement opportunities**

- A physician-driven system that properly documents access to assessment and transplant, based on strict and consistently applied criteria would provide data to better understand urgency and demand, allow programs to adjust operations to meet demand and support greater consistency and equitability in access.
- Tracking surgical demand alone does not track true patient need. There is an opportunity for national collaboration in the development of a data strategy that will accurately measure patient need and access to assessment in a consistent manner across all provinces. Setting benchmarks for waiting times, access, supply, recovery and processing are an essential component of a data strategy.

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<sup>13</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

<sup>14</sup> Canadian Blood Services 2009. Survey of Canadian eye banks unpublished.

<sup>15</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

<sup>16</sup> Canadian Blood Services 2020, Canadian eye and tissue banking statistics 2018; A report of the eye and tissue data committee.

- Developing and advancing a model for forecasting need and demand to inform operational strategies will ensure that supply aligns with demand.
- Sharing patient stories is key to illustrating need, the impact of access challenges and to generate political interest.
- Development of a provincial advisory committee for cornea transplantation with links directly to the appropriate government representatives would promote a collaborative focus on nationwide goals, facilitate routine discussions about demand and waitlists, provide a forum for updates on current metrics, and ensure that all provinces are accountable for improving the system.

## Challenges

- Surgeons operate independently and cornea transplantation may not be the prominent feature of their busy practice. This may present challenges in coordinating efforts to measure demand.
- The reality of provincial authority can't be ignored when we imagine our ideal future state. Loss of vision affects quality of life, but it is not life threatening. From the perspective of funders and the health-care community, this may diminish the sense of urgency for change.

## Supply

### Café lead: Mike Bentley, Manager, Provincial Initiatives, Alberta Health Services

The growth in cornea transplantation in Canada over the last six years has been stagnant, with 3,898 corneal transplants in 2019 compared to 3,891 corneal transplants in 2014.<sup>17</sup>

The donation of corneas recovered for transplantation varies dramatically between provinces from 32 to 164 per million population.<sup>18</sup> The province with the lowest donation rate has the longest estimated transplant waiting times of over two years for non-urgent patients. Most provinces have, at some point, purchased corneas from the United States to supplement their supply. In 2017, 8% of all corneas transplanted in Canada were purchased from the United States, and in 2018 the rate was 3%.<sup>19</sup>

It is important for the Canadian system to find a balance between providing cornea donation as a component of standard end-of-life care, meeting the demand for donors, having sufficient supply to support other uses like research, development and training, and the reality that realizing all potential cornea donors would over supply the system.

## System gaps

- A 2014 analysis of Acute Care Hospitals Admissions, using a strict age criterion of less than 60 years, estimated there were 9,000 potential cornea donors among annual hospital deaths in Canada.<sup>20</sup> We also know that about 50% of deaths in Canada occur outside the hospital environment and that there is significant potential for cornea donation in that population as

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<sup>17</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2014. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>18</sup> Canadian Blood Services 2020, Canadian eye and tissue banking statistics 2018; A report of the eye and tissue data committee.

<sup>19</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>20</sup> Canadian Blood Services, 2014, Estimating Potential Tissue Donors in Canada <https://profedu.blood.ca/sites/mtsi/files/Estimating-potential-tissue-donors-in-Canada-from-2005-2008-An-update-based-on-acute-care-hospital-admissions-data-January.pdf>

well.<sup>21</sup> With only 4,500 cornea donors in 2018, we are missing a significant number of potential donors that would increase supply.<sup>22</sup> In fact, the number of potential cornea donors in Canada would far exceed the demand if all were realized.

- There is no comprehensive data set or established and standardized process to collect data about the number of patients waiting for corneal transplant or their waiting time. The only data available is estimates provided by surgeons and eye banks, which may be inaccurate and/or misleading. In fact, many eye banks report having no insight into these number.
- In many provinces, surgery is scheduled based upon tissue availability as opposed to individual patient need.
- Most eye banks are not required to and do not set targets for supply, recovery and processing that aligns with demand. Without these measures, eye banks will not be capable of aligning supply with demand to meet the needs of patients and surgeons.

### **Improvement opportunities**

- Optimizing all potential donors will be crucial for increasing the supply of donated tissue. This will require improved identification and referral rates within hospitals. At present, 63% of eye banks identify that a lack of compliance in the identification and referral practices lead to missed donation opportunities and has significant impact on their ability to meet demand.<sup>23</sup> Professional education for health-care professionals in donor identification and referral will help reduce missed donation opportunities, as well as routinely offering patients and families the opportunity to donate and provide effective request training for donation coordinators and eye bank staff to improve consent rates of those approached. Ensuring there is the operational capacity to recover and process an increase in donated tissue is also required.
- There was a strong consensus among participants that Canada become self-sufficient in cornea supply.
- Optimizing the existing system with interprovincial sharing and cost recovery will fill current supply gaps and will be more cost effective than importation and will reduce our dependence on supply from the United States.
- Emerging technological advances will require eye banks to take on more complex processing activities that will need to be considered when aligning the expertise and infrastructure required to ensure supply meets demand. Centralization of complex processing may be an option for optimizing resources, creating a critical mass to develop expertise, justifying infrastructure and realizing economies of scale, ultimately resulting in better provision of service and patient care.
- Optimizing existing provincial infrastructure can help develop a coordinated and interprovincial patient-driven supply chain and distribution strategy that aligns supply with demand and ensures patients are scheduled for transplant based on their need, and not based on when the tissue becomes available.

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<sup>21</sup> Canadian Blood Services 2013: Advancing organ and tissue donation: A collaboration of the Canadian Conference of Chief Coroners and Chief Medical Examiners <https://profedu.blood.ca/sites/msi/files/Reference-Manual-Advancing-Organ-and-Tissue-Donation-June-2013.pdf>

<sup>22</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>23</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

- Implement a cost recovery model. At present, eye banks are not compensated for the costs related to the recovery, processing and distribution of corneas to other provinces. This is a significant disincentive to interprovincial sharing and provides no incentive for banks to increase production above their own needs to supply provinces with less capacity and capability. This is the only allograft for which inter-provincial cost recovery is not in place.
- National data collection, metrics, targets and forecasting should be implemented to improve decision making and inform system development initiatives.
- Currently most public awareness efforts are heavily, if not exclusively, organ focused. Public awareness campaigns require a more distinct message related to cornea donation to ensure cornea donation becomes a standard part of end-of-life care in Canada. Blindness is a disability feared by many Canadians; this is a powerful message that could be leveraged to promote cornea donation and transplantation. Instead of uncoordinated provincial approaches to public awareness, there is an opportunity to explore a coherent national strategy in this regard with consistent cornea donation messaging across the country. This work should be outsourced or at least done in collaboration with marketing professionals, given health-care professionals are not experts in this field.

## Challenges

- Eye banks, organ donation organizations and transplant ophthalmologists all identified the lack of financial resources available to eye banks as a primary barrier to supply. With appropriate operational resources, 44% of eye banks said they could increase production within their current infrastructure to a surplus and provide supply to other provinces.<sup>24</sup>
- Eye banking is no longer a simple process. The last decade has seen significant advances in processing techniques, driving eye banking into a new realm of technical complexity. The majority of corneal transplants performed in Canada now require endothelial keratoplasty, an advanced processing technique that removes cellular layers to improve patient outcomes and reduce hospital stay. However, this expertise and processing service is not feasible in all eye banks. In areas where this advanced service is not offered by the eye bank, surgeons perform the processing in the operating room prior to transplant, significantly increasing time in the operating room. These challenges will become more of an issue as technology and techniques continue to advance.
- A lack of operating room time for ophthalmologists was identified as a primary barrier to cornea transplantation. To advocate for additional operating room time and resources, eye banks and transplant surgeons must illustrate demand, challenges related to access and waiting times, as well as the impact on the patients' quality of life and functional status.
- Cornea transplantation is poorly remunerated compared to other procedures such as cataract surgery; which may be a disincentive to the allocation of operating room resources to transplant procedures. Until remuneration models are re-examined by governments, and increased remuneration is provided for cornea transplantation there will continue to be a financial disincentive to performing these procedures.

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<sup>24</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)



- There was discussion, but no consensus, about the utility of donor audits to identify and reduce the number of missed donation opportunities. The value of donor audits often varies depending on the referral system; the more mandated and ubiquitous the referral system, the less potential benefit to audits. Given the significant resources required to execute audits and the fact that we already know large numbers of potential donors are not being referred, it is unclear whether donor audits would be useful for this purpose.

## Access

### Café lead: Dr. Clara Chan, Medical Director, Eye Bank of Canada (Ontario Division)

Access relates to 1) the time-period a patient must wait from referral to assessment for transplant, 2) the time-period a patient must wait from acceptance for transplant to surgery, and 3) the process by which donor corneas are allocated to specific patients.

In the 2020 survey, Canadian eye banks and cornea transplant ophthalmologists were asked to estimate and rate access to cornea tissue, allocation and waitlist management.<sup>25</sup> The following reflect key findings:

- 40% of transplant ophthalmologists indicate referral times for transplant assessment require improvement.
- 45% of transplant ophthalmologists and 75% of the eye banks indicate that wait times for cornea transplant require improvement.
- 20% of transplanting ophthalmologists and 50% of eye banks rate access to cornea tissue as poor.
- Waiting time for urgent patients is estimated to vary from less than one month to more than six months depending on province.
- Waiting time for non-urgent patients is estimated to vary from one month to more than two years depending on province.

### System gaps

- There is no comprehensive data set or established and standardized process to collect data about patient access to cornea transplantation. There are no formal reporting requirements or benchmarks for access. Without data, reporting and benchmarks there are no quality controls or accountability processes in place to protect patients and ensure their access is appropriate.
- There are no standardized protocols for the allocation of donated corneas to waiting patients. To better understand the challenges around allocation of corneas in an environment where the demand exceeds the supply the following example was considered:

If viable cornea tissue becomes available, who should receive the tissue first:

- a. An 82-year-old retired male, with poor mobility and cardiovascular issues. The eye in question has a guarded prognosis, and the other eye has functional vision of around 75%. He does not drive, but enjoys watching

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<sup>25</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

TV, driving and playing chess. He has been on the waiting list for one year since his first surgical consultation.

OR

- b. A 42-year-old single mother of three children, with Fuchs' dystrophy which compromises her vision in both eyes while driving and working as an accountant. She has not developed pain episodes; however, one eye is showing early signs of scarring due to the swelling. She has been on the waiting list for six weeks since her first surgical consultation.

Currently there are no guidelines to advise this decision; the allocation choice would not only vary between provinces, but within provinces based on surgical practices.

### Improvement opportunities

- Establish provincial cornea donation and transplantation working groups with provincial representatives who meet on a routine basis to create a forum for accountability and action. The groups could be tasked with comparing provincial metrics and analysis specific to demand, access and utilization; sharing information; defining benchmarks; refining and aligning practice; as well as national standards to advance system improvements.
- A national waitlist was discussed but was not supported by those in the room, as urgent patients are typically able to receive transplants quickly within the current system. However, a national registry for tissue supply, in terms of surplus and deficit, would facilitate interprovincial sharing and mitigate access challenges.
- National standardization for graft acceptance criteria would also facilitate interprovincial sharing and optimal utilization.
- It is essential to have data systems and communication processes in place that support wait list monitoring and allocation decisions. A national strategy for prioritizing recipient allocation is required; one that utilizes objective criteria to promote standardization between provinces and transplant ophthalmologists. Application of a standardized patient prioritization scoring system, with benchmark waiting times based on priority was suggested. Evaluating this strategy will be required to ensure the added value is not outweighed by the associated administrative burden.
- There are many considerations in defining wait time and interpreting its success. The four-point system used in Ontario, like the system used in Alberta, could serve as a suitable baseline to work from in the development of national standards. See Tables 1 and 2.

**Table 1: Time to patient's first eye specialist appointment:** How long patients waited from the time they consulted an eye specialist or surgeon or central intake office receiving the referral from the patient's doctor, to the patient's first eye specialist appointment.<sup>26</sup>

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<sup>26</sup> Health Quality Ontario. System Performance: Measuring Wait Times for Eye Surgeries: <https://www.hqontario.ca/System-Performance/Measuring-System-Performance/Measuring-Wait-Times-for-Eye-Surgeries>

Priority level of patient's condition	Clinical description	Target time* to patient's first specialist appointment
Priority 1	High probability of disease occurrence or progression impacting morbidity or mortality. Intractable agonizing symptoms.	Patient sees surgeon within 7 days of referral received
Priority 2	Moderate probability of disease progression. Low probability of disease occurrence or progression impacting morbidity or mortality.	Patient sees surgeon within 30 days of referral received
Priority 3	All patients who do not meet the criteria of Priority 2 or Priority 4.	Patient sees surgeon within 90 days of referral received
Priority 4	Minimal risk of disease progression impacting morbidity/mortality.	Patient sees surgeon within 182 days of referral received

\*The target time within which 9 out of 10 patients are seen.

**Table 2: Time from decision to having eye surgery:** How long patients waited from the time they decided with the surgeon or specialist to proceed with the surgery, to having the eye surgery.<sup>7</sup>

Priority level of patient's condition	Target time** from decision to having corneal transplant surgery
Priority 1	Patient has surgery within 24 hours of decision
Priority 2	Patient has surgery within 28 days of decision
Priority 3	Patient has surgery within 84 days of decision
Priority 4	Patient has surgery within 182 days of decision

\*\*The target time within which 9 out of 10 patients are treated.

- Optimize existing provincial infrastructure to develop an interprovincially coordinated and patient-driven supply chain and distribution strategy that aligns supply with demand and ensures patients are scheduled for transplant based on their need, and not based on when the tissue becomes available. This type of universal ‘immediate access’ would require appropriate definition, consensus on a reduction in wait time and/or a reduction of the wait list by a given proportion. It would entail access to operating rooms, tissue grafts, medical services and professionals including transportation to facilities for appointments as well as underlying access to resources and financial support.

## Challenges

- While the supply of corneas is a primary barrier to access in some provinces, access may also be impacted by operating room availability and the volume of surgeries a physician is permitted to schedule.
- Having a low waitlist level may have unintended impacts; for instance, ineffective utilization of operating room resources or advocating for increased support for donation programs may be hampered by the perception that graft supply exceeds demand.

## Utilization

### Café lead: Christine Humphreys, Director, Eye Bank of Canada (Ontario Division)

A 2019 survey of Canadian eye banks and transplanting physicians indicates that the release rate—defined as the percentage of corneas recovered for transplant released and made available for transplant—vary from 53% to 83%. The most common reasons for recovered corneas not being released for transplant being non-optimal tissue quality and donor qualification criteria not met.<sup>27</sup>

Data indicates the utilization rate—defined as the percentage of corneas released to transplant that were utilized for transplant—ranges from 70% to 97% with an overall average utilization rate of 90%. Depending on the eye bank, between 3% to 30% of the corneas released to transplant are not used.<sup>28</sup> The main reasons for non-utilization was non-optimal tissue and lack of access to operating room time.

## System gaps

- On a national level there is no consensus regarding donor acceptance criteria, tissue acceptance criteria, or death-to-recovery and death-to-preservation time limits. A broad range of acceptance criteria for corneal donors and tissue was reported between individual eye banks and among transplanting physicians. Despite national regulations and the Eye Bank Association of America standards, what is considered acceptable risk in one eye bank isn't acceptable to others, and what is acceptable to one transplanting physician is not acceptable to others. This is in addition to individual patient needs that every surgeon takes into consideration.
  - Corneal transplant suitability is dependent on the initial endothelial cell density at the time of preservation. Endothelial cell density decreases with advancing donor age. Transplant ophthalmologists report most commonly accepting donors up to 75 years of age, however the age criteria cut off ranges from 50 to 100 years. With one exception, all eye banks have a cut off between 70 and 85 years. In addition to age, transplanting ophthalmologists have varying opinions on using tissue from donors with a history of diabetes or diabetic co-morbidities, previous cataract surgery, or other vision correction procedures such as LASIK or photorefractive keratectomy.<sup>29</sup>

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<sup>27</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)

<sup>28</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>29</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

- Regarding tissue suitability criteria, Canadian eye banks report that minimum suitability for endothelial cell density for penetrating keratoplasty ranges from 2,000 to 2,200 endothelial cells/mm<sup>2</sup>, while the transplant ophthalmologists surveyed indicated that a minimum cell count suitable for penetrating keratoplasty ranges from 2,000 to 2,600 endothelial cells/mm<sup>2</sup>.<sup>30</sup>
- Canadian eye banks also reported large variations in death-to-recovery and death-to-preservation time limits. For whole globe recoveries, the range in death-to-recovery time limits was from six to 24 hours. Death-to-preservation time limits were almost as broad, with the maximum death-to-recovery time ranging from eight to 24 hours. For in-situ (cornea only) recoveries, the death-to-preservation time limit range from 12 to 24 hours.<sup>31</sup>

## Improvement opportunities

- The system would benefit from an evidence-based and nationally standardized minimum suitability criteria for both tissue donors and corneas accepted for transplantation. This would remove some of the barriers associated with interprovincial cornea sharing, where suitable tissue in one jurisdiction may not be accepted in another.
- Development of a registry to collect data associated with utilization and outcomes would be value added for programs. Establishing a benchmark would encourage programs to aspire to optimal utilization. It was noted that 100% utilization is not feasible, so an aspirational target of 95% and a benchmark of 90% or greater was recommended. This data will be meaningful for decision making and identifying further opportunities for improvement. Consistent messaging to surgeons and technicians regarding utilization benchmarks and optimization will also be important.
- A registry or similar online tool could also be used for national information sharing related to available surplus tissue and unmet tissue requests, those in which tissue is unavailable for a pre-booked surgery or an emergency procedure. This could include a surgical calendar that indicates when the tissue needs to be received by. Eye banks could indicate their acceptance criteria and track the tissue being offered as well as reasons for decline.
- Establishing an advisory group would also optimize utilization and support:
  - improved interprovincial communication,
  - interprovincial allocation and distribution logistics to ensure tissue available for transplant is easily and effectively offered to patients who need it, and
  - inform the development of best practice guidelines, clinical pathways and education.
- When surgeries are concentrated on certain days or scheduled earlier in the week, it increases the likelihood of tissue supply challenges and tissue expiry; especially over weekends. Improved operating room scheduling strategies should be considered to ensure surgeries are spread over the course of the week.

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<sup>30</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>31</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

- Referencing utilization requirements in the Canada Standards Association guidelines may optimize tissue utilization.

## Challenges

- Surgeon and technician bias impacts utilization rates. Bias in relation to the donor age, the patient's vision requirements and certain tissue types that may handle better or clear faster post-operatively.
- Volume of transplant activity may be a factor for bias as well. Surgeons with high volume activity may have more comfort transplanting tissue with lower cell counts as opposed to only accepting higher cell counts or wanting to wait for 'perfect' tissue.
- Eye Bank Association of America accreditation requirements impact utilization. Eye Bank Association of America accredited eye banks are not allowed to accept corneas from non-accredited eye banks without documenting that the establishment is following the Eye Bank Association of America's medical standards by performing compliance audits. This limits the opportunities for utilization of surplus corneas from non-accredited eye banks.

## Interprovincial Sharing and Cost Recovery

### Café lead: Etienne Fissette, Director, Human Tissue Operations, Héma-Québec

In Canada, human tissues such as amniotic membranes, heart valves, skin, tendons, bones and arteries are frequently distributed from one province to another to support patient demand. The organizations providing these tissues recover the costs of recovery, preparation and shipping by collecting a fee. Seven of the nine Canadian eye banks reported purchasing corneas at some point from the United States to meet demand.<sup>32</sup> Yet, interprovincial sharing of corneas is very limited, despite general agreement that it would be beneficial for increasing access to transplantation. It is important to note hospitals and operating rooms currently budget for tissue costs in relation to all other tissue needs; in orthopedic surgery, neurosurgery, spinal surgery, cardiac surgery, dental surgery and plastic surgery. Corneal tissue is not routinely budgeted within hospital or operating room budgets.

### System gaps

- Unlike tissue banks, Canadian eye banks do not collect a cost recovery fee when sharing corneas interprovincially. Although a donated cornea is a generous and altruistic gesture, there is a cost to recover and prepare that cornea for transplantation. Between \$1,880 and \$3,815 are spent to prepare each cornea for surgical use and transplantation.<sup>33</sup> This cost generally includes: staff and supplies necessary to recover and process ocular tissue; shipping costs; laboratory testing; physician time to review the medical file and evaluate each cornea; maintenance of equipment and facilities; and development of innovative eye bank techniques.

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<sup>32</sup> Canadian Blood Services (2020). Canadian Eye and Tissue Bank Statistics 2018. <https://professionaleducation.blood.ca/en/organs-and-tissues/reports/eye-and-tissue-reports-and-surveys>

<sup>33</sup> Canadian Blood Services 2020. Survey of Canadian Eye Banks

## Improvement opportunities

- Eye banks that have achieved their own needs are turning down donors which could address shortfalls in other provinces. In a 2019 survey, more than one-third of Canadian eye banks reported that they would be able to increase their levels of cornea recovery and processing within their current infrastructure to support other provinces. Optimizing the capacity of these programs would limit the practice of declining donors, which may be negatively impacting the system by giving the public and health-care professionals a false sense of the national need. In addition, it would limit the need to import/purchase corneas from the United States. Implement a cost recovery model for cornea tissue to incentivize and support interprovincial sharing of corneas. The cost recovery model must remain 'not for profit' but should permit the eye bank to recoup operational and fixed costs, including staff education and training, as well as research and development. Costs recovered for ocular tissue should not be used to subsidize other hospital programs.
- Incentivize eye banks to optimize their capability, capacity and infrastructure to provide surplus to other regions, create economies of scale, increase recovery and processing expertise and provide more opportunity for innovation, research and development.
- A strong and efficient Canadian eye bank network to facilitate and optimize interprovincial sharing would be ideal. This network could include an efficient, effective, and centralized way to communicate both the need for tissue and the availability of tissue for interprovincial distribution and a data portal which would support and optimize interprovincial sharing and potentially allow for tracking utilization and outcomes. Engagement of surgeons, and donation and eye bank leaders is required to spearhead this initiative and advocate for system improvement with hospitals, governments and funders.
- A cost recovery model and Canadian network will facilitate greater collaboration between eye banks in terms of preparation of tissue and collaboration with education and research initiatives. Though further consideration may be needed to determine whether to inform the next of kin that the donated tissue may be allocated outside their region, the donor families in attendance reported they would prefer their loved one's donated tissue be utilized in another jurisdiction than not used at all.

## Challenges

- Without cost recovery fees, there is no incentive for eye banks with the capability to increase production to share interprovincially as they are not compensated for their costs. The resistance to cost recovery for ocular tissue seems to be related more so to historical practice than any regulatory barrier, given a 2020 review of all provincial legislation identifies no regulatory barriers to cost recovery.<sup>34</sup>
- Two-thirds of Canadian eye banks are accredited by the Eye Bank Association of America. Accredited participants reported restriction on receiving corneas from non-accredited eye banks (one third of all Canadian eye banks) as a challenge for interprovincial cornea sharing. Prior to distributing corneas to another agency, any organization accredited by the Eye Bank Association of America must:

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<sup>34</sup> Canadian Blood Services 2020. Summary of Legislative Provisions Regarding the Sale of Tissue Meeting background document.

- 1) document that the establishment they are distributing to is currently accredited by the Eye Bank Association of America for the eye bank functions performed, OR
- 2) document that the establishment is following the Eye Bank Association of America's medical standards by performing compliance audits.

The Eye Bank Association of America standards make it more complex and costlier for accredited eye banks and non-accredited eye banks to work together.

- Interprovincial cornea exchange raises equity concerns that must be considered. Only surplus ocular tissue should be shared with another province. It would not be appropriate to supply another jurisdiction at the expense of one's own community. There is also a need to ensure surplus allocation to other provinces is done equitably.

## **Interprovincial Knowledge Sharing and Research**

**Café lead: David Hartell, Associate Director, System Development, Canadian Blood Services**

Most eye banks in Canada are hospital-based and constrained financially with limited access to funding for innovation, research and professional education.

### **System gaps**

- There is no coordinated or national approach to professional education and training for hospital-based health-care professionals specific to ocular tissue donation, or pre- and post-mortem eye care for donation purposes. In 2019 surveys, only 60% of organ donation organizations offer limited ocular donation education or training to hospital-based health-care professionals while 78% of eye banks indicate they do provide some education or training in this area.<sup>35</sup>
- There is currently no communication forum within the Canadian eye and tissue banking community for information exchange, practice sharing, or identification of/and collaboration in research studies.
- Though academic research within the ophthalmologic community continues to advance, research and development of innovation within the Canadian eye bank community is very limited. Similarly, basic science research into tissue and biologics occurs in Canadian academia, however there is little eye and tissue bank driven research in relation to process improvement or product development in Canada.

### **Improvement opportunities**

- Over the last three years, Canadian Blood Services and the Canadian organ donation community have developed an evidence-based curriculum to improve the organ donation system. This national curriculum should be adapted to include an ocular and tissue donation focus.

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<sup>35</sup> Canadian Blood Services 2020, Survey of Canadian eye banks, transplant ophthalmologists and organ donation organizations. Forum background document (infographics)



- Improved linkages and collaboration with the Canadian Ophthalmological Society and the Canadian Donation and Transplantation Research Program will provide a significant opportunity for Canadian eye banks to align their programs with research and funding opportunities to advance community driven research.
- Continued engagement between the Canadian Donation and Transplantation Research Community and members of the tissue banking community could lead to the establishment of a national research network for eye and tissue banks, where interested researchers and technicians would connect to identify and design new research opportunities.
- An interdisciplinary community of practice with representation that includes medical directors, administrators, technical experts, patients and donor families will be foundational to share information, advance national guidance and system improvement solutions and both inform and support professional education and training.

## Challenges

- Training and development opportunities within the Canadian ocular tissue system are lacking. Many programs depend on American curriculum as well as technical training provided by the Eye Bank Association of America.

# Building an Improved Corneal Donation and Transplantation System: Consensus Guidance

Through a consensus building exercise, the conference participants identified a vision, mission and the primary features of the ideal Canadian cornea donation and transplantation system, as well as specific short- and long-term goals to create this system.

Our patient and family partners drafted a vision and mission statement capturing the spirit of the discussion to help guide implementation of the forum recommendations.

## Vision Statement

*A sustainable patient-centered cornea donation and transplantation system which optimizes, aligns, and coordinates provincial program activities.*

## Mission Statement

*To provide Canadians with the opportunity to give the gift of vision at end of life, and to equitably share this gift. To support donors, recipients, and their loved ones. To champion the technicians, surgeons, and support staff who make this gift possible. To fully respect the gift by optimizing the utilization and utility of all donated tissue.*

## Recommendation

*To create a Canadian cornea donation and transplantation system that is self-sufficient and eliminates corneal transplant waiting lists within five years.*

Two key themes emerged through the consensus discussions as key goals for the community:

1. The need to increase collaboration between provinces; to work together to optimize performance and achieve equal access and quality outcomes for all patients across Canada.
2. The need for the cornea donation and transplant community to communicate more effectively and with a single community voice with governments, patients, families and key stakeholders such as Canadian Blood Services, the Canadian Donation and Transplantation Research Program and the Organ Donation and Transplantation Collaborative and its working groups.

To achieve these two broad goals, the participants identified key priority areas that need to be addressed by the community. They include:

- Advisory committees
- Community of practice
- National data strategy
- Interprovincial cornea sharing
- Alignment with the organ donation and transplantation community
- Broad stakeholder engagement
- Government partnership
- Accountability
- Public and professional awareness and education
- National research network

## **Key Priorities and Recommendations**

### **Advisory committee**

The development and promotion of a national advisory committee is necessary to identify and advance coordinated system improvement priorities; to provide insight and develop national guidance in response to emerging and critical issues, including access to transplantation, security of cornea supply and pandemic response. A collaborative and coordinated response would be cost-effective, reducing duplication of efforts and focusing on the optimal utilization of limited resources. This advisory body could provide a crucial vehicle to optimize existing infrastructure and expertise, align professional education and public awareness strategies and resources and standardize suitability criteria. It would allow the community to speak with one voice when engaging government partners and national organizations.

The development of collaborative coordinated strategies would optimize all provincial outputs as greater success can be achieved through collaboration than can be realized alone. Any advisory committee should include broad stakeholder representatives who are empowered to advance provincial interests and a national collaborative vision.

### **Community of practice**

Communities of practice recognize informal adult learning and knowledge translation, where a group of individuals who share a common interest or practice enhance their performance and understanding through regular interaction and participation.

A professional community of practice for the tissue donation and transplantation community could include eye banks, organ donation organizations, ophthalmologists and donation coordinators. It is important to also consider how to continue to engage donor families and transplant recipients as integral members of the community. A forum that facilitates communication between provinces, sharing of knowledge, resources, leading practices, and promotes professional education will allow organizations and professionals to capitalize on one another's successes.

Existing programs, processes, and networks within Canadian Blood Services, the Canadian Eye and Tissue Data Committee and the Canadian Ophthalmological Society could be optimized and aligned in advancing the community of practice.

### **National data strategy**

Development of a national data strategy is crucial for the national cornea donation and transplantation system. Objectives identified as being of absolute value include:

- a national registry to facilitate interprovincial sharing;
- national data on demand, access, allocation, utilization, and outcomes;
- forecasts for demand and security of supply management; and
- development of standardized metrics to facilitate national benchmarking to assess system performance, progress and identify further areas for improvement.

Canadian Blood Services and its National Eye and Tissue Data Committee was identified as an area where existing infrastructure could be optimized in relation to data collection, analysis and registry, waiting list and allocation processes.

### **Interprovincial cornea sharing**

Interprovincial cornea sharing would enable those provinces and eye banks with the capacity to exceed demand within their current infrastructure to provide surplus to other provinces that experience challenges in meeting demand. There was strong and consistent support among forum participants to prioritize interprovincial sharing and cost recovery, not only to promote universal access across Canada but also as an enabler for Canadian needs to be met domestically, improve security of supply and reduce our reliance on international importation.

The success of interprovincial sharing and an interprovincial cost recovery system is contingent on the availability of provincial funders to pay cost recovery fees for domestically sourced corneas, compatibility between programs with respect to the donor and tissue suitability criteria, and accreditation standards associated with distribution.

Eye banks are currently base funded as a provincial service and therefore the primary focus will be an interprovincial cost recovery model.

### **Alignment with the organ donation and transplantation community**

Many core processes within organ and tissue donation are inextricably linked and aligned. There are significant national efforts in place to advance system improvement in organ donation and transplantation. Cornea donation can be advanced by aligning with several of the organ donation initiatives in place, such as public awareness, professional education, data collection and interprovincial

sharing processes. These could be done cost-effectively without diverting focus from the organ priorities and with minimal adjustment to existing resources in comparison to the development of a separate cornea donation stream. Further, aligning system improvements in both organ and tissue creates a synergy which may result in greater improvements to both organ and tissue donation and transplantation overall than if these two communities remain siloed and distinct.

### Broad stakeholder engagement

Information exchange processes that engage additional multidisciplinary participants who impact, and are impacted by, the cornea donation and transplantation system will enhance the quality and utility of the discussions. It is important to ensure our provincial and federal funders have visibility to, and are engaged in, this work. Of critical importance for developing a national voice for the ocular community is the involvement of patients and donor families. Patients have experienced the impact of waiting for a cornea transplant, logistical concerns (such as travelling to care facilities), and they know firsthand the critical impact tissue donation has on enhancing Canadians’ quality of life. Donor families are advocates for improved donation opportunities and respecting the generous gift of sight that has been given.

The following key stakeholders were identified as having an important role in advancing the cornea donation and transplantation system:

Primary stakeholders	Supporting organizations
<ul style="list-style-type: none"> <li>• Ocular patients</li> <li>• Donor families</li> <li>• Eye banks</li> <li>• Transplanting ophthalmologists and related eye care professionals</li> <li>• Hospitals and health authorities</li> <li>• Organ donation organizations</li> <li>• Health-care professionals, end-of-life care teams, and those involved in non-hospital deaths</li> <li>• Canadian Blood Services</li> <li>• Héma-Québec</li> <li>• Canadian Eye and Tissue Data Committee</li> <li>• Canadian Ophthalmological Society</li> <li>• Canadian Donation and Transplantation Research Program</li> </ul>	<ul style="list-style-type: none"> <li>• Provincial and territorial governments/Ministries of Health</li> <li>• Regional health authorities</li> <li>• Health Canada</li> <li>• Organ Donation and Transplantation Collaborative</li> <li>• Canadian Standards Association</li> <li>• Public Health Agency of Canada</li> <li>• Lions Eye Bank</li> <li>• Canadian National Institute for the Blind</li> <li>• Vision Loss Rehabilitation Canada</li> <li>• Canadian Society of Transplantation</li> <li>• Eye Bank Association of America</li> <li>• Global Alliance of Eye Bank Associations</li> </ul>

### Government partnership

The optimal functioning of a corneal donation and transplantation system is contingent on both funding and effective partnerships with provincial and federal levels of government, eye banks, organ donation and transplantation community and other non-governmental stakeholders. To be effective, these

partnerships should involve a commonality of purpose wherein all parties are contributing to a shared agenda.

Working collaboratively to engender both community and political will is required to provide material support for these initiatives.

### **Public awareness and professional education**

Improving public awareness and support for cornea donation is crucial for system improvement. Consistent messaging and sharing patient stories across the country would illustrate both the need and the importance of vision for ensuring quality of life.

Enhanced education for health-care professionals is also critical for optimizing tissue donation and transplantation opportunities. Hospital and end-of-life care professionals require consistent training in relation to cornea donor identification and referral practices. Donation coordinators and eye bank staff require consistent effective request training to improve the quality of cornea donation conversations and consent rates.

In addition to optimizing existing organ donation organization and eye and tissue bank infrastructure and programs, Canadian Blood Services' professional education and public awareness resources were identified as an area where existing infrastructure could be optimized.

### **National research network**

Enhancement of existing, and development of new, cornea research strategies and collaboration would; enable formal and informal communication of research and innovation, facilitate the alignment of resources, and promote advancement of eye bank research and technical development. Capturing research data and results would also be important for identifying current gaps and future research opportunities.

The Canadian Donation and Transplantation Research Program was identified as a key research partner in which existing infrastructure and resources could be optimized in collaboration with the eye and tissue community.

## **Next steps and future direction**

This forum was the first time in the past 10 years that the members of the Canadian cornea donation and transplantation community have been assembled to determine gaps in the Canadian system; identify barriers and facilitators for change; and develop recommendations to improve access to, and equity in, cornea transplantation in Canada. The expert guidance developed during this forum is the first step in a broader consultation process to advance system improvement in cornea donation and transplantation in Canada.

Forum participants recognized the importance and key role families and patients must play in advancing the proposed vision and mission and for seeing improvement in equity, access and outcomes for patients across Canada. It is with their passion, experience, voice and dedication that the community will be galvanized into taking action and developing a concrete plan for realizing this bold vision.

The participants also recognized that the success of any initiatives proposed should not be dependent on an initial funding infusion, particularly given the resource strain currently being experienced throughout the Canadian health care system. A strategic approach is therefore required that first optimizes the existing infrastructure and expertise. Proven successes will demonstrate the value of moving forward with additional system development initiatives, at which time supplementary resources will need to be introduced to continue to build on these established successes.

As an anticipated outcome of the forum, the forum planning committee is advancing three distinct manuscripts to publication as an initial step in advancing this work within the greater community.

Canadian Blood Services in collaboration with the Canadian Ophthalmological Society and the Canadian Donation and Transplantation Research Program will convene a forum implementation planning committee to develop an action plan for considering and implementing the recommendations from this report. This committee will engage additional stakeholders develop recommendations to improve access to, and equity in, cornea transplantation in Canada. They will develop a clearly articulated strategic framework that is oriented to include the direct contributions of patients and donor families.

Additional working groups may be formed to further discuss and advance implementation tactics in the areas of governance and stakeholder engagement, optimization, interprovincial sharing, evidence-based practice and data, and professional and public awareness and education.

Participants in the room described the forum as transformational. The vision, evidence-based consensus, excitement and strategy brought forth by the key leaders and partners has a momentum that the community will continue to embrace. Implementation of the forum guidance and achieving system improvements requires further engagement of key stakeholder communities including governments. The community must work in collaboration as it begins to advance guidance to solutions, proposals and policy.

There was universal commitment from forum participants, donor families, recipients and community partners to maintain the momentum of this collaboration in advancing system change. Though services are delivered provincially, we can build a national, system-wide approach to cornea donation and transplantation in Canada. The primary features of an exceptional cornea donation and transplantation system identified here will not only guide execution of the goals identified, it will inform further development of a Canadian system that seeks to eliminate cornea waiting lists and corneal blindness in Canada.

**Figure 1:** Primary features of the ideal cornea donation and transplantation system in Canada.





## Appendix 1: Participant List

### Planning Committee

Debra Beck	Medical Writer Toronto, Ontario
Mike Bentley	Manager, Provincial Initiatives, Alberta Health Services Edmonton, Alberta
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Dr. Clara Chan	Medical Director/Ophthalmologist, The Eye Bank of Canada, Ontario Division Toronto, Ontario
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## Appendix 2: Participant Evaluation

### Forum participants and responses

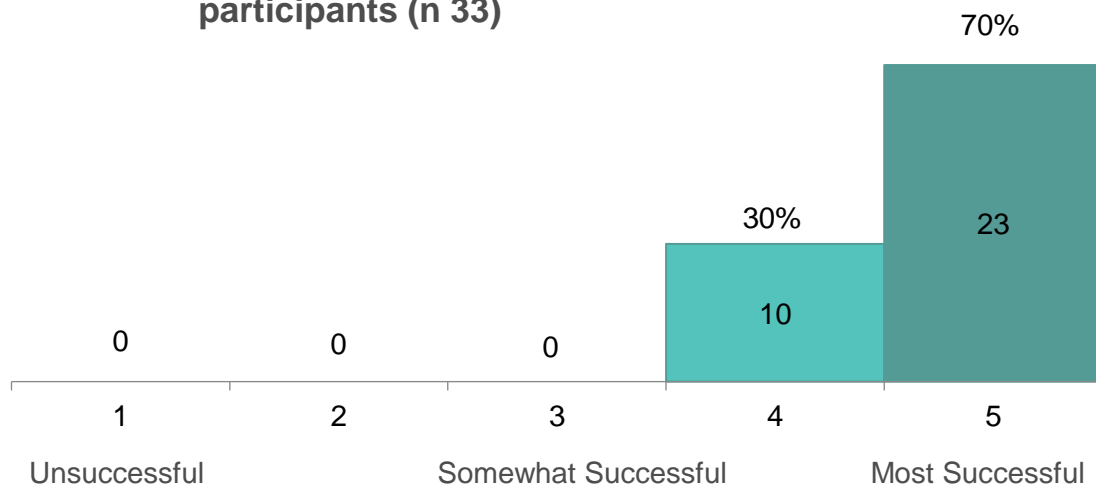
In total, 44 participants took part in the forum, in addition to 10 Canadian Blood Services representatives, support staff and the meeting facilitator. Feedback about the forum was solicited from the 44 participants at the close of the second and final day of the event. In total, 77% of the participants (n=34) formally provided feedback on the forum through anonymous feedback forms.

### Overall ratings

*“Overall, how successful was this forum in meeting its objectives and your anticipated outcomes?”*

Of the 33 participants who responded to this question, 23 (70%) rated the event’s success a 5 out of 5 rating, with the remaining 10 responding participants rating it at 4 out of 5. The overall average for these responses was 4.7 out of 5.

**Rating of overall success from responding participants (n 33)**



### Specific Forum Feedback

*“What did you like most about the forum?” / “What did you like least about the forum?”*



All 34 respondents indicated that there was at least one aspect of the forum that they liked; however, 12 (35%) of the participants who provided feedback indicated that there was nothing they liked least or did not indicate that they disliked any element of the forum (many of whom answered with the word “nothing.”)

The most frequently cited theme among positive elements of the meeting was the level and opportunity for networking, communication, and collaboration (idea sharing), with 22 (65%) of the 34 respondents mentioning this in their responses. Participants also appeared to appreciate the activities during the forum, with 12 respondents (35%) expressing a positive opinion of them, nine of whom specifically cited the World Café sessions as being of value. Seven respondents (21%) cited having a concrete

plan/action items/next steps for "maintaining momentum" or "moving forward" in general among the aspects they appreciated.

Another theme that was mentioned by half of those providing feedback was representation: 13 of the respondents presented a positive opinion on the representation at the forum, including eight who specifically noted the value of having patient and donor family involvement in the forum. Four respondents indicated their desire for broader stakeholder representation.

Additional feedback related to the length of the meeting with 8 respondents (24%) indicating that they felt the meeting was too long and at some points repetitive. One participant specifically noted the "forum was very well organized (beginning with first contact) in terms of content and timing (no wasted time)."

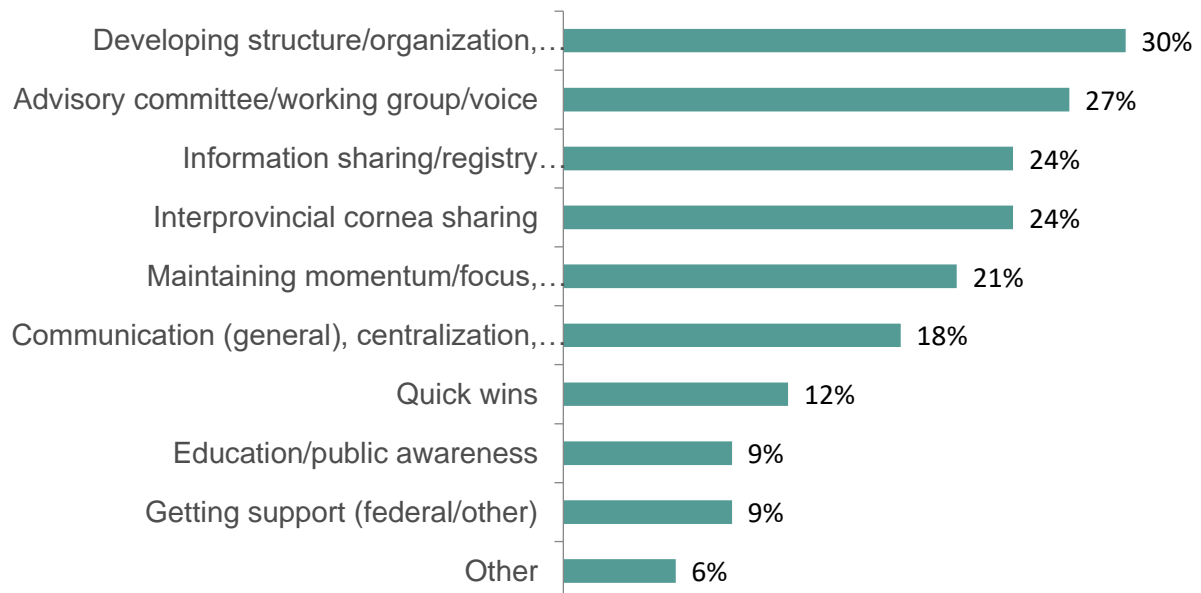
## Important Areas of Focus

*"What is the most important one or two things we should focus our efforts to moving forth?"*



Respondent feedback from 33 forum participants reflected a variety of priorities that the participants felt should be the focus of the work to follow as a result of the forum. Overall, 10 respondents (30%) felt that developing a structure/organization, planning, and/or following through on plans/processes should be among the top priorities to focus on. Similarly, nine respondents (27%) specifically indicated that forming an advisory committee, working groups, or other similar mechanisms to allow for a national voice for cornea donation and transplantation should be an area of focus. Fourteen (42%) of the 33 participants who responded on this item felt that interprovincial cornea and/or interprovincial information sharing should be an area of focus.

### Areas of focus by % of respondents proposing



"Other" includes increasing donation and "patient and provider focus side by side"

Taken together, 27 (82%) of the 33 respondents identified at least one of the topics above as an area of focus coming out of the meeting. Responses provided by the remaining six responding participants which were more abstract (such as “communication,” “to carry this momentum”, “moving forward”, “eye on the ball”, etc.) were generally consistent with these goal areas.

## Gratitude and support



Although this was not specifically incorporated into the structure of the feedback form, 68% of respondents chose to express their appreciation and gratitude to the forum organizers in their comments, with a few specific mentions of the facilitation.

“

Thank you to all the organizers!! □ Thank you! Very informative 2 days - very friendly group □ Very grateful to be here □ Well planned, excellent conference □ Excellent planning (& summaries on each theme) leading to a successful and productive 2-day meeting. Logistics, facilities, food (& Networking meeting) = A++ □ Thank you for the work that has gone out to get this organized □ Excellent facilitation □ Thank you for your efforts on behalf of donor and recipient families □ Very well organized; Good job CBS! □ Well done! Thanks for organizing □ Thank you extremely professional well run. Great use of my weekend! □ Thank you for this opportunity □ This was a success! □ Thanks □ It was great to be part of this forum; keep up the good work □ Thank you □ The facilitator was excellent and propelled us forward and kept us focused. David Kardish rocks! □ Great workshop, thank you! □ Thanks, we were long overdue for this; now there is real hope that change will happen, then things will progress □ A great chance to become familiar with the community and highlight some needs/wants in the community - thanks for the invite!! □ Great learning experience □ Well done. Excellent Session. I'm positive and excited for you.

”

## Appendix 3: Patient Partner Feedback

To provide ample opportunities for Canadian Blood Services to better understand and be responsive to the needs and perspectives of patient partners, a specific questionnaire for patient partners was shared. Anonymized results from the questionnaire for patient partners are summarized here.

### Patient partner questionnaire overview

Patient partner questionnaire responses were received from all five patient partners who participated in the forum, with each having provided a response to each of the following questions:

#### *Recruitment:*

1. What were your main reasons for agreeing to be part of this initiative?

#### *Preparation prior to the forum:*

2. What are your views on the training provided during your engagement? Did the training you received prepare you adequately for your role as a patient or family partner for this initiative?

#### *At the consensus building meeting:*

3. What, if anything, was done well to support you during your participation in the 2-day meeting?
4. What, if anything, do you feel should be done differently to support patient and family partners participate in similar initiatives in the future?
5. Do you feel that you had enough opportunity to contribute personally to the discussions at the meeting?
6. Do you feel that the inclusion of patient and family partners as participants at the meeting made a difference to the outcomes of the meeting?

#### *Overall experience:*

7. What is your overall impression of your experience as a patient or family partner for this initiative?
8. Did you feel that you personally benefitted from your participation? Please explain.

Patient partners were also given the opportunity to provide additional comments if they chose to do so.

### Recruitment

Results suggest that there were a variety of factors that motivated patient partner participation in the forum, including:

- Interest in the field and in learning about corneal transplant processes;

- Gratitude, both towards the donors and their families and toward the medical professionals involved in transplantation;
- Promotional opportunities, including specifically publicizing donor/family stories, and contributing to the promotion of organ/tissue donation in general; and
- An interest in having patient interests broadly represented in the discourse despite barriers to accessibility.



These factors may serve as appropriate focal points for targeted patient partner recruitment for similar initiatives in the future. For instance, potential patient partners may be receptive to recruitment messaging focusing on learning, expressing thanks, telling one’s story and having a voice.

### At the consensus building meeting



In relation to the preparatory training and support that was provided to patient partners both before and during the event, the responses received reflected a consistently positive impression on the part of participating patient partners.

Four out of the five partners specifically expressed that they felt that nothing could have been improved with respect to the support they received during the event, and multiple patient partners expressed the opinion that the pre-forum training and preparatory materials were of high quality and value. All respondents indicated that they had a positive opinion about the training they received, with one respondent indicating that they found the entire event to be educational.

One aspect of the support they received that was particularly appreciated was their being made to feel welcomed, valued, and included during the event, an attitude that was reflected not only in the interactions with other participants but in the organization of the forum. For instance, one patient partner noted that timing the event to have patient partners address the forum near the start of the first day and share their thoughts as the final presentation on the last day, in addition to physically locating the patient partners in the center of the event space, reinforced the centrality and importance of their contributions. As one respondent put it, “I felt I was not just an add-on but an important member of the various discussions.”



It was suggested that a question and answer session for patient partners may have added value to the meeting and that it may have been helpful to have the patient partner stories written out in advance; nevertheless, all five patient partners felt that their inclusion as participants in the meeting made a difference to the outcomes of the meeting, particularly with respect to focusing on or reinforcing the importance of corneal tissue donation and the impact of this gift on the lives of transplant recipients.

Four out of the five patient partners felt that they had sufficient opportunity to contribute personally to the forum’s discussions; however, in some cases respondents felt that the technical nature of the discussions limited the degree to which they could participate. Despite this concern, the patient partners

found every topic of the event to be beneficial and educational for them and valued having the opportunity to listen to others' comments and contribute where they felt comfortable.

Repeated references were made to the support they received from the senior manager who acted as the liaison for patient partners, with three of the five patient partners including an unsolicited expression of gratitude for her support specifically in their feedback.

## Overall experience



All five patient partners responded that they had a positive overall impression of their experience in the forum and felt that they personally benefitted from their participation.

The general reasons for their feeling this way mirrored the factors that motivated their initial participation, with respondents principally citing their having learned a great deal during the forum and expressing an appreciation for having the opportunity to contribute to tissue donation in Canada. Additionally, patient partners valued the opportunity to connect with the other forum participants and one another.

Overall, the feedback provided was consistently positive towards all aspects of the forum, with emphasis on the communication surrounding the forum, the event's facilitation, and their individual participation in it.

"Thank you for allowing me to share our story....my loved one's story. If you only knew how important this is to me; not only does it allow my loved one's legacy to live on, but it helps with my grieving. Thank you from the bottom of my heart. My family thanks you as well."

-Quote from patient partner,  
*modified to preserve anonymity*



## Appendix 4: World Café Think Piece – Demand

### Challenge statement

Current demand for corneal transplantation in Canada can be defined by the number of people consented and actively awaiting surgery. To date, there is no robust way to determine the exact number of patients actively waiting surgery across Canada. Eye banks and half of transplant ophthalmologists reported challenges in meeting demand. However, 49% of ophthalmologists indicated they did not experience any challenges in providing corneal transplantation to meet the demand. Many eye banks report that their waitlists may not be accurate (those no longer needing transplants have not been removed; those who need transplants may not yet have been listed). True demand is likely higher than estimates. In our nationwide survey, 60% of ophthalmologists and 66% of eye banks believe that there is unmet/unknown demand, defined as patients not being referred for corneal transplantation due to their age or perception that there are not enough donors.

### Outcomes and advances in surgical techniques

The demand for corneas for transplantation is increasing on a yearly basis in Canada. This may be attributable to an overall aging population and to refined surgical techniques which allow for better outcomes, wider indications for surgery, and shorter surgical times. Canadian data show that despite increasing donor referrals there has been no significant change in the supply of corneas produced for transplant in Canada over the last five years. In 2018, there were 53,925 deceased donor referrals and 4,469 ocular tissue recoveries. Trends in type of keratoplasty show an increased in DMEK (in 2018, 41% of all EK was DMEK) and DALK, a decrease in PKP, while DSAEK has remained stable.

Improved DMEK outcomes may expand the indications for corneal transplantation, thereby increasing demand. Preloaded DMEK tissues may allow for better time efficiency in some hospitals, thereby allowing for more cases to be completed. However, since the criteria for tissue suitability are stricter with DMEK than with other types of corneal transplants, it may not always be possible to fulfill the tissue needs at any given time. On the other hand, performing DALK where possible may reduce the demand for high endothelial cell count tissue.

### Forecasting

How do we predict if demand will continue to increase? Forecasting demand is important as it allows for efficient allocation of resources over time. This requires a deep understanding of epidemiology of disease and all factors that may increase/decrease demand, such as new technologies and techniques. Both Ontario and Quebec employ demand forecasting. Ontario looks at overall needs (surgery, teaching/training, research), impact of new procedures (i.e. DMEK), and reviews annual targets yearly in coordination with the Ministry of Health. Quebec recovers tissue to meet the demand; surgeon slates are submitted two weeks in advance. Other provinces may simply be maximizing the tissue recoveries within the constraints of local funding and support.

Although there is no nationwide system to forecast demand, B.C. and Ontario have both reviewed changing trends in corneal transplantation and discussed its impact on demand. Overall, these studies have shown an increase in numbers of corneal transplantation over the years, with partial

thickness transplants (DMEK, DSAEK, DALK) on the rise while a decrease in full thickness grafts is noted.

A proposed methodology for demand forecasting should include:

- a. Identify tissue providers, national and international
- b. A baseline level of tissue distribution
- c. A baseline level of tissue utilization
- d. Other sources of information such as hospital reports, cross referencing opportunity,
- e. Wait list information
- f. Feedback from the surgical community

Based on the information collected, demand forecasting recommendations can be established.

## Prevention

The role of prevention in reducing demand is still controversial. Corneal crosslinking may be expected to reduce the need for corneal transplantation in keratoconus, although recent Canadian literature shows it is still too early to tell. Emerging technologies such as DWEK, Rho kinase inhibitors, endothelial cell culture, novel keratoprotheses, and corneal tissue bioengineering may eventually reduce the demand in specific cases. It may still be too early to assess the true impact of these newer technologies on the demand.

Recent nationwide survey showed that prevention in the form of education (i.e. CTL), CXL coverage, trauma prevention, and early screening/referral could play a role in reducing the demand for transplantation.

Beyond this, better phacoemulsification techniques, machines, and viscoelastics, combined with earlier surgery may reduce the need for corneal transplantation secondary to pseudophakic bullous keratopathy. Improving laser technology may also reduce the need for those with more superficial corneal scarring.

To conclude, the cornea donation and transplantation system will not be capable of aligning supply with demand until it has taken the steps to understand and quantify demand and waiting times, for transplant. An eye bank will not meet the needs of patients if it does not set targets for supply, recovery, and processing which align with demand and their surgeons 'and patients' needs. While there are provinces where meeting demand for corneal transplantation is not a primary issue there are others where patients are waiting for years or are not offered transplantation because of the perception that the waiting lists are too long.

## Café discussion questions:

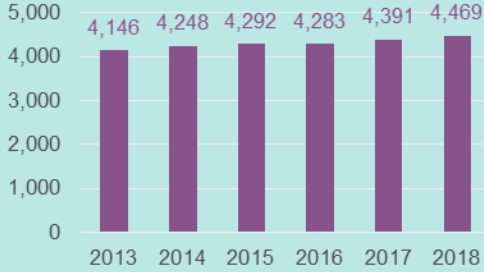
- Define demand for corneal transplantation. How can this be quantified?
- Is it possible to forecast the number of corneas required in the next five years to meet the demand, and do we recommend that demand be forecasted for Canadian programs?
- Current wait list metrics and the process by which waiting lists are monitored vary by province. Should there be a standardized approach within Canada to documenting and managing waitlists?
- What is the role of prevention in demand (CXL, DWEK, better end-of-life eye care)?
- Discuss the impact of current and emerging technologies that may increase or decrease demand.

# Setting the Stage

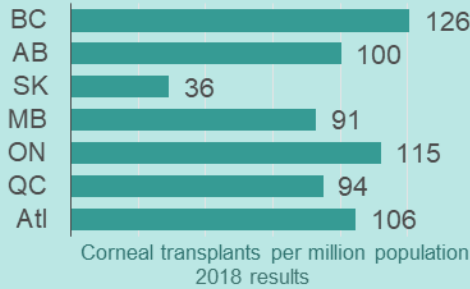
Results from Eye and Tissue Data Committee National Census

Minimal change in cornea donation

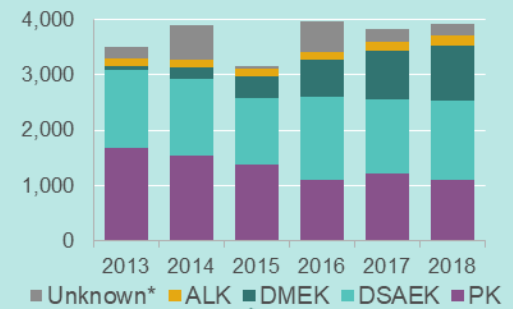
Ocular donors by year



Corneal transplant rates vary between provinces



Minimal change in total keratoplasty



## Unmet/Unknown Demand in Canada

60% of ophthalmologists and 66% of eye banks believe there are patients who are not referred for corneal transplant due to their age or the perception that there are not enough donors.

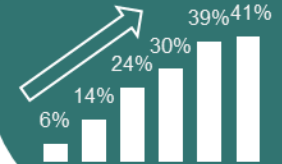
## Challenges

100% of eye banks, 60% of organ donation organizations, and 51% of transplant ophthalmologists reported challenges in meeting demand.

Most significant challenge areas:

- Lack of financial resources to support the eye bank
- Workload of eye bank staff
- Lack of donor referrals
- Availability of operating room time for transplantation

Proportion of EK performed as DMEK



## Looking to the Future

Transplanting ophthalmologists indicate crosslinking will have an impact decreasing demand and to a lesser extent so will DWEK.

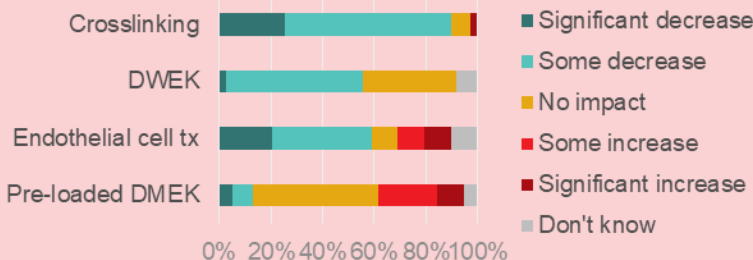
Pre-loaded DMEK and Endothelial cell transplants will result in some increase in demand.

### All eye banks support the development of a national registry

They see a need for, and/or value in, a national registry for corneal transplantation which includes outcome measures, and would support a national registry by providing consistent donation, transplant and outcome data on their corneal patients\*\*

Only Ontario and Quebec engage in demand forecasting to align supply with demand

### Ophthalmologists' Expectations: Impact on Demand



### The Role of Prevention in Reducing Demand

15-18% of ophthalmologists indicated that prevention should or could play a role in reducing Canadian demand in relation to:

- Education/Hygiene
- Crosslinking coverage
- Trauma Prevention
- Early screening/referral/patient identification

13% indicated that they felt prevention could/should play a minimal role and/or noted that dystrophies are not preventable

\*Unknown cases reflect cornea distributions for which the keratoplasty type was not available, and may include non-keratoplasty procedures

\*\*Lion's Eye Bank support is "dependent on the development of the registry (amount of data entry, duplication etc.), data sharing agreements, and the resources"

## Literature Review

### Demand for corneas

Forecasting demand for health services allows for the efficient allocation of resources over time. The process requires an understanding of not just the need for services—in this case, the epidemiology of several corneal diseases and evolving indications for keratoplasty—but also a grasp of new techniques and technologies that may alter the pace or need for the target service. Forecasting ensures that product-line, recovery, production, and distribution planning have a basis in market reality.<sup>1</sup>

Ensuring supply is aligned with demand does not mean all demand is met, nor does it specify the time in which demand for a transplant is satisfied. Aligning supply and demand within the Canadian tissue donation and transplantation systems means understanding production demand, optimizing the use of local and national resources and assets to meet demand, and having mechanisms to address potential risks related to meeting domestic demand.

In our survey of the Canadian eye banking system, only two provinces (Ontario and Quebec) engage in demand forecasting. Just over half of transplant surgeons (59%) and 75% of eye banks believe there is unmet or unknown demand (patients not being referred for corneal transplant due to their age or the perception that there are not enough donors). Only two (5%) of 39 responding transplanting ophthalmologists are aware of or have undertaken demand forecasting for corneal transplantation to planning.

While no attempts have been made to forecast demand in Canada on a country-wide basis, several groups have considered province-specific demand and changing trends in transplantation technique and its impact on tissue demand.

Tan et al, for example, reported in 2014 on the evolving indications for and trends in keratoplasty in British Columbia from 2002 to 2011.<sup>2</sup> They found that overall, the number of keratoplasties rose from 420 in 2008 to 578 in 2011; Fuchs endothelial dystrophy rose to become the top indication for keratoplasty over the 10-year period; and the use of DSAEK (since its introduction in 2007) increased significantly and was supplanting PK for patients with endothelial failure. As well, despite only 30 deep anterior lamellar keratoplasties being performed, an increasing trend was observed after 2008 ( $p=0.0087$ ).

These increases in partial-thickness transplants and resultant decrease in PK has been reported in other places.<sup>3,4</sup> Indeed, 2018 data from the University of Toronto indicated that partial-thickness transplants now account for 85% of all current graft procedures, with DMEK emerging as the “procedure of choice.”<sup>5</sup>

Posterior lamellar keratoplasty is preferred over PK from a cost-effectiveness standpoint,<sup>6</sup> and DMEK has been found more cost effective than DSAEK,<sup>7</sup> but it’s unclear what, if any, effect partial-thickness procedures have on overall tissue demand.

### Are there emerging technologies that will increase or decrease demand?

Corneal collagen cross-linking (CXL) is a minimally invasive, outpatient procedure shown to slow or halt the progression of keratoconus. Corneal CXL uses riboflavin and ultraviolet light to enhance covalent bonding between collagen molecules and increase the strength of corneal tissue making it more resistant to proteolytic enzymes. CXL was first introduced in human clinical studies in 2003 and received EU approval for the treatment of keratoconus in 2006, Health Canada approval in 2008, and U.S. approval in 2016.

The ability of CXL to slow or halt the progression of keratoconus has been demonstrated in controlled trials and suggests that CXL may prevent the need for corneal transplantation.<sup>8</sup> Most studies indicate that CXL likely reduces the need for corneal transplantation due to keratoconus, with reductions ranging from 25% to 53% noted.<sup>9,10,11</sup>

However, these estimates are subject to confounding as it's difficult to separate out the effects of other factors such as improved contact lens design and intracorneal ring segments. Also, the long-term effects of CXL are unclear as are whether the reductions seen in PK numbers might be more due to an increase in endothelial keratoplasty than reduced need for PK because of CXL.<sup>12</sup> A recent Canadian paper on this topic concluded that, while there has been a significant decrease in total transplants for keratoconus since the introduction of CXL, this is likely more due to an increase in endothelial keratoplasty than a decrease in total transplants performed for definitive treatment.<sup>12</sup>

Most studies have shown that CXL is cost effective, but the level of cost-effectiveness is related to assumptions made about the duration of its effectiveness.<sup>13</sup> Godefrooij et al assumed a 10-year effect of CXL and found an incremental cost-effectiveness ratio (ICER) of Euro54,384/quality adjusted life year (QALY), which dropped to Euro10149/QALY assuming a lifelong stabilizing effect for CXL.<sup>14</sup> However, in a sophisticated microsimulation model from 2017 that maximized the potential costs and complications of CXL, while minimizing the potential costs and complications of conventional management of keratoconus, CXL was dominant over conventional management with KP with an ICER of Can\$9090/QALY, well below the well below the range of Can\$20,000 to Can\$100,000/QALY and below US\$50,000/QALY, thresholds generally used to evaluate the cost-effectiveness of health interventions in Canada and the United States.<sup>15</sup>

### **Could tissue engineering and similar technologies reduce demand in the future?**

While CXL may be impacting keratoplasty numbers, there are other technologies in development that also have the potential to reduce demand for corneal tissues. Perhaps the most extreme example comes from a 2018 study by Kinoshita et al that proposes to use injections of human corneal endothelial cells (CECs) supplemented with a rho-associated protein kinase (ROCK) inhibitor into the anterior chamber to increase CEC density.<sup>16</sup> In a small study that enrolled patients with bullous keratopathy, this procedure led to corneal restoration, with attainment of normal corneal thickness and resolution of corneal epithelial edema. Besides being less invasive than endothelial keratoplasty, this technology could markedly decrease the demand for donor tissue as one donor cornea can provide enough cells to treat more than 200 patients.<sup>17</sup>

Other technologies that have shown promise and may reduce demand for corneas longer-term include bioengineered artificial corneas and keratoprotheses<sup>18,19,20</sup>, cell therapies, and gene therapy.<sup>21</sup>

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## Appendix 5: World Café Think Piece – Supply

### Challenge statement

Despite estimated waiting times for elective recipients ranging from three months to more than two years, and despite an aging population which suggests an increasing demand, there has been no significant change in the supply of corneas produced for transplant in Canada over the last five years.

The donation/recovery of corneas for transplantation varies dramatically between provinces from a low of 46 to a high of 188 per million population recovered and released to transplant.<sup>36</sup> The province with the lowest donation rate has the longest estimated transplant waiting times of more than two years for non-urgent patients. Most provinces have, at some point, purchased corneas from the United States to supplement their supply. In 2017, 8% of all corneas transplanted in Canada were purchased from the U.S.

In the last five years the number of organ donors in Canada increased by 38% while the number of tissue donors increased by only 5%. This significant increase in organ donation occurred in an environment where the number of potential organ donors are a fraction of the number of potential tissue donors. A 2014 analysis of acute care hospitals admissions, using strict donation criteria of age <60 estimated 9,000 potential cornea donors in hospital deaths annually<sup>37</sup>. With 4,500 cornea donors in 2018 this indicates a ready source of missed donors to increase supply. It is important to note the number of potential cornea donors in Canada would far exceed the demand if all were realized.

If the complex barriers to organ donation can be breached, so can the barriers to cornea donation. Eye banks, organ donation organizations and transplant ophthalmologists all identify the lack of eye bank financial resources to support cornea recovery and processing as a primary barrier to supply. Fully, 63% of eye banks identify a lack of compliance in the identification and referral of potential cornea donors as a primary barrier as well, with missed donation opportunities having a significant impact on their ability to meet demand. Less than 50% of provinces include cornea donation in donor/death audits to identify missed donation opportunities. A key recommendation of the 2011 *Call to Action* was enhanced collaboration of Canadian Blood Services and community partners to develop more effective mechanisms to identify and refer potential tissue donors and for the system expand its tissue recovery capacity.<sup>38</sup>

The ocular community identified the following approaches to breach the barriers to increased donation and supply: improving public awareness and support for cornea donation; professional education for critical care and end-of-life health-professionals in donation identification and referral to reduce missed donation opportunities; training coordinators and eye bank staff in effective requesting to improve consent rates; and financial resources to ensure capacity to recover, process, and distribute corneas to supply demand. Almost half (44%) of banks indicate that with appropriate resources they could increase production within their current infrastructure to a surplus and provide supply to other provinces.

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<sup>36</sup> Canadian Blood Services 2020, Canadian eye and tissue banking statistics 2018; A report of the eye and tissue data committee.

<sup>37</sup> Canadian Blood Services, 2014, Estimating Potential Tissue Donors in Canada <https://profedu.blood.ca/sites/mtsi/files/Estimating-potential-tissue-donors-in-Canada-from-2005-2008-An-update-based-on-acute-care-hospital-admissions-data-January.pdf>

<sup>38</sup> Canadian Blood Services, 2011. <https://profedu.blood.ca/en/call-action>

To date, there is no robust way to determine the exact number of patients actively waiting surgery across Canada. In fact, several eye banks have no insight into the demand for corneas or the length of waiting lists in their provinces. The cornea donation and transplantation system will not be capable of aligning supply with demand until it has taken the steps to understand and quantify the demand and waiting times for transplant. An eye bank will not meet the needs of patients if it does not set targets for supply, recovery and processing which align with its surgeons' and patients' needs.

Six of nine Canadian eye banks have responded to the significant and increasing demands for a supply of DSEAK corneal grafts by implementing this processing capability. Four of nine eye banks are currently processing DMEK grafts. However, significant processing continues to occur by ophthalmologists in the operating room. Over 80% of ophthalmologists indicate that eye banks should process all DSEAK and DMEK tissue for transplantation, eliminating the need to use valuable OR time for this work. Emerging technological advances will require eye banks to take on more complex processing/production activity. A key recommendation of the 2011 *Call to Action* report was to consolidate existing Canadian tissue processing activities into a smaller number of higher volume processing facilities to make the system more efficient and better able to meet the needs of Canadian patients.<sup>3</sup>

All Canadian eye banks use hypothermia as a storage method as compared to storage in organ culture, a methodology more commonly used in Europe that extends the length of time corneas can be stored prior to transplant, theoretically increasing utilization and supply. Currently no Canadian banks are pursuing this methodology; it may be an area for further research and discussion.

An adequate supply of corneas will be of little use if there is no capacity to transplant them. A lack of operating room time is identified as a primary barrier to cornea transplantation. To advocate for additional operating room time, eye banks and transplant programs must be able to illustrate demand and the challenges to access in relation to waiting times and the impact on our patients' quality of life and functional status to make a case for the allocation of OR resources. Governments must also consider the compensation structure for corneal transplantation. When other ophthalmological procedures provide greater physician compensation there may be a financial disincentive to performing corneal transplants.

### **Café discussion points:**

- To manage supply, we must understand and quantify demand.
- Supply is only one barrier to meeting demand; access to operating room time is a key barrier which requires assessment and mitigation.
- Procedure compensation may be a disincentive to transplantation and requires assessment.
- Supply targets, both national and provincial, for cornea donation and processing are needed and progress to targets needs to be monitored.
- Interprovincial sharing of corneas should be encouraged, as programs with the capacity to rapidly increase production could address gaps in programs with less capability.
- Collaborations within a centers of excellence models should be considered as increasing demand for complex processing of corneal tissue will increase the capital, staffing and expertise requirements of all eye banks and present significant challenges to smaller programs.



## **Café Discussion Questions:**

### **Should Canada be self-sufficient in its supply of corneas rather than bridging the gap by increasing importation from the United States?**

If the consensus is yes, should supply, donation and processing targets be established for increased production with a goal of self-sufficiency?

How should these targets be established?

### **What strategies should be prioritized and resourced to increase/align supply to demand?**

- **Cornea Recovery Capacity**

Should programs with capacity be incentivized to overproduce to supply programs with shortfalls, or should the focus be that all provinces resource their internal programs to supply their provincial demand?

- **Cornea Processing Capacity**

Should we shift to a collaborative center of excellence model, or should the focus be for all provinces to develop capability for complex processing?

- **Operating Room Capacity and Procedural Compensation**

Should national access/transplant targets be established to encourage provinces to align surgical resources to meet targets, or should the establishment of targets be left to provincial discretion?

- **Public Awareness**

Should public awareness campaigns include a distinct focus on cornea donation, or are the current campaigns sufficient in their general approach to tissue donation?

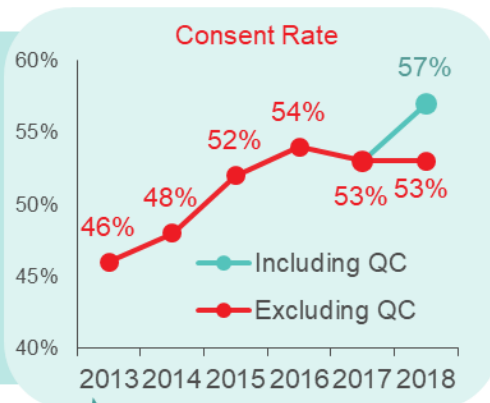
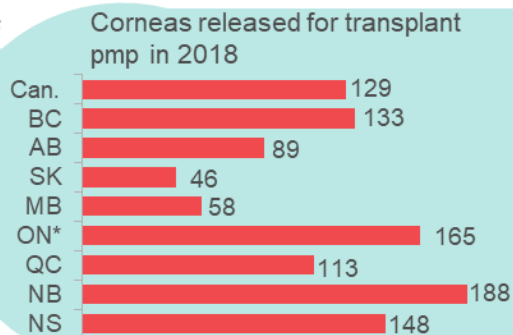
- **Donor Audits to Reduce Missed Donation Opportunities**

Should all provincial donor audits include an audit of cornea donation potential, or should the audit of cornea donation potential be left to the discretion of the province?

# Setting the Stage

Results from Eye and Tissue Data Committee National Census

**Cornea release rates range between provinces from <50 per million population (pmp) to >180 pmp.**



## Referrals and Consents

All provinces, except SK, PE and NL, have mandatory referral or similar legislation for both organ and tissue. NS has legislation pending.

### Barriers to making or accepting referrals:

- Lack of resources/staffing, budgeting for staff & varying availability to address referrals
- Educating healthcare providers on donor identification, referral, and mandatory consideration
- Having trained retrieval teams in outlying communities

Consent rates have been increasing, but 43% of consent approaches are not successful

**44%** of eye banks indicate consent rate significantly impacts their ability to meet the demand for corneas

## Public Awareness

**80%** of organ donation organizations

indicated their public awareness campaigns have no specific focus to ocular donation.



**78%** of eye banks indicate further training in effective requesting will improve consent rates, as will monitoring individual team member performance to identify areas for improvement/training.

### Barriers to Meeting Demand

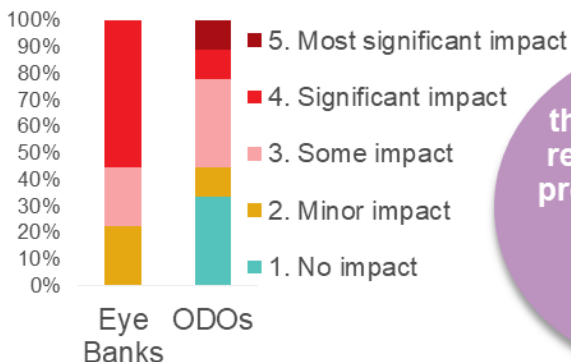
Transplanting ophthalmologists identified a **lack of access to OR time** and a **lack of financial resources/compensation** as primary barriers in meeting demand



## Recovery and Missed Opportunities

**55%** of eye banks report missed donation opportunities have a significant impact on their ability to meet demand.

Only 22% of donation organizations indicate missed opportunities as having a significant impact.



**63%** of eye banks reporting identified the lack of recovery staff as a significant factor in not recovering potential donors

### Service Coverage

33% of eye banks recover ocular donors from all hospitals in their province while 55% limit recovery to specific hospitals or geographic regions

**Four (44%) of the nine eye banks report there are NO provincial metrics in place to assess hospital ocular donor referral performance.**

- All/most hospitals in our region
- Hospitals in specific geographic regions
- Only from the eye bank's urban centre (or those transferred to it)
- Other\*\*



\*Ontario does not determine intention for transplant prior to recovery; Ontario results reflect all cornea/globe recoveries.

ETDC national census results indicate that there were no cornea recoveries from PEI donors in 2018.

\*\*Other: Lion's Eye Bank (Alberta): "We recover for donors within Southern Alberta. For those outside of Calgary, Medicine Hat and Lethbridge, we consider all options to facilitate donation in a local facility near the donor/donor family to support ocular donation and our team will travel to them."

## Literature Review

### How can we increase the supply of corneas for transplant?

The reasons potential cornea donors decide for or against donation are complicated and beyond the scope of this discussion. However, several strategies have been shown to improve donation rates, including educational efforts geared towards adjusting the donation message to be more congruent with the real, lived experience of corneal donation,<sup>1,2</sup> and understanding the barriers healthcare professionals with direct clinical contact with dying patients have to discussing donation.<sup>3,4</sup>

Switching from whole globe enucleation to in-situ corneoscleral disc excision has been reported to improve donation rates, (and after a transient learning curve, provide similar cultivation performance and clinical results).<sup>5</sup>

Failure of clinical staff to identify and refer potential donors is a known factor that militates against increasing donation rates. Legislation requiring mandatory referral of potential donors has been a successful strategy for increasing donation rates, both for tissues and organs.<sup>6-9</sup> Routine notification and request (RNR) increased corneal tissue availability by 25% in Ontario when it was implemented in January 2006.<sup>7</sup> Increases were even greater in other provinces that had less established tissue donations systems. These increases were associated with significant decreases in waiting time from time of diagnosis to corneal transplantation. Electronic clinical decision support may facilitate this process and increase donation rates.<sup>10</sup> Whether the bumps in donation rates that have been reported are sustainable in the long-term is unclear.<sup>11</sup>

Recognizing that deceased organ donation rates in Canada remain below their predicted potential, a national consensus conference was held in 2016 focused on improving deceased donor identification and referral and health system accountability. While this conference was focused to organ donation, the recommendations seem applicable to cornea and tissue donation as well. Among the consensus statements generated were three aimed to health-care professionals:<sup>12</sup>

- 1) *Donation should be consistently addressed as part of end-of-life care but only after a decision to withdraw life-sustaining treatment;*
- 2) *HCP know how and when to identify and refer potential donors; and*
- 3) *transplant candidates be informed of local allocation guidelines and performance.*

*Recommendations directed at the health care system level included:*

- 1) *national adoption of clinical criteria to trigger identification and referral;*
- 2) *dedicated resources to match donation activities, including transfer of a potential donor;*
- 3) *performance measurement through death audits;*
- 4) *reporting and investigation of missed donation opportunities (MDO);*
- 5) *recognition of top performers; and*
- 6) *missed donor identification and referral be considered a preventable and critical safety incident.*

### Preparation and processing of tissue for corneal transplantation – Survey findings

Availability of pre-cut corneas for split-thickness transplants may be a way of reducing surgical times and increasing efficiency. Based on our survey results, a majority of EK tissue is currently being processed by eye banks and there is strong support for eye bank pre-processing of DSAEK tissues for surgeons. For DMEK processing, there is less consensus but still strong support

Currently, about 70% of DSAEK tissue in Canada is prepared by eye banks and 14% by surgeons. The remainder is a combination of both. For DMEK, the corresponding rates of eye-bank-cut and surgeon-cut tissue is 43% and 35%, respectively.

Fully 89% of eye banks in Canada think they should pre-process all DSAEK tissue for surgeons; 32% of transplanting ophthalmologist agree. For DMEK, 81% of eye banks support providing prepared tissue, while 43% of surgeons support this.

All banks reported that their corneal preservation method is hypothermic storage.

### **Graft preparation for DSAEK and DMEK: Surgeon-cut versus pre-cut**

Traditionally, penetrating keratoplasty (PK) was the gold standard for treating corneal decompensation. In recent years, however, PK is rapidly being supplanted by endothelial keratoplasty (EK), which allows for selective replacement of diseased endothelial tissue. Descemet's stripping endothelial keratoplasty (DSAEK) is currently the most widely used EK method.

DSAEK has several advantages over PK, including better tectonic stability, fewer wound and suture-related complications, and an easier post-operative course with earlier and more predictable visual rehabilitation.<sup>1</sup> It is also preferred by patients.<sup>2</sup> Endothelial cell survival and graft survival at five year post-procedure is similar or better with DSAEK compared to PK.<sup>3,4</sup> With DMEK, a newer procedure in which only the endothelium is transplanted, even better outcomes can be expected.<sup>5</sup>

However, with DSAEK and DMEK, there is an added expense incurred for donor tissue preparation and the possible use of an insertion device (either specialized forceps or a customized device) during the procedure. In a cost-effectiveness study, DSAEK was found to be preferred over PK by a large margin, although both procedures readily meet the World Health Organization threshold for a cost-effective intervention.<sup>6</sup>

Several studies have looked at whether pre-cut and surgeon-cut tissue are of similar quality and offer similar outcomes.<sup>7</sup> Price et al conducted an elegant study that randomly assigned one cornea from each of 20 pairs of retrieved corneas to be pre-cut at an eye bank for next-day use or surgeon-dissected intraoperatively using a comparable microkeratome and protocol. The corneas were randomly assigned to 40 subjects having DSAEK. No differences were noted for endothelial cell loss, visual and refractive outcomes, or detachment rates between groups.<sup>8</sup>

Similarly, in 119 consecutive eyes treated with DSAEK, Ragunathan showed no differences in complication rates between pre-cut and surgeon-cut organ cultured donor corneas. There were also no correlations between BCVA and central graft thickness or graft asymmetry index in the two groups.<sup>9</sup> Hofmann et al looked at the risk of re-graft and found that pre-stripped donor corneas for DMEK not only simplified the technique for the surgeon and reduced costs, but also appeared to reduce the rate of re-graft compared to surgeon-prepared tissue (4.1% vs. 10.8%; no p-value given).<sup>10</sup>

In another study, conducted at a low-volume Canadian eye bank, mean ECD after dissection of DSAEK tissue was only 34 cells/mm<sup>2</sup> less than before dissection, confirming that ECD is preserved when DSAEK tissue is prepared in advance of surgery by trained technicians.<sup>11</sup>

Since Descemet's is a delicate membrane, the preparation of a donor graft for DMEK can be challenging for the trained eye bank technician and the ophthalmic surgeon alike. In a 2019 paper on eye bank-supplied DMEK tissue, Ostrander et al found significant variation in the amount of experience and the comfort levels U.S. eye bank technicians reported for DMEK processing. More than half (58%) reported that peeling and 42% said marking was "extremely difficult" or "somewhat difficult." About half (46%) of respondents to the survey said they had between one and three years of experience preparing DMEK grafts and only 12% had less than one year of experience.

One issue to consider is the relative costs of surgeon-cut versus pre-cut tissue. Yong et al conducted an economic evaluation of pre-cut cornea grafts in DSAEK and found that highest cost was associated with the surgeon-cut approach (\$13,965 per procedure), followed by purchasing pre-cut corneas from an eye bank (\$12,659), followed by eye-bank pre-cutting (\$12,421).<sup>12</sup> Procedural volume, of course,

had an impact, but they found that as long as case volume exceeded 290 cases annually, eye-bank preparation of tissue was the most cost effective option. It should be noted that this study was conducted at the Singapore National Eye Centre and Singapore Eye Bank and costs were converted to US dollars. Procedure costs were based on charges for nonsubsidized Singapore citizens as of June 2014. Singapore public hospitals operate on a cost recovery basis, so these charges reflect the true costs (including fixed costs). Pre-cut purchased tissue was assumed to come from SightLife in Seattle and included shipping and storage.

Since surgeon are ultimately responsible for transplantation, they should be involved in eye-banking practices and advocate for continued research into this area.<sup>13</sup>

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## Appendix 6: World Café Think Piece – Access

### Challenge address

#### What is an appropriate waiting time to receive a corneal transplant in Canada?

National standardized comprehensive data are available on corneal transplant surgery and cornea donation.<sup>39</sup> There are currently no comprehensive data on demand (the number of patients waiting for corneal transplant) or access (their waiting time), no standardized process to collect these data, and no formal reporting of demand, waiting times or benchmarks for access. While there are no systems in place to quantify demand and access, surgeons and eye banks have provided estimates on waiting times.

In our most recent environmental scan of Canadian eye banks and transplanting surgeons, two key factors were identified in terms of access to corneal tissue: allocation of tissue and waitlist management.

- 40% of ophthalmologists indicate referral times for transplant assessment require improvement.
- 44% of eye banks rate access to corneal tissue as poor.
- 19% of transplanting ophthalmologists rate access to corneal tissue as poor.
- 45% of ophthalmologists and 75% of eye banks indicate that wait times for corneal transplant require improvement.
- Estimates for waiting time for non-urgent patients vary from one to three months to more than two years depending on province.
- Estimates for waiting time for urgent patients vary from less than one month to more than six months depending on province.

#### Consider the following examples:

- 1) An 82-year-old retired male, with poor mobility and cardiovascular issues is at the top of a surgeon's waiting list, after a one year waiting period since the first surgical consultation. The eye in question has guarded prognosis, and the other eye has functional vision of around 75%. He does not drive, but enjoys watching TV, driving and playing chess.
- 2) A 42-year-old single, working mother of three children has Fuchs dystrophy which compromises vision in both eyes while driving and working as an accountant. She has not developed pain episodes; however, one eye is showing early signs of scarring due to the swelling. She has been on the transplant list for six weeks since her surgical consultation.

If a corneal tissue becomes available, who should receive the tissue first, assuming that the tissue is viable for both surgical procedures being considered?

### Café Discussion Questions:

1. How should success in terms of access to corneal tissue be measured? Which metrics or outcome measures should be used? How should 'wait time' be defined?
  - Wait time is most commonly defined relative to the date patient is seen in consultation by a transplant ophthalmologist and placed on the transplant waiting list; a minority indicate that they define it based on the date of referral to ophthalmologist for transplant assessment.

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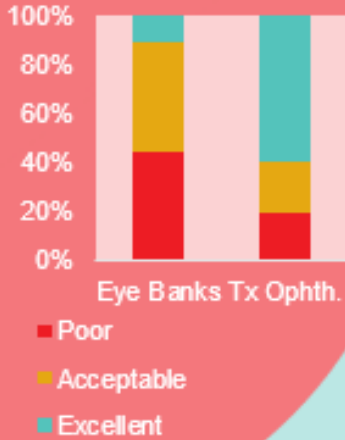
<sup>39</sup> Canadian Blood Services 2020, Canadian eye and tissue banking statistics 2018; A report of the eye and tissue data committee.



- 85% of transplanting ophthalmologists report that patients are able to be seen in consultation in less than 6 months; 15% indicate wait times of up to two years.
2. Priorities: Emergent, Urgent, Elective.
    - 33% of the ophthalmologists indicate that non-urgent patients wait between one and two years for transplant.
      - a. Should benchmarks for access be established? Should a four-level priority system be used, such as in Ontario?
      - b. Should patient selection criteria be defined and standardized nationally?
      - c. If a province or program is unable to deliver, should the province obtain tissue from elsewhere, including internationally, *no matter what* in order to meet the agreed upon benchmarks?
  3. Should access to corneal transplantation be monitored and reported consistently across Canada?
  4. Allocation:
    - a. Should all provinces and programs work under the same allocation criteria nationally?
    - b. Should there be a centralized provincial or national waiting list?
    - c. What is the role of donor characteristics in allocation? Would more flexible acceptance criteria make more tissue eligible for patients further down the list?
    - d. What is the role of recipient characteristics such as age, occupation, degree of disability, ocular comorbidities (scarring, bullae, pain), systemic health in allocation?

## Allocation

How do you rate your access to corneas for transplantation?



**44% of eye banks and 19% of transplanting ophthalmologists rate access to corneas as poor**

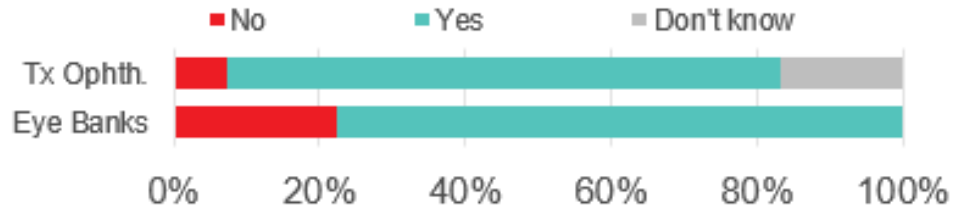
All eye banks reported having an established process to allocate corneas.

**22% of eye banks do not believe the cornea allocation process is fair and equitable.**

Less than 25% of transplanting ophthalmologists surveyed believe that patient specifics and wait time were a factor in allocation decisions.



Do you feel the eye bank's allocation of corneas for transplantation within your region is fair and equitable?



## Waiting List Management

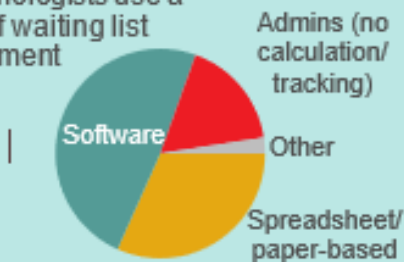
**45% of ophthalmologists & 75% of eye banks indicate wait times for corneal transplant require improvement**

Eye banks estimate wait time for non-urgent patients varies from 1-3 months to more than 2 years depending on province

85% of transplanting ophthalmologists reported that patients are seen in consultation in less than 6 months, but 15% indicate wait times of up to 2 years

**One-third of ophthalmologists surveyed indicate their non-urgent patients wait longer than one year for transplant.**

Transplanting ophthalmologists use a variety of waiting list management systems



Most respondents indicated that waiting times of <1 month would be appropriate for emergent patients and waiting times of <3 months would be appropriate for urgent patients, **but 20%-25% of ophthalmologists believe that these patients are not accommodated in that time.**

Classifying a patient as urgent (requiring prompt action) or emergent (requiring immediate action) is commonly based on these factors:

Bilaterally blind  
Persistent debilitating pain

Infection  
Perforation

**89%** of transplanting ophthalmologists believe there are enough transplanting ophthalmologists in their respective provinces to provide appropriate access to corneal transplantation ("don't know": 3%)



## Literature Review

### How do different countries (or provinces) manage access and allocation?

#### The United Kingdom

In the U.K., clear and concise policies (less than four pages each) for the allocation and acceptance of corneas for cornea transplantation and patient selection for corneal transplantation have been developed by the Ocular Tissue Advisory Group (OTAG) on behalf of National Health Service Blood and Transplant (NHSBT).

The allocation policy was developed in 2017. At that time there were more than 150 centres undertaking cornea transplantation in the U.K., an estimated 4,000 corneal transplants being done yearly and an estimated need for 4,500 corneas yearly. Selected details from allocation policy<sup>40</sup>:

- There is currently no national transplant list for corneal transplantation; each centre holds its own list locally. Requests for tissue are made by or on behalf of the treating ophthalmologist to Tissue & Eye Services, NHSBT.
- The vast majority of transplants done are non-priority. To allocate corneas fairly to patients waiting for routine, non-priority corneal transplants, OTAG developed a system of corneal allocation on a first come first served basis. In this system, surgeons may request any number of corneas for transplantation but are only allocated more than one cornea if all the primary requests have been fulfilled for that day. Additional requests will then be met providing there are enough corneas for allocation.
- Pediatric patients less than eight years of age have priority over older patients because of the risk of amblyopia.
- There is an “informal” arrangement for age matching, a concern expressed by some, particularly for pediatric patients. Formally, a maximum upper age differential of 30 years was proposed and approved by OTAG.
- NHS Tissue & Eye Services now offer pre-cut DSAEK tissue and there are plans to expand provision of pre-prepared DMEK tissue.

There is a separate policy document for patient selection for corneal transplantation.<sup>41</sup> Excerpts are provided below:

- Criteria for ‘urgent’ classification include:
  - Impending perforation (presence of a descemetocoele).
  - Actual perforation.
  - Loss of corneal tissue leading to exposure of the intraocular contents.
  - Uncontrolled disease that would lead to loss of the eye or unrecoverable loss of vision without transplantation (e.g. overwhelming infection).

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<sup>40</sup> Full policy document available here: [https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/4954/cornea\\_allocation\\_policy.pdf](https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/4954/cornea_allocation_policy.pdf)

<sup>41</sup> The full document (including conditions considered for transplantation, patient selection, contraindications, re-transplant, etc.) can be found here: [https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/4953/cornea\\_selection\\_policy.pdf](https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/4953/cornea_selection_policy.pdf)

- In patients with a high risk of allograft rejection due to prior sensitization, selection for transplantation will first be made according to the anticipated benefit to visual function of a surviving corneal transplant.
- “In the interest of equity and justice all centres should work to the same allocation criteria
- Compliance to these guidelines is expected and non-compliance “will be handled directly by NHSBT...”

## Ontario, Canada

Priority levels and target times for eye surgeries in Ontario are set by surgeons, specialists and health-care administrators across the province, based on clinical evidence, to guide treatment decisions and to improve patient access and outcomes.

Wait times for eye surgeries including cataract, corneal transplant, glaucoma, and vitrectomy (retina) surgeries in Ontario are measured and reported. Those wait times are for two periods. (Data excludes patients who did not have the surgery after their first appointment with a surgeon.)

**Time to patient's first eye specialist appointment:** How long patients waited from an eye specialist or surgeon or central intake office receiving the referral from the patient's doctor, to the patient's first eye specialist appointment.

Priority level of patient's condition	Clinical description	Target time to patient's first specialist appointment
Priority 1	High probability of disease occurrence or progression impacting morbidity or mortality. Intractable agonizing symptoms	Patient sees surgeon within 7 days of referral received
Priority 2	Moderate probability of disease progression. Low probability of disease occurrence or progression impacting morbidity or mortality.	Patient sees surgeon within 30 days of referral received
Priority 3	All patients who do not meet the criteria of Priority 2 or Priority 4	Patient sees surgeon within 90 days of referral received
Priority 4	Minimal risk of disease progression impacting morbidity/mortality	Patient sees surgeon within 182 days of referral received

**Time from decision to having eye surgery:** How long patients waited from deciding with the surgeon or specialist to proceed with the surgery to having the eye surgery. These wait times vary depending on the type of eye surgery. (See table below.)

Priority level of the patient's condition	Target time from decision to having...				
	Cataract, cornea - other, ocular trauma, ophthalmic plastics, orbital surgery, retina - other, strabismus and glaucoma - other surgeries	Corneal transplant surgery	Glaucoma surgery	Vitrectomy surgery	Combination cataract and other procedures surgery
<b>Priority 1</b> Patient has surgery within...	24 hours of decision; not included in the data	24 hours of decision	24 hours of decision	24 hours of decision	24 hours of decision
<b>Priority 2</b> Patient has surgery within...	42 days of decision	28 days of decision	14 days of decision	7 days of decision	7 – 42 days of decision
<b>Priority 3</b> Patient has surgery within...	84 days of decision	84 days of decision	42 days of decision	42 days of decision	42 - 84 weeks of decision
<b>Priority 4</b> Patient has surgery within...	182 days of decision	182 days of decision	112 days of decision	84 days of decision	84 - 182 days of decision

*glaucoma surgery: Eye pressure lowering surgery*

### Italy<sup>42</sup>

Access in Italy is considered to be “excellent” and allocation is “fair and equitable.” Surgeons have ready access to tissue at all times and patients are booked electively. Emergency cases (which are rare) have priority, as do pediatric patients, after which allocation favours public hospitals (where most donation and recovery takes place) and high-volume transplant centers.

There is no regional waiting list, rather each surgeon manages his/her own waiting list and then these are collated on a hospital level. The eye bank monitors the list of requests for tissue monthly.

From *the date of referral to ophthalmologist for transplant assessment*, urgent patients wait less than one-month, emergent patients (<20/200 BVCA) wait less than one to three months, and non-urgent patients wait between three to six months. This latter waiting time (three to six months for non-urgent patients) is considered “appropriate access” or an “appropriate waiting time.”

<sup>42</sup> Information on access and allocation in Italy is drawn from survey responses from Diego Ponzin, MD, Medical Director, The Veneto Eye Bank Foundation, Italy.

Interestingly, despite this, there remains unmet need for corneal transplantation in Italy, with a lack of donor referrals being the primary challenge and a secondary challenge being a lack of financial resources. The challenge in their system, he reported, revolves around a lack of motivation and cooperation from some hospital administrators and staff regarding referrals for donation.

An estimated 40% of corneas released for transplant go unutilized. The two factors that are the greatest cause of unutilized corneas are non-optimal tissue quality and donor qualification criteria not being met. Italy uses organ culture for corneal preservation. An estimated 50% of corneas are sent to other regions of Italy (other than the Veneto region), and an estimated 10% are sent outside Italy. The eye bank in Veneto has EEBA (European Eye Bank Association) accreditation and does not accept corneas from non-EBAA accredited banks.

Cost recovery for ocular tissue distributed to hospitals or other eye banks:

- Costs recovered per cornea for transplant: PK: 1,400 Euros. (\$2,055 CAD) DSAEK/DMEK: 2,200 Euros (\$3,230 CAD)
- Costs recovered for research or teaching tissue varies.
- Costs recovered for corneas shipped outside of Italy are the same as domestic rates, plus transportation.

## Australia<sup>43</sup>

Domestic supply of corneas is reported to meet demand in Australia and the participants are well placed to ensure that supply sustainably meets future demand. Tissue is recovered on an as-needed basis, usually from major public hospitals or from the coroner's office.

Australia uses a communitarian model of allocation that ensures a cooperative relationship and removes eye bank competition for tissue placement, resource waste, and the development of a marketplace. Each Australian Eye Bank recovers from their jurisdiction and allocates in their jurisdiction. Jurisdictions without an eye bank (Tasmania, Northern Territory and the Australian Capital Territory) are co-managed by the local medical staff or Donatelif e retrieval teams (Donatelif e is the donation agency of the Australian Commonwealth Government's Organ and Tissue Authority) and tissue transferred to the closest eye bank. Similarly, those eye banks allocate the next available tissue back into those jurisdictions when requests for tissue are made.

Surgeons request tissue from their local eye bank. In the case of a shortfall, the eye bank will arrange tissue from another jurisdiction. The corneal tissue processing costs vary and are determined by the individual eye bank based on a cost-recovery price structure (e.g. materials used, wage brackets within each State), with costs reimbursed directly to the AUEB by the Medicare system or the recipients health insurance company. (Australia has a two-tiered public, private system.) The prices are outlined publicly in the Australian Prosthesis Register. An eye banks processing price does not change regardless of if the tissue is used locally or nationally or regardless of private or public patient status, however interstate transfers may incur freight costs, which are either covered by the receiving eye bank or receiving hospital.

As an example, the cost for a cornea from the Lions Eye Donation Service is \$2,600 AUD (\$2,300 CAD). Cost-recovery for a cornea for endothelial keratoplasty is \$3,260 AUD (\$2,895 CAD).

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<sup>43</sup> Information on access and allocation in Australia was provided by Heather Manchin, RN, MBA, Project Officer, Lions Eye Donation Services, Melbourne, Australia. For more details see *Eye Banking in Australia*

## Appendix 7: Word Café Think Piece – Utilization

### Challenge address

Eye banking on a national level is an interesting phenomenon. It's not surprising that individual eye banks and transplanting physicians have different acceptance criteria for corneal tissue, but what is surprising is the broad range. Despite national regulations and standards (and for those banks that are EBAA accredited, EBAA standards), what is considered acceptable risk in one eye bank, isn't acceptable to others as pertaining to donor medical screening. Eye bankers will tell you that there is significant variation in tissue criteria on a transplanting physician level when making cornea offers. Every surgeon wants the best outcome for their patient, so there is naturally additional individual patient needs to take into consideration.

There is a plethora of literature on donor and tissue criteria and the impact to cornea transplant outcomes. Two key studies with very large cohorts are the Cornea Preservation Time Study, and the Cornea Donor Study. These studies looked at donor criteria and technical criteria as measures of quality and assess their impact on transplant outcomes. The application of selection criteria impacts one critical system measure: utilization. In the CPTS study more than half of the surgeons were very selective of donor cornea tissue; that is, 58% would cancel a scheduled DSAEK case if the cornea donor did not meet their specified range of parameters even if it met their local eye bank's standards.

As part of this 2020 consensus forum we gathered information from eye banks and transplanting physicians related to utilization. Our survey findings indicate the *release rate*, the percentage of corneas recovered for transplant that were released and made available for transplant, varies from 53% to 83%. The most common reasons for recovered corneas not being released for transplant was non-optimal tissue quality and donor qualification criteria not met.

Data indicate the *utilization rate*, the percentage of corneas released to transplant which were utilized for transplant, ranges from 70% to 97% with an overall average utilization rate of 90%. Dependent on the eye bank, between 3% and 30% of the corneas released to transplant are not used. The main reasons for non-utilization was non-optimal tissue and lack of access to operating room time.

Corneal transplant suitability is dependent on the initial endothelial cell density (ECD) at the time of preservation. ECD decreases with advancing donor age. One large study found that ECD decreased with advancing donor age by 84.2 endothelial cells/mm<sup>2</sup> per decade (this approximates to 0.3% per year). However, 31.2% of the corneas of the oldest age group were still eligible for transplantation. Transplant ophthalmologists report accepting donors up to 75 years of age predominantly, however, the range in cut off values is 50 to 100 years. With one exception, all eye banks have a cut off between 70 and 85. In the U.S. Corneal Donor Study (CDS), the researchers concluded that, for the clear majority of patients, the age of the donor doesn't matter. As self-reported by a physician involved in the study, one of the benefits was that surgeons involved in the study were required to accept all tissue offered to them, so it helped to eliminate some of the age bias.

Interestingly, Canadian eye banks report that minimum ECD for PK ranges from 2,000 to 2,200, while the ophthalmologist surveyed simultaneously indicate that a minimum cell count for PK ranges from 2,000 to 2,600. The European Eye Bank Association (EEBA) reports that 70% of eye banks have a 2000 ECD minimum, while others have a 2,100 to 2,500 ECD minimum. A sub study from CDS determined that preoperative ECD was not predictive of graft failure caused by endothelial decompensation, however, the six-month ECD was predictive of subsequent failure.



Interestingly, after five years' follow-up, 40 of 277 participants with a clear graft had an ECD below 500 cells/mm<sup>2</sup>.

Another area of substantial variation is preservation time. Canadian eye banks reported large variations in death-to-recovery and death-to-preservation time limits. For whole globe recoveries, the range in death-to-recovery time limits for corneas was 18 hours (maximum of six to 24 hours). Death-to-preservation time limits were almost as broad as the maximal death-to-recovery times, ranging from eight to 24 hours. For in-situ recoveries, the death to preservation time limit ranges between 12 to 24 hours. Although there are a number of factors that contribute to preventing release of corneas for transplant, there is literature to support increasing the Canadian minimums and narrowing the range of death to recovery and death to preservation times.

With the emergence of endothelial keratoplasty (EK) surgeries as the preferred method for corneal transplant, a self-sufficient eye bank will likely have surplus of tissue. Surplus corneas arise in a number of different scenarios.

- As volumes of EK requests go up and PK requests go down, it's likely there will be more surplus PK-quality tissue available. Corneas with cell counts lower than the minimum accepted for DSAEK or DMEK preparation are often surplus and may end up being used as lamellar tissue as opposed to optical transplants.
- Those donors with higher cell count but a significant history of diabetes are not preferable for use as DMEK tissue but may be used for DSAEK provided the rim size is adequate for cutting. However, corneas from individuals with mild or short-term diabetes without diabetic co-morbidities may be an option for DMEK if prepared by skilled surgeons and eye bank staff. One of the drawbacks to using this type of tissues for surgeon prepared DMEK is the requirement to send a "backup" tissue in case stripping the endothelium is unsuccessful.
- As the population ages, more and more donors are referred for donation after cataract removal and lens implant. A higher proportion of post-cataract surgery eyes may result in inherent lower cell counts because of subclinical surgical damage to the endothelium. However, not all ECDs are impacted to the same degree by cataract surgery. Where cell counts permit, DMEK is also an option in these cases, although much more difficult in many cases.
- As LASIK, PRK, and other vision correction technologies become increasingly popular, this impacts the quality of donor tissue for transplant. Not all transplanting ophthalmologists are receptive to using tissues from these donors, whether it be for EK or lamellar purposes. However, many surgeons will.

### **Café Discussion Questions:**

- In cornea utilization, what role does individual bias play when technicians are assessing donor suitability and transplanting physicians are accepting corneas?
- Are the current utilization rates acceptable?
- How can we improve and optimize cornea utilization rates?
- Should there be a benchmark for utilization rate?
- What strategies would increase the utilization of donated corneas?
- Would standardized donor criteria increase utilization?
- Is variance in cornea release rates a concern? If so, how could we address?
- What happens with PK quality tissue that doesn't have a high enough cell density? Is it reasonable to expect corneal utilization rates at close to 100% when EK is the preferred method of corneal transplant?



## **What strategies should be prioritized and resourced to maximize utilization rates?**

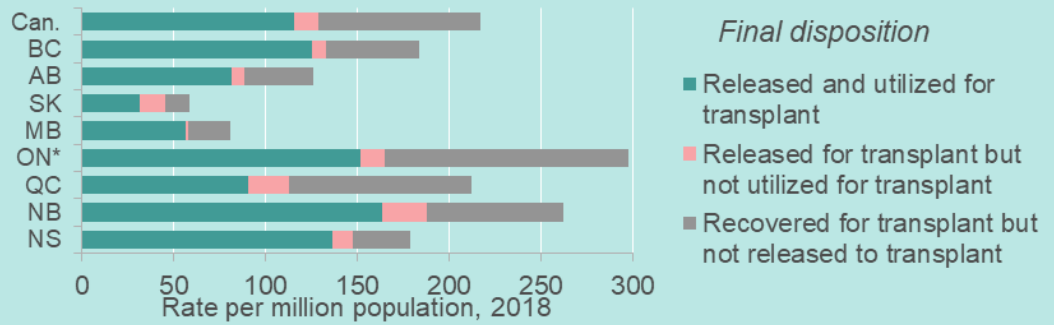
- Standardized minimal donor criteria
- Standardized minimal tissue criteria
- Development and maintenance of a national on-line tool for sharing information on:
  - available surplus tissue
  - unfulfilled tissue requests, surgical calendar, and when tissue needs to be received
  - minimum criteria for acceptance from each bank
  - tracking of tissue offered and reasons for decline

# Setting the Stage

Results from Eye and Tissue Data Committee National Census

There are substantial disparities in rates of cornea recovery for transplantation between provinces, with less than 50 corneas recovered for transplant per million population in some provinces and more than 200 per million population in others.

Corneas recovered for transplantation by graft disposition



Final disposition

- Released and utilized for transplant
- Released for transplant but not utilized for transplant
- Recovered for transplant but not released to transplant

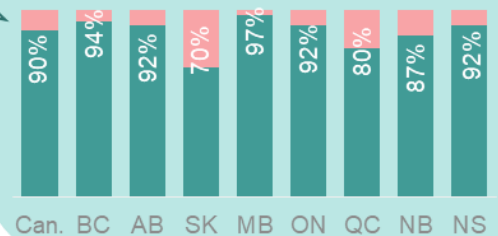
Cornea release rates vary widely between provinces



Corneas released for transplant per million population, 2018

**90%** of corneas released for transplant are utilized for transplant

Most provinces report utilization of 87%-97% of corneas released to transplant, with select exceptions.



## Suitability

Minimal cell count for keratoplasty procedures varies from 2000 to 2600, with 2000 being the most commonly used standard among ophthalmologists and eye banks (or 2200 by eye banks for EK procedures)

Most banks and ophthalmologists use an age cutoff of 75 (if a limit is used) for corneal donors, ranging from 70 to 85. For banks with a minimum age limit for DMEK, 50 was most commonly used.

The most common tissue expiry limit was 14 days for both ophthalmologists and eye banks, with limits for acceptable death to recovery time for whole globe recoveries being between 6 and 24 hours and 8 to 24 hours for death to preservation times.

### Support for national standardization:

The most common recommendation for donor suitability criteria to be standardized across all programs were **EBAA standards**. Other potential areas for standardization in addition to Health Canada and CSA standards include select diseases symptoms of infection (e.g. tick bites/lyme disease, increased WBC, potential pneumonia, febrile-West Nile, dementia, sepsis) and definitions for acceptable tissue issues (cell count, expiry, arcus, scars, etc.) as well as donor issues (diabetes, relative donor-recipient ages), number of procurement cultures, and patient compliance with treatment.

### Opposition to national standardization:

"There are EBAA and HC standards in place...Additional standards that are any different from EBAA/HC may reduce number of corneas being made available nation-wide if the corneas have to meet those additional criteria..."



Factors which are commonly the greatest causes of non-utilization:

- Non-optimal tissue quality
- Donor qualification criteria not met
- Availability of surgeon or access to OR time
- Other site-specific issues:
  - Surgeon handling/contamination
  - Failed preparation/positive cornea culture
  - Tissue expiry



All eye banks would support interprovincial sharing of corneas

- |  |   |
|--|---|
| <p><b>Proposed conditions:</b></p> <ul style="list-style-type: none"> <li>Would not have an adverse impact on local waiting lists</li> <li>Limited to surplus corneas only</li> <li>Cost recovery</li> </ul> | <p><b>Barriers to implementation:</b></p> <ul style="list-style-type: none"> <li>Transportation/border legislation</li> <li>Timing (last-minute requests, delays in shipping)</li> <li>Need for consistent standards for acceptability/accreditation (e.g. EBAA) – implementing SOPs</li> </ul> |
|--|---|

\*Ontario does not determine intention for transplant prior to recovery; Ontario results reflect all cornea/globe recoveries. ETDC national census results indicate that there were no cornea recoveries from PEI donors in 2018.

## Literature Review

### Preservation time/tissue expiry as a means of increasing utilization rates

All Canadian eye banks report using hypothermic cold storage. Most report a maximum suitable time from death to preservation of tissue of 24 hours for both whole globe and *in situ* recovery. Most eye banks keep tissue ranging from 10 to a maximum of 14 days. However, some surgeons refuse tissue that is much younger than this 14-day cut-off and have expressed a preference for not using tissue that is stored for more than eight days.

The Cornea Preservation Time Study (CPTS) was designed to definitively determine the effect of preservation time (PT) on DSAEK and endothelial cell loss.<sup>1,2</sup> DSAEK was chosen since it was, at the time the study was initiated, the most common keratoplasty procedure performed.

Before the initiation of the CPTS in 2012, the general consensus among corneal surgeons and eye banks in the United States was not to use donor corneal tissue preserved for more than seven to eight days for domestic PK and/or endothelial keratoplasty, but no formal survey had been conducted to specifically determine a practice pattern. This preference existed despite a US FDA approval for Optisol GS that allowed for up to 14 days PT and ample evidence that exported donor tissue is commonly and successfully used beyond eight days in other countries.

The study was started in 2012 and finished in 2017 and included 1,330 eyes from 1,090 individuals that underwent DSAEK (94.4% for Fuchs dystrophy). Participants were randomly assigned to endothelial keratoplasty performed with donor corneas with a 0-7-day PT or an 8-14-day PT. Forty clinical sites and 70 surgeons participated in the study. Donor corneas came from 23 U.S. eye banks.

For the primary outcome measure—the number of eyes with corneal graft failure (defined as regrafting for any reason or a cloudy cornea that does not clear) within three years of surgery—the study was unable to conclude that the success rate with donor corneas preserved 8 to 14 days was similar to that of corneas preserved seven days or less (noninferiority margin not met), primarily because of a small uptick in graft failure with PTs of 12-14 days.<sup>2</sup> PT up to 11 days can be expected to have little influence on outcomes, the trialists suggested.

For the other primary outcome, endothelial cell density (ECD) at 3 years from surgery, ECD decreased from baseline by 37% in the 0-7 day PT group and by 40% in the eight to 14 day PT group ( $p=0.03$ ).<sup>3</sup> When analyzed as a continuous variable, longer PT was associated with lower ECD. Endothelial cell loss (ECL) was comparable from four to 13 days' PT. An extension to four years showed similar findings. The authors concluded that, "although endothelial cell loss three years after Descemet stripping automated endothelial keratoplasty is greater with longer preservation time, the effect of preservation time on endothelial cell loss is comparable from four to 13 days of preservation time." Factors associated with a lower ECD at three years included donors with diabetes, lower screening ECD, a diagnosis of pseudophakic/aphakic corneal edema (PACE) in the recipient, and operative complications.<sup>4</sup>

Donor corneal rim cultures were taken in 784 cases in CPTS.<sup>5</sup> The overall rate of infection across the entire cohort was low and PT was not associated with a higher rate of positive donor rim culture.

The findings of CPTS are further supported by several smaller studies, including a 2017 prospective assessment of 990 donor corneas, where longer death-to-preservation time (DPT) was not associated with corneal grading or endothelial cell density (ECD).<sup>6</sup> ECD, where DPT was less than 12 hours, was better if corneas were refrigerated, and prolonged DPT had no significant impact on the secondary outcomes of primary graft failure or graft infection at 30 days after transplantation.

## Other studies on the impact of donor age, surgeon acceptance, and other factors on utilization

Donor age has also been suggested as a restriction that can reduce utilization of available corneas or prolong wait time. However, the Corneal Donor Study (CDS) demonstrated that donor age was not a factor in graft survival after PK for endothelial disease. Five-year graft survival for transplants at moderate risk for failure (principally Fuchs dystrophy or PACE), were similar using corneas from donor  $\geq 66$  years of age and donors  $< 66$  years.<sup>7</sup> In a 10-year follow-up study, most penetrating corneal grafts for Fuchs dystrophy or PACE remain clear at 10 years. However, recipient diagnosis of PACE and a history of glaucoma were both important predictors of graft failure. ECD and corneal thickness were associated with subsequent graft failure, but even with an ECD of  $< 500$  cells/mm<sup>2</sup> at five years, the probability of graft survival at 10 years was 71%.

In 2015, a retrospective chart review of 70 eyes with Fuchs endothelial dystrophy that underwent DSAEK showed that cornea donor age had a statistically significant but weak impact on postoperative ECD at years one and two. Other donor parameters, including donor death to preservation time and donor ECD, did not significantly impact postoperative ECD.<sup>8</sup>

Surgeon request for donor corneas with endothelial cell density above 2,500 cells/mm<sup>2</sup> for DSAEK for the purpose of avoiding dislocations and graft failure and improving one-year cell counts, does not appear to be supported by current data.<sup>9</sup> In a recent paper, Potapenko found that cell counts below 2,300 did not influence graft survival.<sup>10</sup>

Woodward et al looked at the impact of different surgeon acceptance parameters on cost and availability of donor tissue for transplantation; the researchers designed a statistical model to arbitrarily restrict donor age and tissue parameters (ECD).<sup>11</sup> A minimum ECD restriction of 2,300, 2,500, or 2,800 cells/mm<sup>2</sup> would reduce cornea tissue availability to 87.7%, 70.6%, or 36.5% of current levels, respectively. If donor age were restricted to  $\leq 70$ ,  $\leq 65$ , or  $\leq 60$  years, the percentage of corneal tissue available would decrease to 89.5%, 74.3%, or 57.5% of current levels, respectively. Costs would increase.

Candidate cornea donors are considered eligible if they have, among other criteria, no communicable disease that would put the recipient at undue risk for contracting disease from their transplants. This includes sepsis caused by any microbial source, although it must be noted that some researchers have suggested that corneas recovered from septicemic donors do not necessarily harbor pathogenic organisms and may be suitable for transplantation.<sup>12,13</sup>

The FDA lists 10 signs to screen for in donors related to sepsis. Gustave and colleagues assessed whether these 10 signs if met by donor candidates correlated with a higher incidence of sepsis and found that the only sign associated with active septicemia was positive blood cultures.<sup>14</sup> Sixty-five percent of donors with clinical signs of sepsis were reviewed and cleared as appropriate for corneal donation (did not have sepsis at time of death). When considering signs of sepsis, the authors concluded that, "there is no clear cut-off at which the number of signs correlate with a higher likelihood of septicemia. These signs largely represent the physiologic response to shock (all types), not just septic shock."

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## Appendix 8: World Café Think Piece – Interprovincial Sharing and Cost Recovery

### Challenge address

There are many international exchanges of biological products of human origin, such as the worldwide bone marrow registry and programs that exist for sharing stem cells from umbilical cord blood. Various countries are coming together to increase opportunities of providing compatible stem cells to save lives. Currently, here in Canada, human tissues such as amniotic membranes, heart valves, skin, tendons, bones, and arteries are distributed from one province to another to support patient demand with tissues collected and prepared in Canada. The organizations providing these cells and tissues receive financial compensation (cost recovery) to cover the costs of collection, preparation and shipping.

Unlike tissue banks, Canadian eye banks do not cost recover when sharing corneas interprovincially. Eye banks and ophthalmologists identify this lack of cost recovery as a barrier to interprovincial cornea exchange. Currently interprovincial sharing is very limited even though there is a consensus that it would be beneficial in promoting access to transplantation.

Locally and periodically, the number of corneas available may exceed requirements. At the same time, patients elsewhere may be waiting for a cornea that will allow them to regain their sight. Is it not our responsibility to use the surplus to the benefit of these patients?

A 2020 review of all provincial legislation identifies no regulatory barriers to cost recovery. Two jurisdictions, Nova Scotia and Saskatchewan, have included specific references in their legislation that overtly support cost recovery practices; legal counsel's opinion is that while providing clarity these specific references were not necessary. The lack of cost-recovery practice seems to be related more to historic practice than any regulatory barrier.

In Canada, a health intervention is generally considered to be cost-effective if its cost falls below the threshold of approximately \$40,000-\$50,000/QALY (quality-adjusted life year). According to Hirneiss et al (2006), over ten years after PK surgery, considering graft survival and discounting, a cost utility of 9,551 euros per QALY was gained (equivalent to USD \$11,557). This is well within the acceptable limits for cost effectiveness in Canada and can be attributed to the substantial gain in quality of life relative to the cost and maintenance of a transplant.<sup>44</sup> In a 2011 cost benefit analysis conducted by the Canadian Blood Services, the estimated cost of a corneal donation averaged \$2,300 (in 2010 CAD), ranging from \$2,100 to \$2,500 per cornea, depending on average donor yield and varying cost estimates.<sup>1</sup>

Eye banks, donor agencies and transplant physicians have identified several barriers that limit interprovincial cornea exchange. Cost recovery is a primary factor. A cornea comes from a donation, a generous, altruistic gesture. But the preparation to make a cornea adequate for transplantation is not free and includes the salaries of individuals that recover ocular tissues, delivery expenses, materials necessary for recovery and preparation, costs of laboratory tests, time for reviewing the medical file, time required for the evaluation and preparation of the cornea, cost and maintenance of equipment and facility, or development of innovative techniques, among others. Between \$1,880 and \$3,815 are spent to produce each cornea that will eventually be

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<sup>44</sup> Canadian Blood Services, 2011. Cost Benefit Analysis Cornea Transplantation  
[https://profedu.blood.ca/sites/msi/files/1.cost-benefit-analysis\\_cornea-transplantation-may-3\\_-3012.pdf](https://profedu.blood.ca/sites/msi/files/1.cost-benefit-analysis_cornea-transplantation-may-3_-3012.pdf)

grafted. Banks with the capability to increase production to share interprovincially currently feel restricted to do so as they are not compensated for their costs.

While seven of the nine Canadian eye banks import or purchase corneas from the United States at times, more than one-third of Canadian eye banks report that they would be able to increase the recovery and preparation of corneas to support another province, providing that they could recover the costs required to prepare such corneas. Is this not a clear sign of lack of interprovincial collaboration?

For lack of communication and organization, substantial sums of money are being sent across the border rather than being invested in supporting and developing a network of Canadian eye banks. Worse still, the price of a cornea from the USA is generally higher than the price of a cornea produced in Canada. So why not focus on the Canadian Eye Banks?

A barrier raised by eye banks is the Eye Bank Association of America (EBAA) restriction on receiving corneas only from accredited eye banks. Indeed, any EBAA accredited organization engaging with another establishment that performs eye banking functions, prior to distribution to the non-accredited bank must either document that the establishment is currently EBAA accredited for the eye bank functions performed or document that they are in compliance with EBAA medical standards by performing compliance audits. EBAA standards make it for more complex and costlier for accredited banks and non-accredited banks to work together.

How do we address the issue that an American association, neither necessary nor mandatory in Canada, puts constraints on collaboration between Canadian eye banks? One-third of Canada's eye banks are not EBAA accredited. Aside from the six Canadian eye banks that have accreditation, no other international eye bank has opted for EBAA accreditation. While banks value the technical training and operational standards provided and audited by EBAA accreditation. It would be a shame to deprive a Canadian of a cornea simply because of a non-mandatory requirement of a foreign association.

Of course, the interprovincial corneal exchange raises ethical concerns that must be considered. First, it is imperative that only the surpluses in a province would be shared. There is no question of an eye bank supplying another jurisdiction at the expense of its own community. Second, the next of kin who consents to the donation of the cornea must be informed that the tissue removed can come to the aid of any Canadian citizen. In conclusion, the ethical consideration that remains outstanding is that of the allocation of surpluses. How do we ensure that excess corneas are offered fairly across Canada?

Interprovincial corneal exchange does exist, but many adjustments are needed to optimize the benefits it could bring to the Canadian system.

### **Café Discussion Questions:**

- Should we encourage sharing amongst Canadian banks rather than relying on American eye banks?
- Should Canada adopt a cost recovery model to incentivize and support interprovincial sharing of corneas?
- What is required to develop and manage a strong and efficient Canadian eye bank network to facilitate inter-provincial sharing?
- To avoid restrictions imposed by the EBAA, would it not be simpler for eye banks not accredited by the EBAA to distribute the corneas directly to the hospital, as they do with other allografts?
- How do we ensure inter-provincial sharing is fair and equitable?



# Support



## All eye banks support the interprovincial sharing of corneas

### Proposed conditions:

- Would not have an adverse impact on local waiting lists
- Limited to surplus corneas only
- Cost recovery

### Barriers to implementation:

- Transportation/border legislation
- Timing (last-minute requests, delays in shipping)
- Need for consistent standards for acceptability/ accreditation (e.g. EBAA) – implementing SOPs

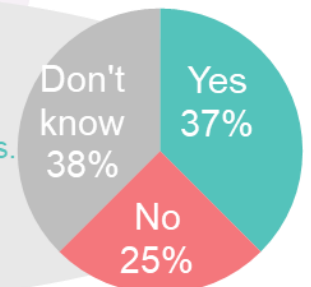
### All eye banks support the development of a national registry

All eye banks see a need for, and/or value in, a national registry for corneal transplantation which includes outcome measures

All eye banks would support a national registry by providing consistent donation, transplant and outcome data on their corneal patients\*\*

Approximately 70% of transplant ophthalmologists and 50% of eye banks support cost recovery for corneas both within provinces and inter-provincially

37% of eye banks have the capability to increase recovery to distribute corneas to provinces with unmet demand, if compensated for costs. 38% indicated they don't know if they could and 25% indicated they cannot increase even with resources.



## Costs and Cost Recovery

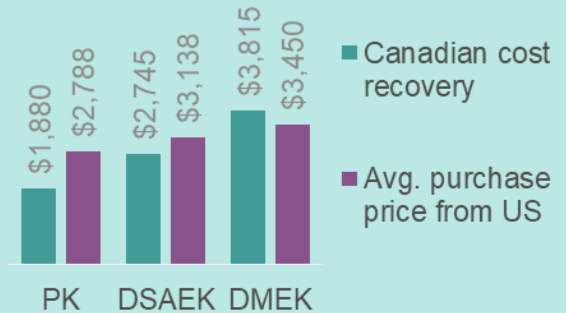
Only the BC and Quebec eye banks indicated that they recover costs for ocular tissue distributed to hospitals or other eye banks.



58% of transplant ophthalmologists and 67% of eye banks\* indicated that not recovering costs is a barrier to optimizing corneal recovery, production and interprovincial sharing.

Seven of the nine Canadian eye banks have purchased corneas from the United States to supplement their supply and meet demand.

Cornea costs recovered vs. US costs (CAD)



## Interprovincial/Inter-Bank Compatibility Issues

### Technological



Most eye banks make use of digital/electronic documentation for referral, as well as documenting consent, recovery, processing, and distribution; however, some banks still rely on paper-based documentation only for all operational components. Among programs with digital documentation systems, few rely on the same data management software or platforms.

### Accreditation standards



Six of the nine eye banks indicated that they were EBAA accredited. EBAA accredited banks typically do not accept corneas from banks without this accreditation.

There is no common understanding about the value of EBAA accreditation; however, the reporting requirements for EBAA accreditation and the difficulty associated with sharing grafts from a non-accredited bank to an accredited bank present meaningful challenges.

\*Based on 6 eye banks reporting

\*\*Lion's Eye Bank support is "dependent on the development of the registry (amount of data entry, duplication etc.), data sharing agreements, and the resources"



## Literature Review

*Martin et al:* Little has been written on the ethical issues related to transnational eye banking; Martin and colleagues wrote what is probably the definitive work on this topic to date in 2017. While a discussion on transnational eye banking is beyond the scope of this consensus forum, a few of the ethical issues raised by Martin et al are relevant to a discussion of interprovincial sharing of corneal tissue and will be summarized here. These include, among other things, concerns over self-sufficiency, equity in resource distribution, and donor autonomy.

Self-sufficiency in cornea donation and transplantation is being pursued by each province in Canada, and interprovincial sharing should be done in such a way as to not undermine the pursuit of self-sufficiency or compromise provincial autonomy. That said, it has been suggested that regional collaboration (e.g. shared eye banking services) may be a reasonable 'permanent' option to ensure that smaller provinces can meet their needs for corneal transplantation in a timely manner.

Transnational sharing of organs and tissues is complicated by donor expectations that their donation will be used to meet the needs of the population where (or near where) they live. Martin et al suggest that where there is a possibility that donated tissue may be exported, disclosure of this possibility should be required as part of the informed consent for donation, "First, because exportation may significantly alter the processes and outcomes of donation, and thus may influence the donation decision, and second because the information is likely to be inherently valued by decision makers even when it does not influence the decision." Failure to provide full disclosure, they suggest, could result in a loss of trust in the procurement and allocation system, and a subsequent decline in consent rates. Would this concern apply to interprovincial sharing?

Sharing of surplus corneas from one province to another might also raise questions of equitable allocation. Which provinces and patients receive shared tissue and are there perhaps patients in other provinces whose need is greater? A discussion of allocation should form part of decision making for eye banks considering interprovincial sharing.

## Reference

1. Martin DE, Kelly R, Jones GL, Machin H, Pollack GA. Ethical issues in transnational eye banking. *Cornea*. 2017;36:252-257.

## **EBAA rules (excerpted) on sharing with non-EBAA certified eye banks**

### *3.510 Eye Bank Functions Performed by Another Establishment*

Any EBAA accredited organization engaging with another establishment that performs eye banking functions prior to distribution must either:

1. Document that the establishment is currently EBAA accredited for the eye bank functions performed; OR
2. Document that the establishment is in compliance with EBAA medical standards, state and federal regulations appropriate to the eye bank functions performed. This option requires a written agreement and the EBAA accredited organization is responsible for performing compliance audits. Policies and procedures shall describe the audit plan, scope, and frequency.

## Appendix 9: World Café Think Piece – Interprovincial Knowledge Sharing and Research

### Challenge address

Eye banks in Canada, for the most part, are hospital based, constrained financially and have limited access to funding for innovation, research and professional education. There is no coordinated or national approach to training or professional education in the Canadian eye banking community.

Two thirds of Canadian eye banks are accredited by or maintain an affiliation with the Eye Banking Association of America (EBAA). EBAA is an American accreditation body for eye banking, which maintains medical standards, collects data, surveys and monitors adverse events/trends, and educates eye banking medical directors as well as technicians. The latter is a certification that is referred to as CEBT (Certified Eye Bank Technicians). EBAA events (required to maintain CEBT) are U.S.- based and costly.

Canadian Blood Services and the Canadian organ donation community have united over the past three years to develop an evidence-based national curriculum to guide organ donation that is grounded in family perspectives (qualitative research). This national curriculum is focused on organ donation and has little applicability to ocular or tissue donation but could be adapted.

Forty per cent of provincial organ donation organizations indicated that they have no specific professional education content directed to health professionals in hospitals addressing ocular donation and pre-mortem and post-mortem eye care. Two of the nine banks reported they do not have standardized professional education directed to health professionals in hospitals with specific content addressing ocular donation and pre-mortem and post-mortem eye care.

In September 2019, the Canadian Eye and Tissue Data Committee held a strategy and planning session and identified the following gaps in the Canadian system: there currently is no forum within the Canadian eye and tissue community for communication, to share practice, design collaborative research studies, identify and mitigate system challenges, or to advocate for system improvement strategies and resources.

There have been previous attempts for the community to come together and collaborate in a 'community of practice' with no effect, largely due to lack of funding and the onerous tasks of organizing and facilitating. Canadian Blood Services had previously supported a Tissue Expert Advisory Committee, but this was disbanded with the completion of the *Call to Action*<sup>45</sup> report, which made several recommendations for system change. The Canadian Donation and Transplantation Research Community has engaged members of the tissue banking community over the past year and is open to the idea of establishing a national research network for tissue banks, but to date nothing has been put in place.

In the critical care/organ donation and transplantation community, a successfully executed and growing community of practice is that of the Donation Physician Network (DPN), with well over 100 participating members as well as many more interested. The DPN, chaired by Dr. Sonny Dhanani and facilitated by Canadian Blood Services, delivers scientific lectures, case discussions and provides recording on demand. Canadian Blood Services is currently advancing a second community of practice, the Donor Coordinator Network (DCN).

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<sup>45</sup> Canadian Blood Services, 2011, <https://profedu.blood.ca/en/call-action>

Basic science research into tissue and biologics occurs in Canadian academia, however, there is little eye/tissue bank-driven research in relation to process improvement or product development in Canada. Indeed, this lack of coordination between academia and eye banks was highlighted in the 2011 *Call to Action*, with a recommendation that Canadian Blood Services create linkages between tissue operations and networks of researchers and facilitate tissue research by providing access to grants, directly or through collaborations with other funding agencies. The tissue community has expressed interest in linking the role of the ETDC to research and development and identified the Canadian Donation and Transplantation Research Program as a potential partner and advocate for eye and tissue bank research.

### **Relevant comments from the forum survey of eye banks and organ donation organizations:**

- Expressed desire for a formalized national working group and communication strategy for collaboration and promotion of new technology, public education, increasing efficiency, and minimizing costs.
- Ongoing support and resources for donation educators (coordinators) to support ocular donation education for frontline care providers.
- Development of a national body like EBAA for Canadians, rather than requiring EBAA accreditation and education through U.S. (costly, challenging with standards built for US models, etc.)
- Training courses within Canada for our technicians; a skill transfer course or interprovincial training would be beneficial; some of the larger more skilled eye banks could offer to become training sites.

### **Café Discussion Questions:**

1. How can the community better share knowledge and expertise between programs and provinces?
2. Is there a need for a national advisory committee?
3. Is there a need to develop a community of practice?
4. If there is a need, what would the committee and community of practice look like? And who would run it? What would be the role of that committee and/or network?
5. What are the professional education needs of eye bank professionals? Is pursuing Canadian-based skills training for cornea recovery and processing a benefit to eye banks?
6. What are the professional education gaps/needs and opportunities in relation to critical care and end-of-life health professionals in the identification and referral of ocular donors and increasing the supply of donor corneas?
7. Can the community align and unite to collaborate in national research and/or product development?
8. What are cornea donation and eye bank research opportunities or priorities that could improve access to donation and transplantation?