

Canadian Eye and Tissue Data Committee Report

Canadian Eye and Tissue Banking Statistics

2019

Organs & Tissues for Life Extracts of the information in this report may be reviewed, reproduced or translated for educational purposes, research or private study but not for sale or for use in conjunction with commercial purposes. Any use of the information should be accompanied by an acknowledgement of Canadian Blood Services and the Eye and Tissue Data Committee as the source. Any other use of this publication is strictly prohibited without prior permission from Canadian Blood Services.

Canadian Blood Services assumes no responsibility or liability for any consequences, losses or injuries, foreseen or unforeseen, whatsoever or howsoever occurring, which might result from the implementation, use or misuse of any information or recommendations in this report. This report contains recommendations that must be assessed in the context of a full review of applicable medical, legal and ethical requirements in any individual case.

Production of this report has been made possible through a financial contribution from Health Canada, and the Provincial and Territorial governments. The views expressed herein do not necessarily represent the views of the Federal, Provincial or Territorial governments.

For more information, please contact:

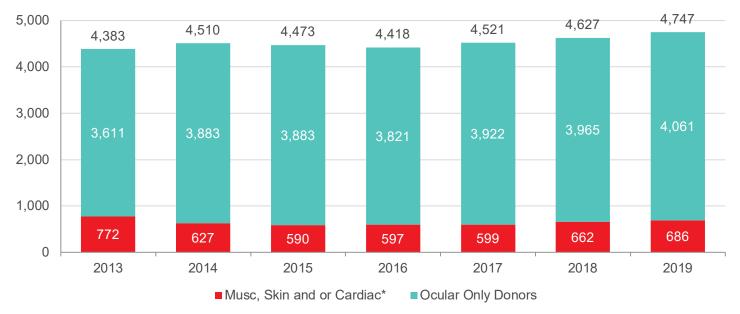
Organ and Tissue Donation and Transplantation Canadian Blood Services 1800 Alta Vista Drive Ottawa, ON K1G 4J5 Canada

Comments or questions?

Comments or questions are welcome and can be sent to **transplantregistry@blood.ca**. All suggestions will be considered for inclusion in future reports.

This report is accessible online at

https://professionaleducation.blood.ca



Executive Summary

System Performance Data

Beginning in 2012, Canadian Blood Services, on behalf of the Eye and Tissue Data Committee (ETDC), has received data submissions from all Canadian eye and tissue programs. Data definitions have been established and data training delivered to the Canadian eye and tissue community.

Canadian Blood Services maintains and collates data for review by the ETDC. Each year a summary report is generated. The purpose of this report is to provide information and insights into the Canadian recovery, processing and distribution of ocular and tissue allografts across Canada.

Prospective data collection was initiated in 2012. In 2019, data was submitted from 16 eye and tissue banks and one recovery program representing a census of all Canadian eye and tissue banking activity (results were not available for select metrics for certain programs, as indicated). Data on allografts imported by Canadian tissue banks from the United States was available for the first time in 2016; however, data on allografts imported directly by Canadian hospitals from the United States is not readily available.

Deceased donors by year

National Results on Key Metrics

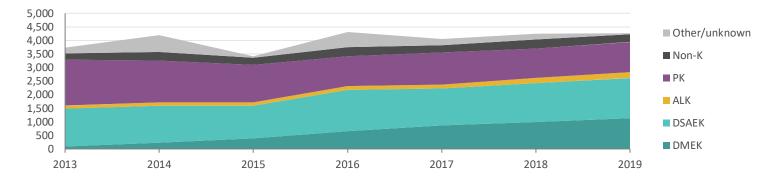
In 2019, Canadian eye and tissue banks received 57,968 deceased donor referrals for potential tissue donation, which represents an 7% increase relative to 2018; 55% of those approached consented to tissue donation, based on data from 8,643 approaches.

Hospitals were the referring agency for 86% of referrals for actual deceased donors in 2019, an increase from 83% in 2018. The second largest source, accounting for 6% of referrals in 2019, was extended care facilities such as nursing homes and hospices.

In 2019, tissue was recovered from 4,747 deceased donors, representing a 3% increase from the previous year. Tissue was recovered from 115 living donors, a 42% decrease from 2018.

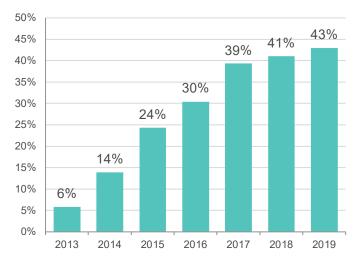
Results relating to ocular tissues in 2019 were generally comparable to 2018 results; there was a 3% increase in the number of donors from whom ocular tissue was recovered in 2019 (n=4,607) relative to the previous year, and a 1% increase in ocular production for transplant, with 2019 seeing the release of 4,817 corneas for transplant.





Cornea distribution for transplant, including penetrating keratoplasty (PK), endothelial keratoplasty (EK) and anterior lamellar keratoplasty (ALK) reflected comparable results to 2018 distributions, with precise differences being influenced by the number of cases in which the surgery type was not available. In 2019, 3% of corneas distributed for transplantation were imported from the United States – no change from 2018.

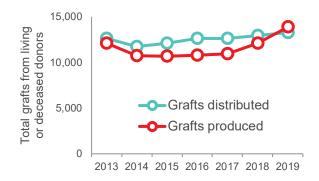
Proportion of EK performed as DMEK



The demand for DMEK (Descemet's Membrane Endothelial Keratoplasty) continues to increase, with

both the total number of corneal grafts used for this purpose and the proportion of EK procedures performed as DMEK continuing to rise.

Total musculoskeletal, skin, amnion, and cardiac tissue production and distribution



In 2019, there were 13,874 musculoskeletal, skin, amnion, and cardiac grafts produced and released to inventory nationally with 13,276 being distributed for transplant in total. The production of musculoskeletal, skin, amnion, and cardiac grafts increased by 15% relative to 2018, while the total number distributed for transplant increased by 2% of 2019 levels.

Acknowledgements and Future Directions

This prospective data collection provides all jurisdictions with comprehensive analysis of tissue donation activity as well as the Canadian production and distribution of ocular and tissue graft, documenting changes in system performance from 2013-2019.

Canadian eye and tissue programs are to be commended on their leadership and their contributions to the collection and collation of system performance data. This data supports all programs and stakeholders in their valuable efforts to provide the donation and allograft services Canadians require.

Table of Contents

Executive Summary	3
System Performance Data	3
National Results on Key Metrics	3
Acknowledgements and Future Directions	5
1.0 Introduction	7
2.0 Canadian view of tissue donation and transplantation, 2019	9
3.0 Comparative analysis	. 10
4.0 Canadian eye and tissue banking deceased donation activity, 2019	. 12
5.0 Canadian eye & tissue banking living donation activity	. 17
6.0 Canadian Eye & Tissue Production and Distribution Activity, 2019	. 19
Conclusion	. 31
Appendix A	. 33
Appendix B	. 36
Appendix C	. 37
Appendix D	. 38

1.0 Introduction

Canadian Blood Services received a mandate from Canadian federal, provincial, and territorial governments in 2008 for organ and tissue donation and transplantation. This mandate encompasses activities that contribute to the development of leading practices, professional education, public awareness, system performance and data and analytics. Aligning with its roles relating to managing the national supply of blood, blood products, stem cells, as well as a cord blood bank and related services for all provinces and territories (excluding Quebec), Canadian Blood Services leads and provides support for an integrated, interprovincial system for donation and transplantation for all of Canada.

In 2012 the Canadian tissue community directed Canadian Blood Services to facilitate the development and implementation of national data collection, analysis, and reporting on national tissue donation, production, and distribution activity. This represents a milestone in the development of systematic monitoring of Canadian tissue banking activity. To oversee the collection, management and release of national data, an Eye and Tissue Data Committee (ETDC) was established in 2012; this committee is chaired by members of the tissue community and composed of representatives from each provincial tissue program as well as Canadian Blood Services representatives (see Appendix B). The ETDC encompasses two working groups who provide insight and recommendations to the larger committee in relation to data elements, data definitions (see Appendix A), data collection, data submission, quality assurance and training, collation, analysis and release and publication.

Prospective data collection was initiated in 2012 from all eye and tissue banks operating in Canada (see Appendix C for a list of contributing programs). Canadian Blood Services acts as the repository for the collected data and provides support for data management, analytics, and publication/reporting of results, in addition to providing secretariat and administrative services for the ETDC. This cooperative effort has enabled the development of multiple published products and stakeholder presentations. Results are provided by all Canadian eye and tissue banks operating in eight out of the thirteen provinces and territories and constitute a comprehensive census of tissue banking activity, with limited exceptions. A summary of products produced and or distributed by each eye and tissue banks is detailed. (see Appendix D).

The value of this data to the community was recognized and validated with the 2017 publication "<u>Development of</u> <u>national system performance metrics for tissue donation, production, and distribution activity</u>" in the international Journal of Cell and Tissue Banking.

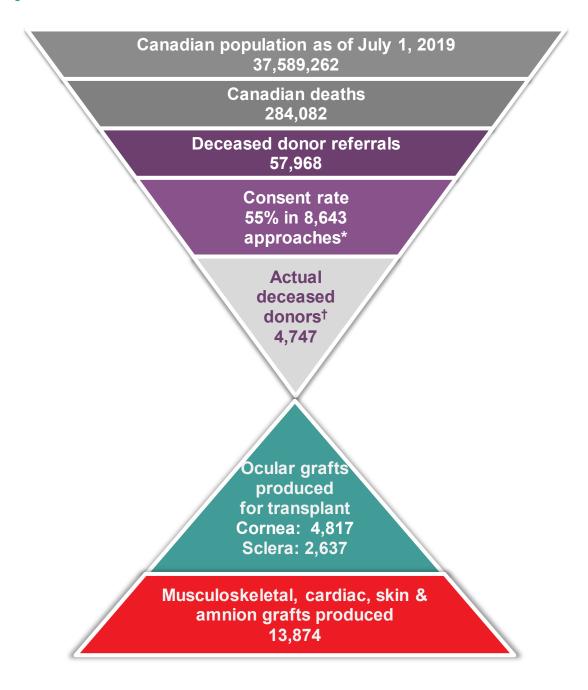
The results presented report on Canadian eye and tissue banking donation, production, and distribution statistics for Canadian eye and tissue banks for January 1 to December 31, 2019 as well as Canadian system activity for 2013 through 2019. This represents the first report for which data is available for seven consecutive years, allowing for insight into provincial and national trends to will inform individual tissue bank operations and strategy.

Canadian Blood Services and the Eye and Tissue Data Committee would like to express our sincere appreciation to the members of the Canadian tissue community who participate in this data collection or the time and expertise they provide to the collection and collation of national activity data.

1.1 Canadian eye and tissue banks



2.0 Canadian view of tissue donation and transplantation, 2019



Population and death data sourced from Statistics Canada. Chart adapted from the Australian Government, Australian Organ and Tissue Donation and Transplantation Authority, Annual Report 2013-2014, Figure 8: Australia's potential organ donor population.

^{*10} programs collect data on the number of approaches and consent rate; this data documented a 55% consent rate.

[†]Refers to donors from whom tissues were recovered following cardiac or neurological death. See Appendix A for definition.

3.0 Comparative analysis

3.1 Canadian eye and tissue banks

Type of bank	2013	2014	2015	2016	2017	2018	2019
Comprehensive tissue banks*	6	6	6	6	6	5	5
Eye banks	4	4	4	4	4	5	5
Musculoskeletal banks	3	3	3	3	3	3	3
Skin banks	1	1	1	1	1	1	1
Cardiac banks	1	1	1	1	1	1	1
Surgical bone banks**	2	1	1	1	1	1	1
Recovery***	1	1	1	1	1	1	1
Total	18	17	17	17	17	17	17

*Comprehensive is defined as recovering and processing more than one tissue type and reporting to a common administration.

A surgical bone bank is defined as a bank which recovers only surgical bone. Some musculoskeletal and comprehensive banks recover surgical bone. *A recovery organization provides tissue recovery services but does not process or distribute tissue.

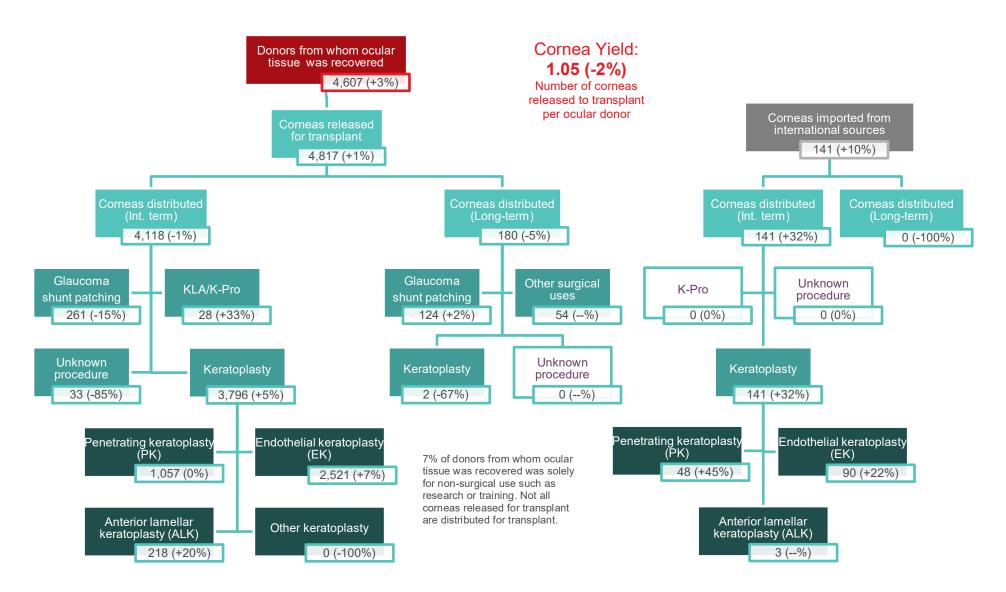
3.2 Canadian eye and tissue banking activity

Total Canadian activity*	2013	2014	2015	2016	2017	2018	2019	% Change (2018-2019)
Deceased donor referrals	41,594	45,154	46,381	45,609	50,506	53,925	57,968	7%
Total deceased donors from whom tissue was recovered	4,383	4,510	4,473	4,418	4,521	4,627	4,747	3%
Donors where ocular tissue was recovered: includes for transplant and for research and training	4,146	4,248	4,292	4,283	4,391	4,469	4,607	3%
Deceased donors where bone, cardiac and or skin was recovered	772	627	590	597	657	662	686	4%
Surgical bone donors	700	669	549	456	379	186	91	-51%
Total intermediate-term preserved corneas distributed to transplant – keratoplasty and unknown procedure**	3,504	3,891	3,162	3,969	3,820	3,926	3,970	1%
Musculoskeletal, skin and cardiac grafts processed and released into inventory from deceased donors	11,297	9,709	9,856	9,731	10,032	11,328	13,344	18%
Musculoskeletal and amnion grafts processed and released into inventory from living donors	718	1024	822	1,050	896	768	530	-31%
All musculoskeletal, skin, cardiac, and amnion grafts processed and released into inventory (living and deceased donors)	12,105	10,733	10,678	10,781	10,928	12,096	13,874	15%
Total musculoskeletal, skin, cardiac, and amnion grafts distributed to transplantation (living and deceased)	12,605	11,740	12,119	12,632	12,652	12,963	13,644	5%
Total: All eye and tissue grafts produced and released into inventory (deceased & living donors)	17,602	16,570	16,241	17,366	17,412	18,222	21,627	19%
Total: All eye and tissue grafts distributed to transplantation (deceased & living donors)	17,820	17,131	16,595	18,650	18,327	18,973	20,172	6%

*Some minor variation of totals from previous reports due to additional quality assurance reviews and data reconciliation

** Data limitations: Intermediate-term corneas that were distributed with the end use identified as "unknown" was included with the total keratoplasty procedures, as the majority of corneas are used for keratoplasty. The following number of corneas were reported as "unknown": n=33 (2019), n=219 (2018); n=230 (2017); n=555 (2016); n=64 (2015); n=632 (2014); n=220 (2013)

3.3 Cornea processing and distribution, 2019, with % change from 2018

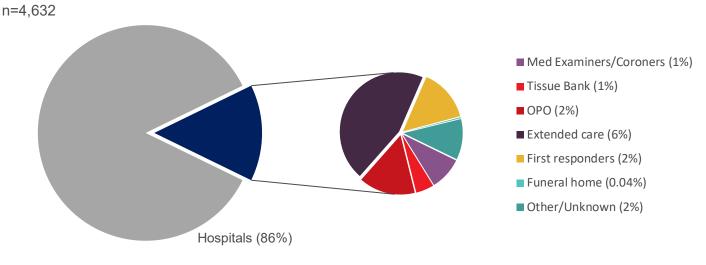


4.0 Canadian eye and tissue banking deceased donation activity, 2019

4.1 Total donor referrals

A total of 57,968 deaths were identified and referred for initial screening and consideration of tissue donation potential in 2018, a seven per cent increase from 2018 (n=53,925) and an 15% increase from 2017 (n=50,506). Approximately one sixth of realized donors in 2019 were non-hospital referrals, which is consistent with 2018 and 2017 results.

Actual donors by source

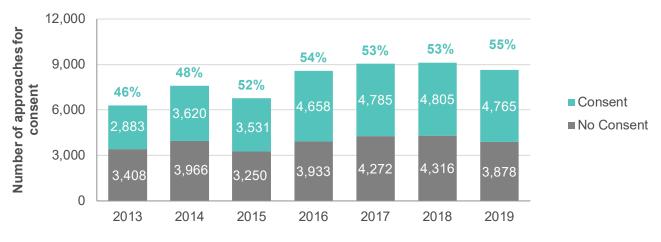


4.2 Consent Rate²

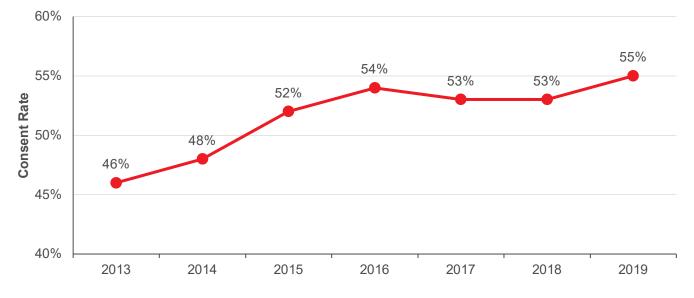
In 2019, 10 programs provided data on 8,643 approaches for deceased tissue donation. This was a decrease of five percent from 2018 (n=9,121). A consent rate of 55% was identified, which is the highest consent rate to date.

² Please note: The counts for consent rate values will be subject to minor adjustments on review.

Consent rate for tissue donation

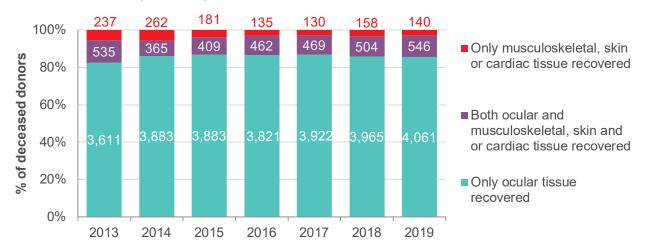


Consent rate for tissue donation (all programs excluding Quebec)



4.3 Deceased donor: national analysis

In 2019, there were 4,747 consented deceased donors from whom tissue was recovered in Canada, an increase of three percent from 2018 (n=4,627) and an increase of five percent from 2017 (n=4,521). 85.5% of these donors were ocular-only donors, as was approximately the case in 2018 (85.7%) and 2017 (85.5%).

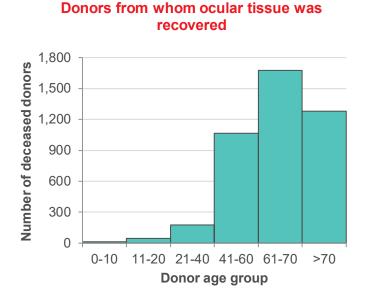


Deceased donors by tissue type

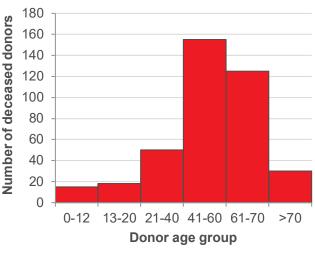
The 2019 total number of consented deceased donors from whom tissue was recovered represented the highest number recorded to date. Nationally, year-to-year variation in deceased donors has been limited over the past seven years, averaging 4,526 donors per year over this period, with each year's total being within five per cent of the seven-year average. The number of donors from whom ocular tissue is recovered has also remained within four per cent of the average for the past six years (n=4,348).

The age distributions for deceased donors in 2019 are essentially equivalent to the respective age distributions in the previous year.

Deceased tissue donor age distribution, 2019

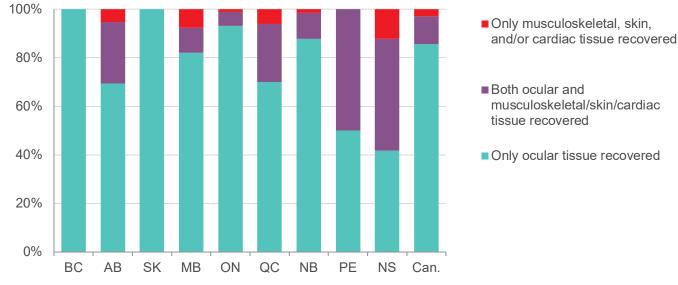






Age data available for 4,339 deceased donors (91% of total)

4.4 Deceased donor: 2019 provincial analysis

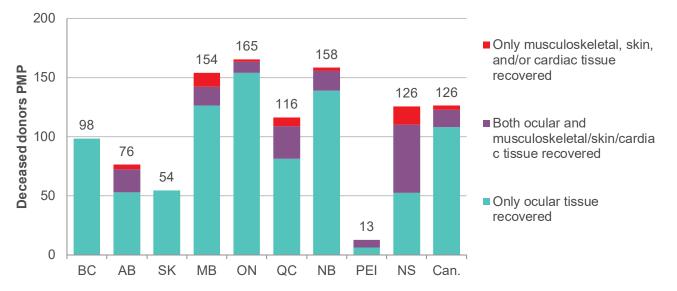


Deceased donors by tissue type recovered

PE results reflect PE donors whose recoveries were performed by the NS program. NB donors whose recoveries were performed by the NS program are included in NB results.

Total deceased tissue donors

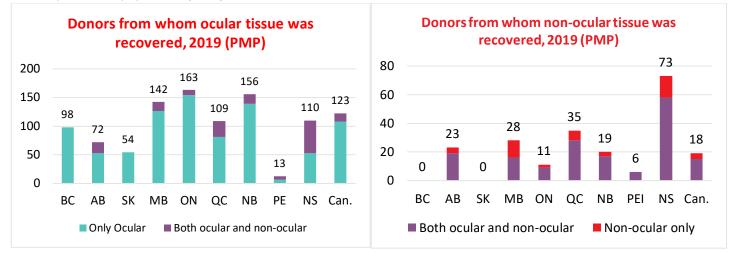
Results per million population (PMP)



Musculoskeletal, cardiac, and skin tissue is not recovered in BC, SK, or NL. Per million population rates based on Statistics Canada population estimates by province as of July 1, 2019 (<u>Table 17-10-0134-01</u>). PE results reflect PE donors whose recoveries were performed by the NS program. NB donors whose recoveries were performed by the NS program are included in NB results. National rates are based on the entire national population.

Deceased tissue donors by tissue recovered

Results per million population (PMP)

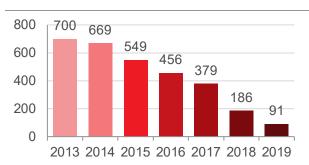


Musculoskeletal, cardiac, and skin tissue is not recovered in BC, SK, or NL. Per million population rates based on Statistics Canada population estimates by province as of July 1, 2019 (<u>Table 17-10-0134-01</u>). NB donors whose recoveries were performed by the NS program are included in NB results. National rates are based on the entire national population.

5.0 Canadian eye & tissue banking living donation activity

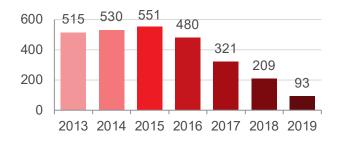
5.1 Surgical bone donation

In 2019, three programs reported recovering bone from living donors; this involves recovering femoral heads during total hip replacement surgery. 2019 results suggest the ongoing continuation in the trend of decreasing living donor bone recovery, with a corresponding decrease in the number of surgical bone grafts released.

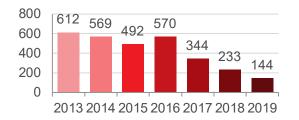


Surgical bone recoveries (donors)

Surgical bone released into inventory



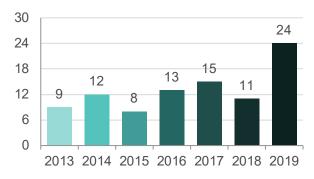
Surgical bone distributed



5.2 Amnion donation

In 2019, amnion living donation and production activity is similar to that seen over the past six years. Distribution of amnion has increased relative to 2018, reaching the highest recorded level to date

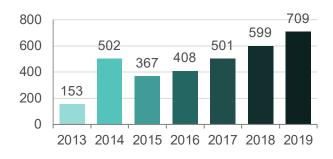
Amnion donors



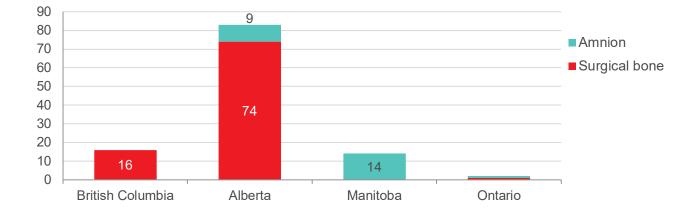
Amnion released into inventory



Amnion distributed

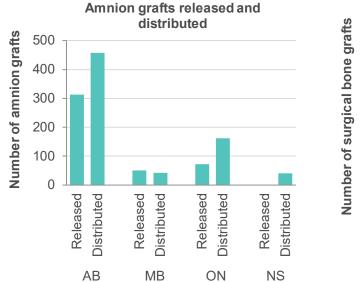


5.3 Living donation: 2019 provincial analysis

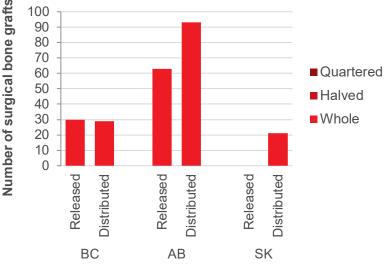


Living donors from whom tissue was recovered

Living donor surgical bone and amnion released and distributed



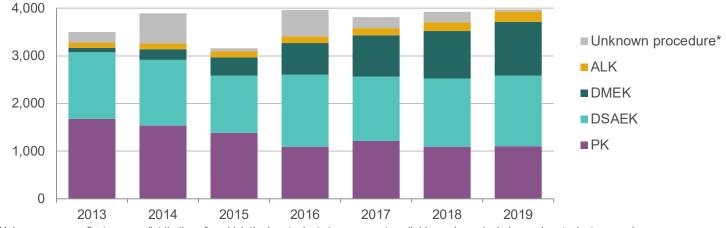
Surgical bone grafts released and distributed



6.0 Canadian Eye & Tissue Production and Distribution Activity, 2019

6.1 Total corneas distributed for transplant

In 2019, Canadian eye banks distributed 4,439 corneas for surgical use, including 4,259 intermediate-term preserved corneas of which 3,937 were known to have been utilized for penetrating, endothelial, or anterior lamellar keratoplasty. This represents a six percent increase from the 3,706 corneas distributed for these types of keratoplasty in 2018. In addition, two long-term preserved corneas sourced in Canada were also distributed for keratoplasty, although the keratoplasty type was not available in these cases. The final use could not be determined for an additional 33 corneas in 2019, a large decrease from what was seen in 2018 (n=219). It is likely that these were used for keratoplasty, but the procedure type was not recorded. In 2018, 289 intermediate-term preserved corneas were utilized in non-keratoplasty procedures including K-Pro, keratolimbal allografts, and glaucoma shunt patching.



Intermediate-term preserved cornea distribution for keratoplasty

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

2018: One cornea distributed for keratoplasty other than PK, DMEK, DSAEK, or ALK.

2017: Five corneas distributed for keratoplasty other than PK, DMEK, DSAEK, or ALK, including one case in which the cornea was distributed for an EK procedure other than DMEK/DSAEK.

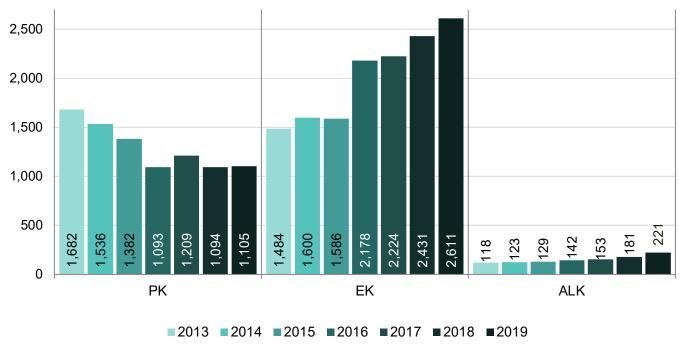
2016: One cornea distributed for keratoplasty other than PK, EK, or ALK.

2015: One cornea distributed for keratoplasty other than PK, EK, or ALK.

2013: One cornea distributed for EK for which specific procedure type could not be determined.

Of all cornea transplants performed in Canada in 2019 for which the keratoplasty type could be determined, 66% were for EK, which is the same as the proportion in 2018 (66%) and slightly higher than 2017 (62%).

In 2019, five Canadian eye banks (Eye Bank of British Columbia, Eye Bank of Ontario, Héma-Québec's Banque d'yeux du Québec & Banque d'yeux du CUO, Nova Scotia's Regional Tissue Bank, and the Lion's Eye Bank in AB) provided processing service, with all five providing precutting service for DSAEK. Three centres, the Regional Tissue Bank of Nova Scotia, Eye Bank of Ontario, and Quebec's Banque d'yeux du Québec & Banque d'yeux du CUO provided pre-stripping service for DMEK. In remaining regions, the processing is completed by the surgeon in the operating room.



Intermediate-term preserved cornea transplants by procedure type

Not shown:

2018: One cornea distributed for keratoplasty other than PK, EK, or ALK. 2017: Four corneas distributed for keratoplasty other than PK, EK, or ALK.

2016: One cornea distributed for keratoplasty other than PK, EK, or ALK.

2015: One cornea distributed for keratoplasty other than PK, EK, or ALK.

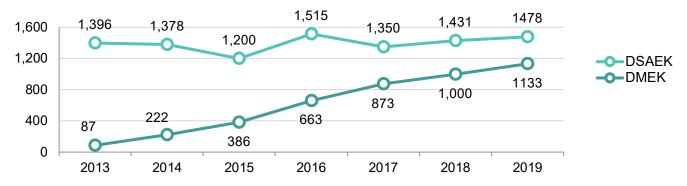
There is a decreasing trend in the number of intermediate-term preserved corneas distributed for PK, with the most pronounced decrease occurring between 2013 to 2016 at a rate of 13% per year; numbers have remained relatively stable since 2016. This is accompanied by an increase in the number of intermediate-term preserved corneas distributed for EK; numbers were consistent between 2013 to 2015, but between 2015 to 2016 increased by 37%, and then has since has continued to rise by an averaged rate of six per cent per year. Intermediate-term preserved corneas distributed for ALK has remained relatively stable between 2013 to 2019.

6.2 Types of endothelial keratoplasty

In EK, either the eye bank prepares the corneal tissue prior to surgery, or the surgeon prepares the corneal tissue in the operating room, removing specific layers of the cornea. Preparation or pre-cutting can be done manually (peel) or with a microtome (automated). There are two common methodologies; in Descemet's Stripping (automated) Endothelial Keratoplasty (DSAEK), the prepared (cut) graft is comprised of the donor tissue endothelium, the Descemet's membrane, and a thin, partial layer of the donor tissue's stroma. Descemet's Membrane Endothelial Keratoplasty (DMEK) involves the transplantation of only the Descemet's membrane and endothelial layer of the cornea. The DMEK peel is a more technically challenging procedure than DSAEK and has been reported to provide better post-transplant patient visual acuity, lower rejection rates and faster visual recovery.

The demand for DMEK continues to increase, with a growth in DMEK procedures of 13% in 2019. In 2019, 43% of corneas known to have been used for EK procedures were used for DMEK.

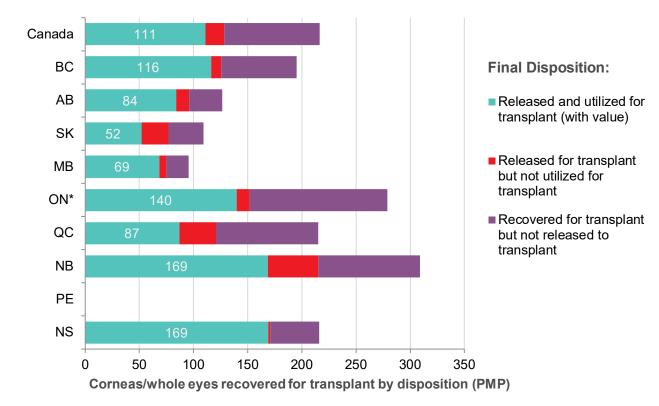
Types of endothelial keratoplasty



Not shown: 1 cornea distributed for EK for which specific procedure type could not be determined (2013). In 2019, 33 intermediate-term corneas were distributed with the end use identified as "unknown" compared to 219 in 2018, 230 in 2017,555 in 2016, 64 in 2015, 632 in 2014, and 220 in 2013. The high number of unknowns impacts the acuity of this data.

6.3 Ocular tissue production and distribution: 2019 provincial analysis

Corneas/whole globes recovered with the intention for transplant



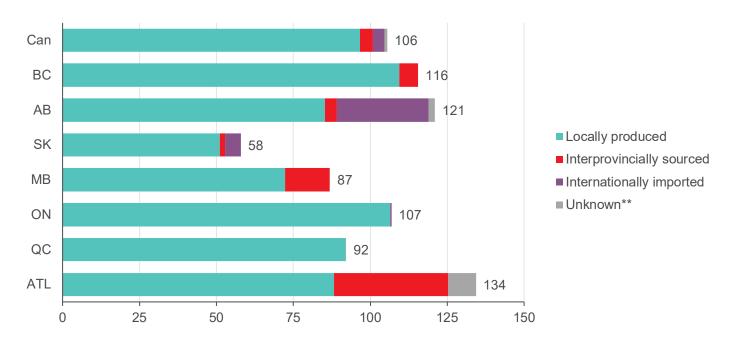
Results per million population (PMP)

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

NL donors were at one time processed by the NB program; however, as of the time of this report, NL donor recoveries were not being processed. As such, the NL population is not included in the NB recovery rate. PE results reflect PE donors whose recoveries were performed by the NS program; NB donors whose recoveries were performed by the NS program are included in NB results. Per million population rates based on Statistics Canada population estimates by province as of July 1, 2019 (<u>Table 17-10-0134-01</u>). National rate is based on the entire national population, including NL, YT, NT, and NU.

Intermediate-term preserved corneas distributed for keratoplasty

Results per million population (PMP)

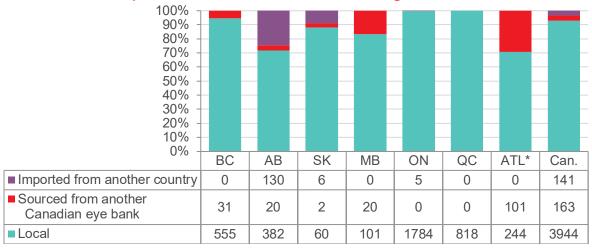


*Atlantic patients are transplanted in Nova Scotia and New Brunswick; rate calculation includes populations of all Atlantic provinces (NS, NB, PE, and NL).

**Unknown cases reflect cornea distributions for which the procedure type was not available and may include non-keratoplasty procedures. Results presented do not include long-term preserved cornea distribution.

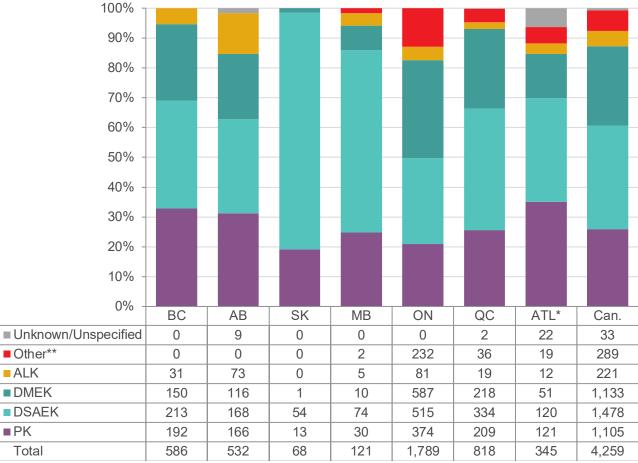
Per million population rates based on Statistics Canada population estimates by province as of July 1, 2019 (<u>Table 17-10-0086-01</u>). National rate is based on the entire national population, including NL, YT, NT, and NU.

Source of intermediate-term preserved corneas distributed for surgical use



* Atlantic patients are transplanted in Nova Scotia and New Brunswick

Corneas sourced from another Canadian eye bank in Alberta include corneas transferred between Alberta eye banks. Results presented do not include long-term preserved cornea distribution.



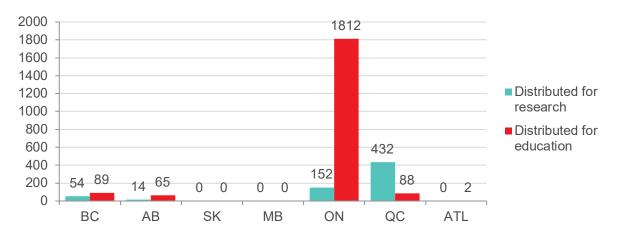
Intermediate-term preserved corneas distributed for surgical use by type of surgery

*Atlantic patients are transplanted in NS and NB.

**Includes K-Pro, KLA, glaucoma shunt patching, and other surgeries.

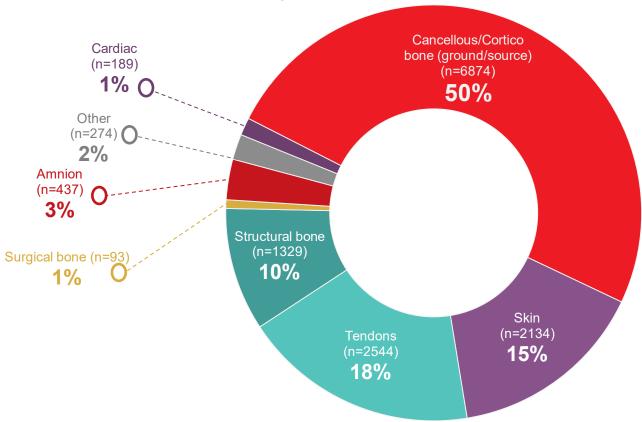
Ocular non-surgical tissue distribution

In 2019 there were 2,708 ocular grafts produced and distributed for research and education. All these grafts were distributed within the province where they were produced.



6.4 Musculoskeletal, skin, cardiac, and amnion tissue grafts processed and released to inventory

In 2019, ten tissue banks processed and released 13,874 musculoskeletal, cardiac, skin, and amnion grafts from deceased and living donors into inventory for transplant. 2019 total production increased by fifteen percent from the previous year (n=12,096) and is the highest recorded.

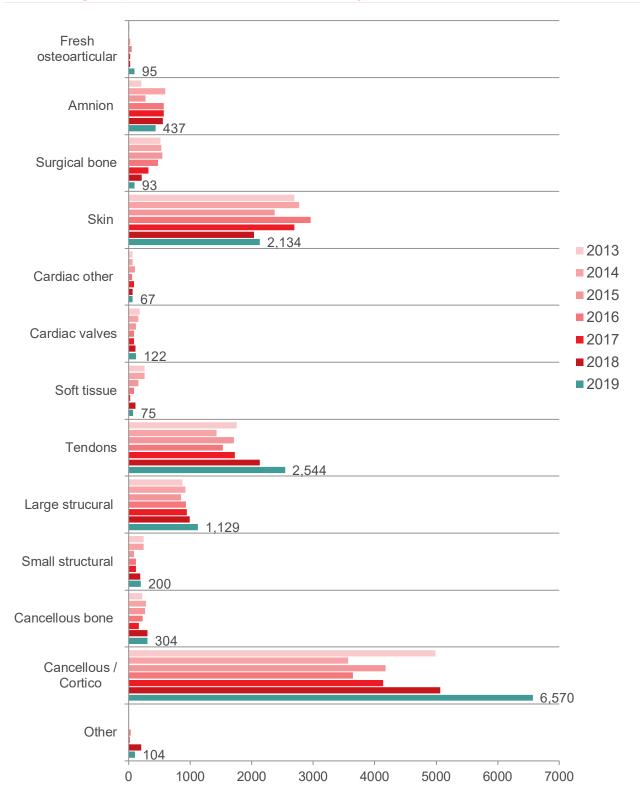


Grafts processed & released to inventory

Production and release of musculoskeletal grafts from deceased donors has increased from 2018, with cancellous/cortico bone increasing by 30% and structural bone increasing by 12%. This is countered by a decrease in the production and release of surgical bone from living donors, which lowered by 55% between 2018 and 2019.

There was an increase in the production and release of tendons in 2019 by 19%, and a slight increase of 0.5% in the production and release of skin.

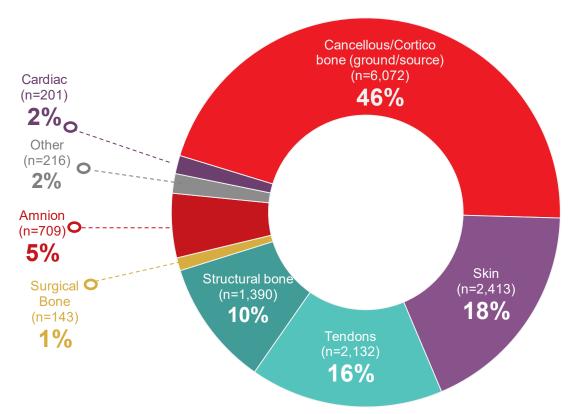
There was a significant increase in grafts processed and released that were characterized as "Other" in 2019. This is composed of fresh osteoarticular (n=95) and soft tissue (n=75).



Number of grafts processed & released to inventory, 2013-2019

6.5 Musculoskeletal, skin, cardiac, and amnion tissue grafts distributed to transplant

In 2019, eleven tissue banks distributed 13,276 musculoskeletal, skin, cardiac, and amnion grafts to transplantation, which was an increase of graft distribution compared to 2017 (n=12,652) and 2018 (n=12,648). While ten banks produce allografts, an eleventh has a relationship with American processors who produce allografts from donors recovered by that bank and return them for distribution.



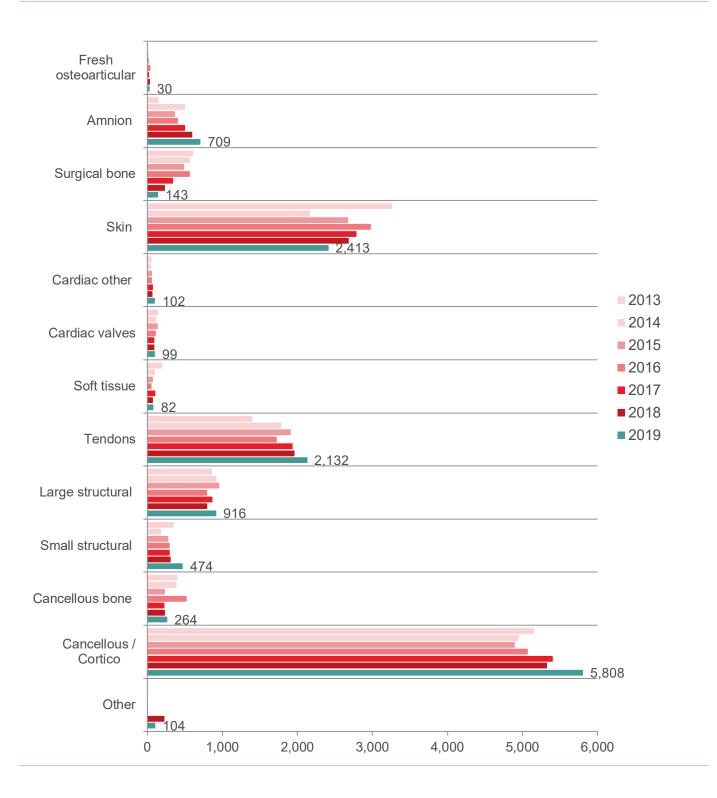
Grafts distributed to transplant

Distribution of musculoskeletal grafts from deceased donors in 2019 increased 7% from 2018. There was a decrease in the distribution of surgical bone from living donors, which lowered by 38% between 2018 and 2019.

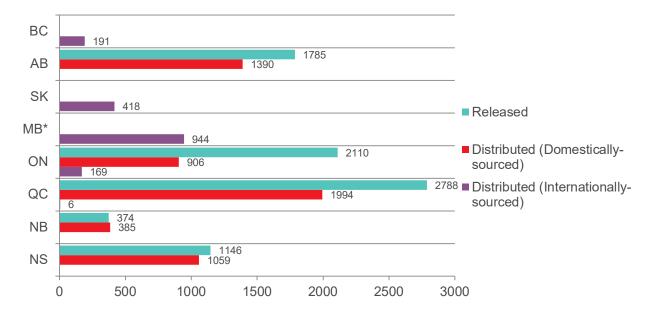
The number of tendons distributed has increased 9% from 2018, while skin distributed has decreased 10% from 2018.

There was a increase in grafts distributed that were characterized as "Other" in 2019. This is composed of fresh osteoarticular (n=30) and soft tissue (n=82).

Number of grafts distributed to transplant



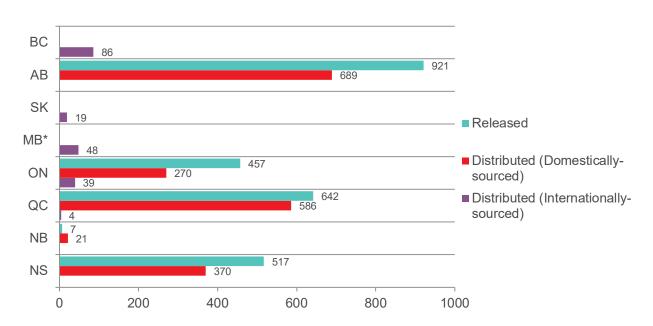
6.6 Deceased donor musculoskeletal, skin, and cardiac tissue: 2019 provincial analysis



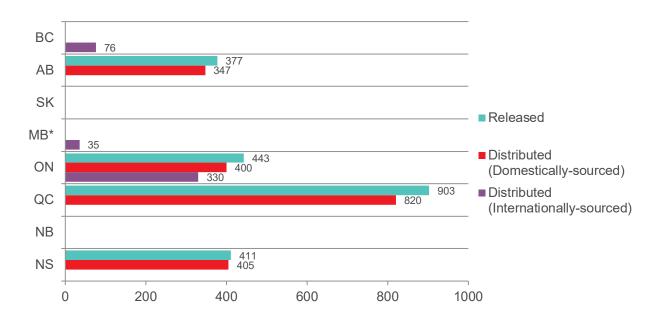
Musculoskeletal grafts released/distributed for transplant

* Tissue Bank Manitoba is a recovery organization that sends tissues to a US partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

Tendon grafts released/distributed for transplant



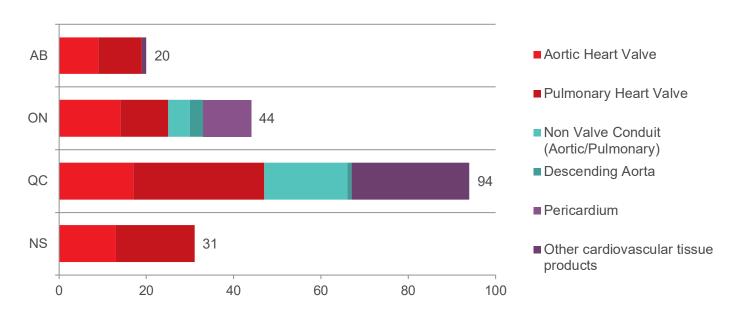
* Tissue Bank Manitoba is a recovery organization that sends tissues to a US partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

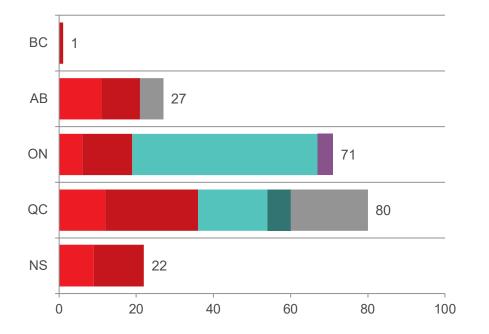


Skin grafts released/distributed for transplant

* Tissue Bank Manitoba is a recovery organization that sends tissues to a US partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

Cardiac grafts processed and released for transplant





Cardiac grafts distributed for transplant

- Aortic Heart Valve
- Pulmonary Heart Valve
- Non Valve Conduit (Aortic/Pulmonary)
- Descending Aorta
- Pericardium
- Other cardiovascular tissue products

Conclusion

2019 represents the seventh consecutive year for which the Eye and Tissue Data Committee has been able to collect and report on key metrics relating to the eye and tissue donation and transplantation system in Canada on a national scale. With the support of eye and tissue banks in Canada, and in collaboration with Canadian Blood Services, this census of Canadian tissue recovery, allograft production, and distribution gives visibility to national results and trends to help inform on the operational capacity of individual eye and tissue banks, as well as providing insight on patterns and trends to inform both national and regional strategy, planning, and policy development.

In particular, issues identified through the data collected and reported on by ETDC with respect to corneal transplantation, including interprovincial variability in corneal transplantation and insufficient growth in corneal donor availability, provided the impetus for the Cornea Donation and Transplantation National Consensus Forum for Improving Access in Canada hosted by Canadian Blood Services in February of 2020.³ This represents a unique opportunity for 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, to collaborate and identify opportunities and solutions.

It is hoped that the initiatives stemming from this forum will result in improvements to access to corneal transplantation and improved communication among eye banking programs, professionals, and other stakeholders. One such initiative under development that is targeted for initiation in 2021 is the establishment of a national forum for the tissue community to engage, share practice expertise, identify challenges, collaboration opportunities or system improvement priorities. Notwithstanding the contributions made by professional associations and groups such as the Canadian Ophthalmological Society, communication channels within the ocular donation and transplantation community are often limited and largely informal, so this is considered to be a critical step in the advancement of a national corneal donation and transplantation system.

Growth needed in Canadian eye and tissue donation

Results for 2019 suggest a 3.1% increase in ocular donors relative to 2018, which represents a 12% increase over 2013 (a rate of approximately 1.8% more ocular donors each year from 2013 to 2019). While the increase in ocular donation reflected by the 2019 results is encouraging, it would be premature to interpret these results as predictive of continued growth in the future, but it remains the case that additional growth is needed. The ocular donation system in Canada has

³ Summaries of the proceedings are available at <u>https://profedu.blood.ca/en/organs-and-tissues/reports/cornea-donation-and-transplantation</u>

not yet reached a point of self-sufficiency: on the contrary, in 2019 10% more corneas were imported from international sources for transplantation as compared with 2018 at a national level. Additionally, there have been just under 4,000 intermediate-term preserved corneas distributed for keratoplasty for five of the past six years, including 2019), reflecting very little change over time in cornea graft availability.

The problems associated with our donor supply are more pronounced in relation to non-ocular tissue donations, which have evidenced relatively little change over time. The total number of donors providing non-ocular tissue donations in 2019 remains 11% lower than in 2013 and within 7% of the average number of donors across the previous six years. Tissue donation from living donors in particular has been decreasing with living donor surgical bone donations steadily decreasing by 87% from 2013 to 2019. Conversely, results suggest that demand for non-ocular tissue does not reflect a similar degree of stability, with non-ocular tissue distribution in 2019 exceeding 2018 distributions across all categories (with the exception of surgical bone from living donors), with 2019 distributions of tendons and for small structural and cancellous/cortico musculoskeletal grafts attaining seven-year highs in 2019. In 2017, the Saskatchewan Health Authority Donation Program ceased production of non-ocular grafts and finished distributing their remaining inventory in 2018. 2019 was the first full year that they relied solely on imports to meet demand.

In addition, results suggest that there remain geographic discrepancies in donation, with BC, Alberta, and Saskatchewan reporting fewer than 100 donors per million population in 2019 and the remaining provinces (with the exception of PEI) reporting 116 donors per million population or more. It should be noted that referrals and donor evaluation are in part dependent on staffing capacity.

In keeping with this finding, Alberta and Saskatchewan relied in part on international banks in sourcing ocular grafts for transplant. Similarly ocular tissue production continues to evidence substantial variation between provinces, with production in provinces such as Manitoba and Saskatchewan resulting in the release of corneal grafts for transplant at rates that are less than half the rates in provinces like Ontario, New Brunswick, and Nova Scotia, relative to their respective populations.

It would be advisable to explore strategies that (a) promote increases in donor availability and (b) maximize donation opportunities within the available domestic donor supply (potentially through enhancements in interprovincial cooperation). These goals are among the themes explored as part of the 2020 national consensus forum in relation to ocular donation.

Appendix A Terms, definitions, and abbreviations

Amniotic membrane

The innermost layer of the placenta consisting of a thick basement membrane and an avascular stromal matrix. It is used as a graft and as a dressing to facilitate ocular surface reconstruction and to promote healing. Its use in plastic surgery (burns, wound care), orthopedic, dental and general surgery is increasing.

Deep anterior lamellar keratoplasty (DALK or ALK)

A partial thickness corneal transplant procedure used to treat disease or injury confined to anterior layers of the cornea: the epithelium, Bowman's layer and stroma. DALK is most often used to treat keratoconus and corneal scarring.

Cancellous/cortical bone

There are two types of osseous tissue that form bones; cancellous "spongy" bone and cortical "compact" bone. Tissue banks mill/grind bone into cancellous cortical particles or powder which is used to pack bone voids in surgical repairs.

Chipped bone

Bone that has been processed into morsels; chipped bone is used to pack bone voids in surgical repairs.

Consent

Signed documentation of approval to proceed with donation from the donor or legal next of kin.

Consent (rate)

The ratio of donors where consent for donation is obtained to the number of donor families approached for consent.

Deceased donor

A donor from whom tissue is recovered following cardiocirculatory or neurological determination of death.

Descemet's membrane endothelial keratoplasty (DMEK)

Transplantation of only the Descemet's membrane and endothelial layer of the cornea. The preparation (processing) of the cornea is done manually. DMEK has been described as a more technically challenging surgical procedure than DSAEK but also has been reported to provide better, post-transplant patient visual acuity, lower rejection rates and faster visual recovery.

Descemet's stripping (automated) endothelial keratoplasty (DSAEK)

A partial-thickness cornea transplant involving the transplantation of donor tissue endothelium, Descemet's membrane and a thin, partial layer of the donor tissue's stroma. The preparation (processing) of the cornea is automated utilizing a microtome.

Distribution

A process that includes the receipt of a request for tissue, selection and inspection of the appropriate tissue and subsequent shipment and delivery of the tissue to the end user (surgeon) for utilization.

Endothelial keratoplasty (EK)

A corneal transplant procedure where only a patient's compromised posterior layers of the cornea are removed and replaced by similar posterior corneal layers of a donor cornea. The advent of this procedure occurred in the early to mid-2000s after fifty years of performing penetrating keratoplasty in nearly all corneal transplant surgeries. EK has clearly established itself as the standard of care for patients with endothelial dysfunction. There are a number of types of EK procedures including DSAEK and DMEK. They can be performed manually (peel) or automated (microtome).

Eye and Tissue Data Committee (ETDC)

A Canadian committee chaired by members of the tissue community and composed of representatives from each provincial tissue program as well as Canadian Blood Services representatives with the purpose to oversee the collection, management and release of national eye and tissue allograft data.

Fresh osteoarticular

Osteoarticular refers to a bone graft that contains a joint surface; such as a knee. Fresh refers to the fact that, in order to preserve viability of joint tissue, the graft is not frozen or cryopreserved. These grafts are refrigerated and usually transplanted within weeks of recovery.

Keratoplasty

A surgical procedure, also known as corneal transplantation, where the procedure involves a replacement of abnormal host tissue with healthy corneal tissue from a donor. The replacement of the corneal tissue can either be partial or full depending on the severity of damage in the cornea.

Living donor

A donor where tissue is recovered from a live person; such as femoral heads which are recovered during total hip replacements or amnion which is recovered from the placenta in live births.

Ocular

A general term which refers to the tissues of the eye which include the cornea and the sclera.

Penetrating keratoplasty (PK)

Corneal transplant with replacement of all layers of the cornea but retaining the peripheral cornea.

Per million population (PMP)

To provide comparative data donation ratios such as the number of donors per million population - may be presented. For reports generated by the Eye and Tissue Data Committee the numerator - # of donors - refers to the province where the donor was identified and recovered as opposed to the province of the recovery organization.

Preservation, intermediate-term

Cornea or corneal section preserved in a solution that maintains cellular and/or ultrastructure viability for 14 days. Intermediate term preservation is currently utilized at 2-8°C storage temperatures. Examples of intermediate term storage media are: Life4°C, Optisol GS, and Eusol.

Preservation, long-term

Cornea or corneal section stored in a solution that is designed to maintain tissue ultrastructure for greater than 14 days and up to five years depending on the technique. Viability is not maintained. Examples are ethanol and glycerin preservation. Other media, such as albumin, may be used in conjunction with ionizing radiation to preserve the tissue ultrastructure.

Processing

The steps taken following recovery to prepare tissue for transplantation. This is essentially a manufacturing process where tissue is manipulated, treated and packaged into forms required by surgeons for interventions and through which quality control and quality assurance processes determine safety and the product release to transplantation. Packaging is considered a type of processing.

Recovery

Obtaining tissue from a donor that is intended for use in human transplantation, therapy, research or education. The surgical removal of donated tissue for future processing; recovery generally occurs in an operating room or dedicated recovery suite.

Referral

A referral is when a death is referred to a donation organization or tissue bank for consideration or evaluation of donation potential. In some jurisdictions all deaths are referred and in others frontline health professionals may do a pre-screening and only refer deaths which have no obvious contraindications to donation.

Released to inventory

Refers to grafts that has been evaluated, and deemed safe and suitable for transplantation, by a medical director, through the appropriate quality review and made available for transplantation. Prior to release grafts in the production process are considered quarantined.

Sclera

The sclera is the part of the eye commonly known as the "white". It forms the supporting wall of the eyeball, and is continuous with the clear comea. Scleral grafts are widely used in ophthalmologic surgery.

Soft tissue

A generic term for muscle, fat, fibrous tissue or other supporting tissue matrix. In tissue banking it often refers to fascia lata; the sheets of fibrous tissue enveloping, separating or binding together muscles and organs. Fascia lata is processed into grafts for use in surgical repairs.

Structural bone

Structural bone grafts are intended to support weight and are classified into large or small. Large grafts include femurs, fibulas and humerus. Small grafts include sized grafts such as cortical dowels, wedges, and rings.

Surgical bone

Femoral heads can be recovered from total hip replacements and evaluated for suitability to transplant. These femoral heads are referred to as surgical bone. Surgeons grind the femoral head in the operating room to produce cancellous powder or particles. With the advent of bank produced pre-packaged cancellous and the increasing regulatory requirements the demand for surgical bone has declined.

Tendon

A band of tough, inelastic fibrous tissue that connects a muscle with its boney attachment. Tendons commonly banked for use in sports medicine surgery include Achilles, Patellar and Tibialis.

Yield

Yield refers to the number of grafts which are recovered and released (deemed suitable) for transplant per donor. Yield can be affected by contamination, recovery technique, processing technique and donor factors such as age and comorbid diseases.

Appendix B Eye and Tissue Data Committee membership

Member	Title	Program
Gary Rockl (Chair)	Tissue Innovation Specialist	Héma-Québec, Québec City, QC
Kimberly Dodds (Vice Chair)	Director	Tissue Bank Manitoba, Winnipeg, MB
Mike Bentley	Manager, Transplant Services	Comprehensive Tissue Centre, Edmonton, AB
Ryan Funk	Senior Tissue Specialist	Southern Alberta Tissue Program, Calgary, AB
Christine Humphreys	Director	Eye Bank of Canada (Ontario Division), Toronto, ON
Nadya Savoie	Director	NB Organ and Tissue Program Horizon Health Network
Michelle Bonnier	Manager, Alberta Health Services	Southern Alberta Organ and Tissue Program, Calgary, AB
Cynthia Johnston	Quality Leader	Regional Tissue Bank, Halifax, NS
Natalie Smigielski	Clinical Specialist, Tissue Program	Trillium Gift of Life Network, Toronto, ON
Ellen Sokol	Deceased Donation Coordinator	Saskatchewan Health Authority Donation Program, Saskatoon, SK
Balram Sukhu	Director	Mount Sinai Allograft Technologies, Toronto, ON
Alison Halliday	Senior Technologist	Ontario Professional Firefighters' Skin Bank, Toronto, ON
Roberta Fransishyn	Acute Care Director, Misericordia Eye Bank	Misericordia Health Centre, Winnipeg, MB
Ivan Yan	Head Technologist	Eye Bank of British Columbia, Vancouver, BC

Canadian Blood Services members

Jim Mohr	Kyle Maru	Bailey Piggott
A/Associate Director, Deceased	Sr. Data Analyst, Information	Data Analyst, Information
Donation	Management	Management

Appendix C List of contributing programs

British Columbia

- Eye Bank of British Columbia, Vancouver
- Island Health Bone Bank, Victoria

Alberta

- Southern Alberta Tissue Program, Calgary
- Lions Eye Bank of Calgary, Calgary
- Comprehensive Tissue Centre, Edmonton

Saskatchewan

• Saskatchewan Health Authority Donation Program, Saskatoon

Manitoba

- Tissue Bank Manitoba, Winnipeg
- Misericordia Eye Bank, Winnipeg

Ontario

Trillium Gift of Life Network manages the collation and submission of data from Ontario eye and tissue banks including:

- Eye Bank of Canada (Ontario Division), Toronto, Ontario
- The Hospital for Sick Children Tissue Laboratory, Toronto, Ontario
- Ontario Professional Fire Fighters Skin Bank, Toronto, Ontario
- Mount Sinai Allograft Technologies, Toronto, Ontario
- Lake Superior Centre for Regenerative Medicine, Thunder Bay, Ontario

Trillium Gift of Life Network supports tissue recovery and therefore qualifies as a recovery organization.

Québec

• Héma-Québec, Saint Laurent: Banque d'yeux du Québec & Banque d'yeux du CUO

New Brunswick

• New Brunswick Organ and Tissue Program; Ocular and Tissue Division, Saint John and Moncton

Nova Scotia

• Regional Tissue Bank, Halifax

Appendix D

List of products programs produce^{*}

Canadian eye banks	PK corneas	DSAEK corneas	DMEK corneas	Sclera	Amnion
Eye Bank of British Columbia	Y	Y	Y	Y	Ν
Lions Eye Bank of Calgary	Y	Y	Y	Y	Ν
Comprehensive Tissue Centre (AB)	Y	Ν	Y	Y	Y
Saskatchewan Health Authority Donation Program	Y	Y	Y	Y	Ν
Misericordia Eye Bank	Y	Y	Y	Y	Y
Eye Bank of Ontario	Y	Y	Y	Y	Y
Héma-Québec	Y	Y	Y	Y	Ν
New Brunswick Organ and Tissue Program	Y	Y	Y	Ν	Ν
Regional Tissue Bank (NS)	Y	Y	Y	Y	Ν

as of publication

Canadian tissue banks	Cancellous bone	Structural bone	Rib or cartilage	Tendon	Fresh osteo	Soft tissue	Cardiac	Skin
Island Health Bone Bank (BC) (Surgical Bone)	Y	Ν	Ν	Ν	Ν	Ν	Ν	N
Southern Alberta Tissue Program	Y	Y	Y	Y	Y	Y	Ν	Y
Comprehensive Tissue Centre (AB)	Y	Y	Y	Y	Y	Y	Y	Y
Tissue Bank Manitoba*	Y	Y	Y	Y	Y	Y	Ν	Y
RegenMed (ON)	Y	Y	Ν	Y	Ν	Y	Ν	Y
Mount Sinai Allograft Technologies (ON)	Y	Y	Ν	Y	Y	Y	Ν	Ν
Hospital for Sick Children, Tissue (ON)	Ν	Ν	Ν	Ν	Ν	Ν	Y	Ν
Ontario Professional Firefighters Skin Bank	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Y
Héma-Québec	Y	Y	Ν	Y	Ν	Ν	Y	Y
New Brunswick Organ and Tissue	Y	Y	Ν	Y	Ν	Ν	Ν	Ν
Regional Tissue Bank (NS)	Y	Y	Ν	Y	Ν	Y	Y	Y

* Relationship with US programs who process MB donors and return tissue for distribution