Canadian Blood Services
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

Canadian Eye and Tissue Data Committee Report

Canadian eye and tissue banking statistics

2018

Organs & Tissues for Life

Permission for use of data

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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.

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Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Foreword

Joint message: Chair, ETDC and Director, OTDT, Canadian Blood Services

The Canadian Eye and Tissue Data Committee (ETDC) works diligently to assemble and provide annual national reports on eye and tissue data in Canada. The 2018 ETDC report provides information that supports assessment and improvement of Canadian eye and tissue banking. The value of the information captured has been recognized regionally, nationally, and internationally.

With this information, provincial programs can assess activity trends that may be used to inform their operational strategies. National organizations, such as the Canadian Ophthalmological Society, use this data to inform discussions on national practice and policy.

Six years of sequential data analysis has provided insight into emerging national trends and will continue to inform individual tissue banks about operations and strategy goals for the future.

Results from this report shed light on several issues in operational planning and policy development that warrant further consideration, such as:

- A lack of growth in Canada's tissue donation and production allograft production and product development in the face of the aging Canadian population
- A need to explore emerging products and technologies, particularly in the context of continuing growth in the demand for DMEK and in relation to new tissue allograft options
- Further investigation into the ongoing provincial variance in corneal donation and transplantation rates is required
- Improvements necessary in supply and demand alignment as well as the development of national communication mechanisms

We express our appreciation to those who contributed to the development of this report from each contributing program, including the program representatives who directly participate in the ETDC and those who contribute to the collection, collation, validation, and submission of eye and tissue donation activity data to the committee.

Canadian Blood Services remains committed to working collaboratively with the Canadian tissue community, providing continued support for national data collection, collation, and reporting on Canadian eye and tissue banking activity. The annual ETDC reports represent a testament to what can be achieved through inter-organizational and inter-provincial cooperation and collaboration.

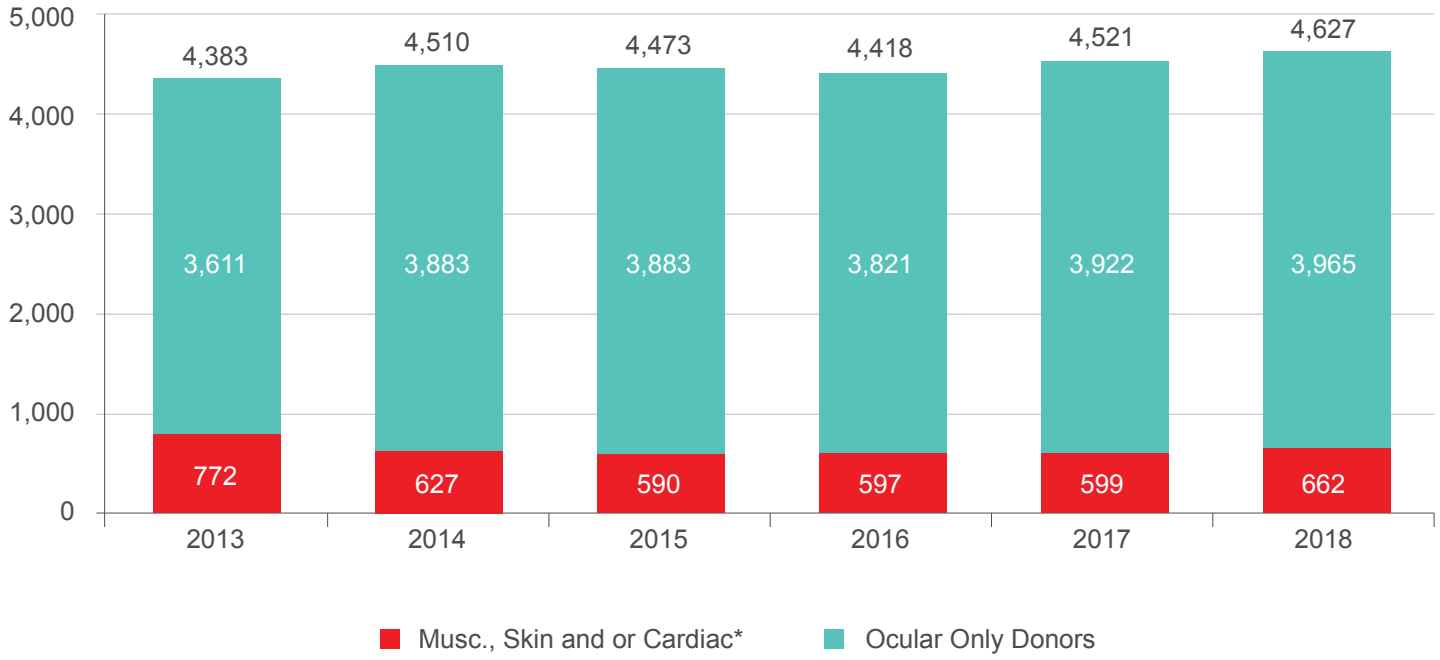
We look forward to continuing to work together to develop and disseminate quality information that is key to delivering a better future for Canadian eye and tissue donation.

Cynthia Johnston, BSc, CTBS, CMDRT
Chair, Eye and Tissue Data Committee;
Regional Tissue Bank Transplantation Services
Nova Scotia Health Authority

Amber Appleby, RN, BScN, MM
Director, Organ and Tissue Donation and Transplantation
Canadian Blood Services

Summary

Deceased donors by year, 2013–2018



* Results include donors where ocular tissue was also recovered

System performance data

Beginning in 2012, Canadian Blood Services, on behalf of the Eye and Tissue Data Committee (ETDC), received data submissions from all Canadian eye and tissue programs. Data definitions were 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 2018, 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.

National results on key metrics

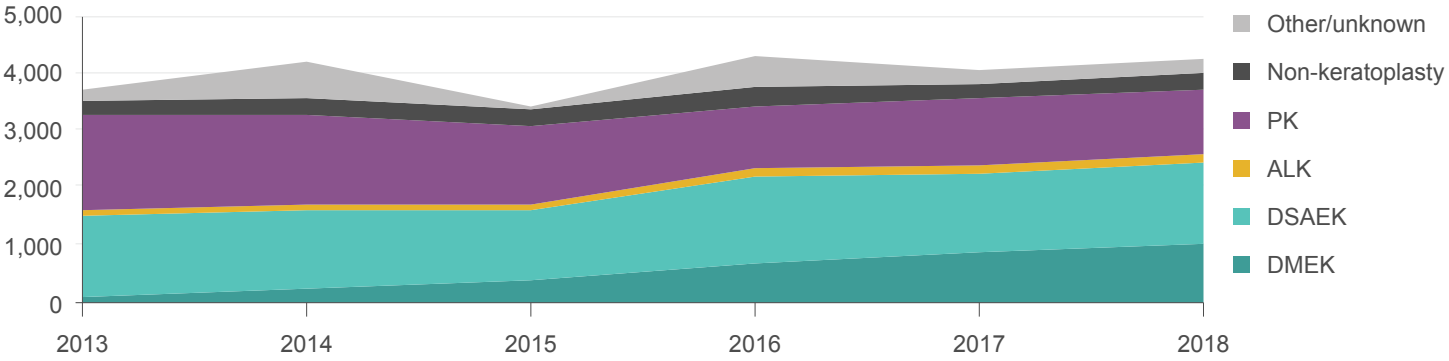
In 2018, Canadian eye and tissue banks received 53,925 deceased donor referrals for potential tissue donation, which represents a 7% increase relative to 2017; 57% of those approached consented to tissue donation, based on data from 10,082 approaches.

Hospitals were the referring agency for 82% of referrals for actual deceased donors in 2018, as was the case in 2017. The second largest source, accounting for 7% of referrals in 2018, was extended care facilities such as nursing homes and hospices.

In 2018, tissue was recovered from 4,627 deceased donors, representing a 2% increase from the previous year. Tissue was recovered from 197 living donors, a 50% decrease from 2017.

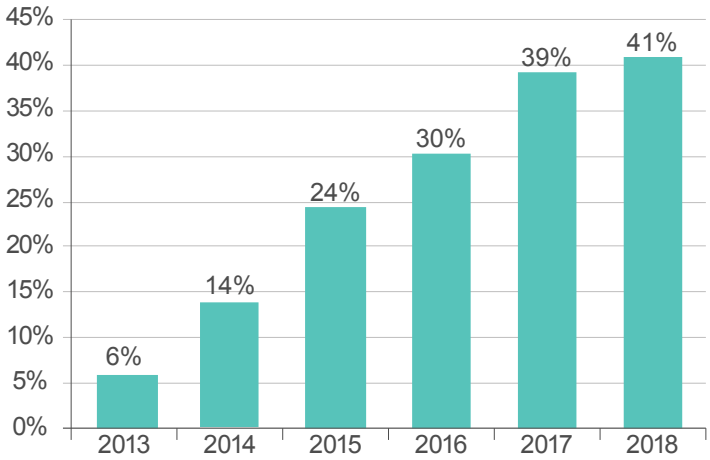
Results relating to ocular tissues in 2018 were generally comparable to 2017 results; there was a 2% increase in the number of donors from whom ocular tissue was recovered in 2018 (n=4,469) relative to the previous year, and a 2% increase in ocular production for transplant, with 2018 seeing the release of 4,780 corneas for transplant.

Intermediate-term preserved cornea distribution



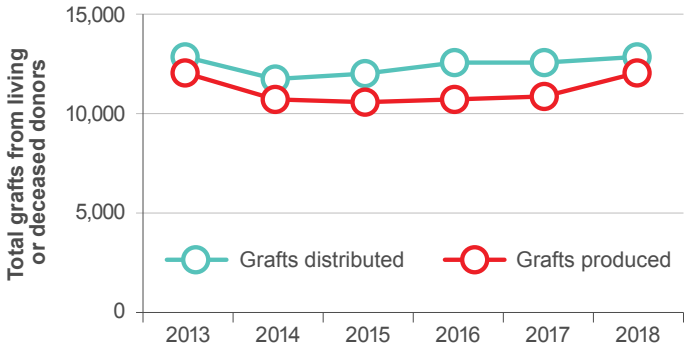
Cornea distribution for transplant, including penetrating keratoplasty (PK), endothelial keratoplasty (EK) and anterior lamellar keratoplasty (ALK) reflected comparable results to 2017 distributions, with precise differences being influenced by the number of cases in which the surgery type was not available. In 2018, 3% of corneas distributed for transplantation were imported from the United States. This is a decrease from 2017, which saw 8% of corneas distributed for transplantation imported from the United States.

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, albeit at a decreased rate than the previous five years.

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



In 2018, there were 12,096 musculoskeletal, skin, amnion, and cardiac grafts produced and released to inventory nationally with 12,963 being distributed for transplant in total. The production of musculoskeletal, skin, amnion, and cardiac grafts increased by 11% relative to 2017, while the total number distributed for transplant increased by 2%.

Acknowledgements

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 to 2018.

Canadian eye and tissue programs are to be commended for 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.

Introduction

Canadian Blood Services received a mandate from Canadian federal, provincial, and territorial governments in 2008 for organ and tissue donation and transplantation. To fulfil this mandate, Canadian Blood Services works with the organ and tissue donation and transplantation community to improve national system performance through the development of leading practices, professional education, public awareness and data analysis and reporting. The organization also manages clinical programs that support interprovincial sharing of organs.

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 and Canadian Blood Services (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, release and publication.

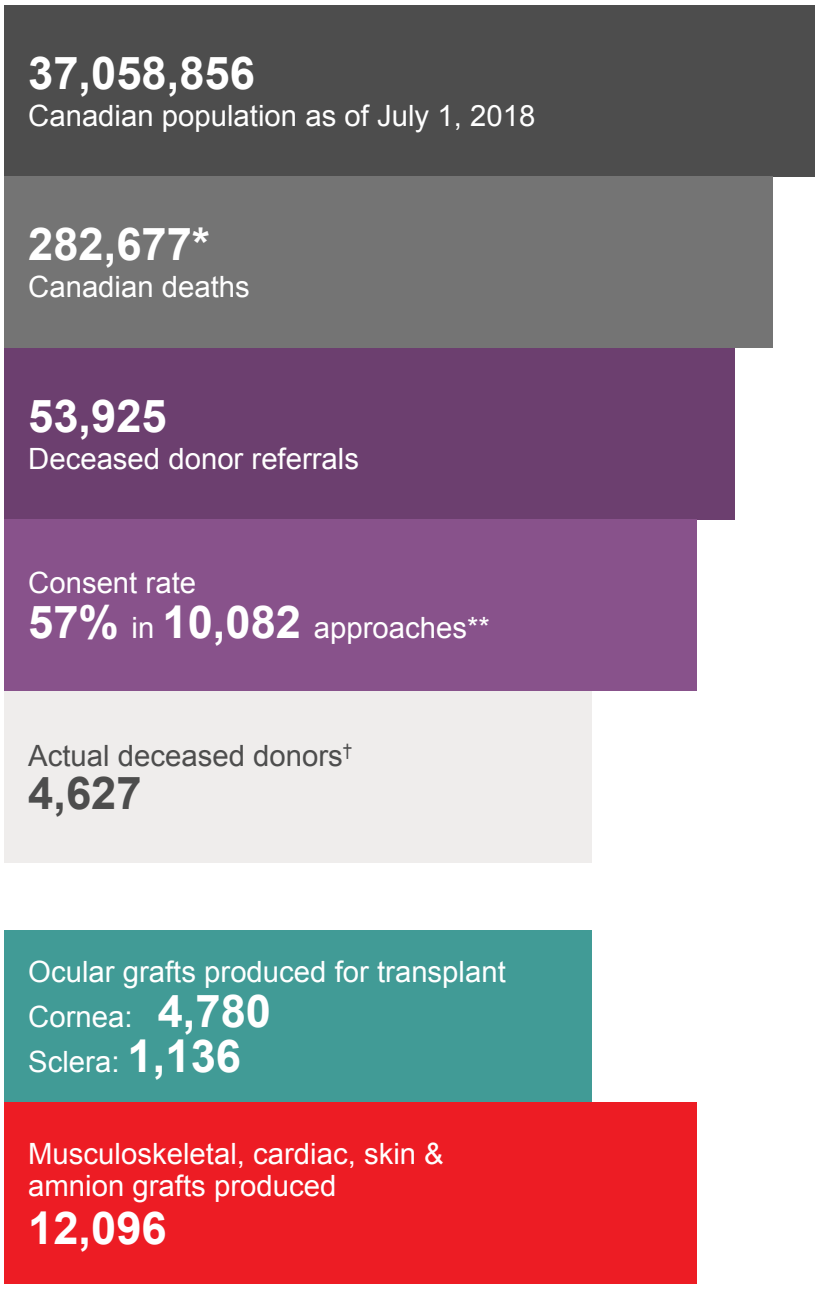
Prospective data collection was initiated in 2012 from all eye and tissue banks operating in Canada (see Appendix C for a list of contributing programs). Canadian Blood Services acts as the repository for the collected data and provides support for data management, analytics, and publication/reporting 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 available (see Appendix D).

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

The results presented here report on Canadian eye and tissue banking donation, production, and distribution statistics for Canadian eye and tissue banks from Jan. 1 to Dec. 31, 2018 as well as Canadian system activity from 2013 through 2018. 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 for the time and expertise they provide to the collection and collation of national activity data.

Canadian eye and tissue banks

View of tissue donation and transplantation



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.*

* Statistics Canada. Table 13-10-0715-01 Deaths, by place of death (hospital or non-hospital).

** 11 programs collect data about the number of approaches and consent rate; this data documented a 57% consent rate in 10,082 approaches in 2018.

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

Comparative analysis

Canadian eye and tissue banks

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

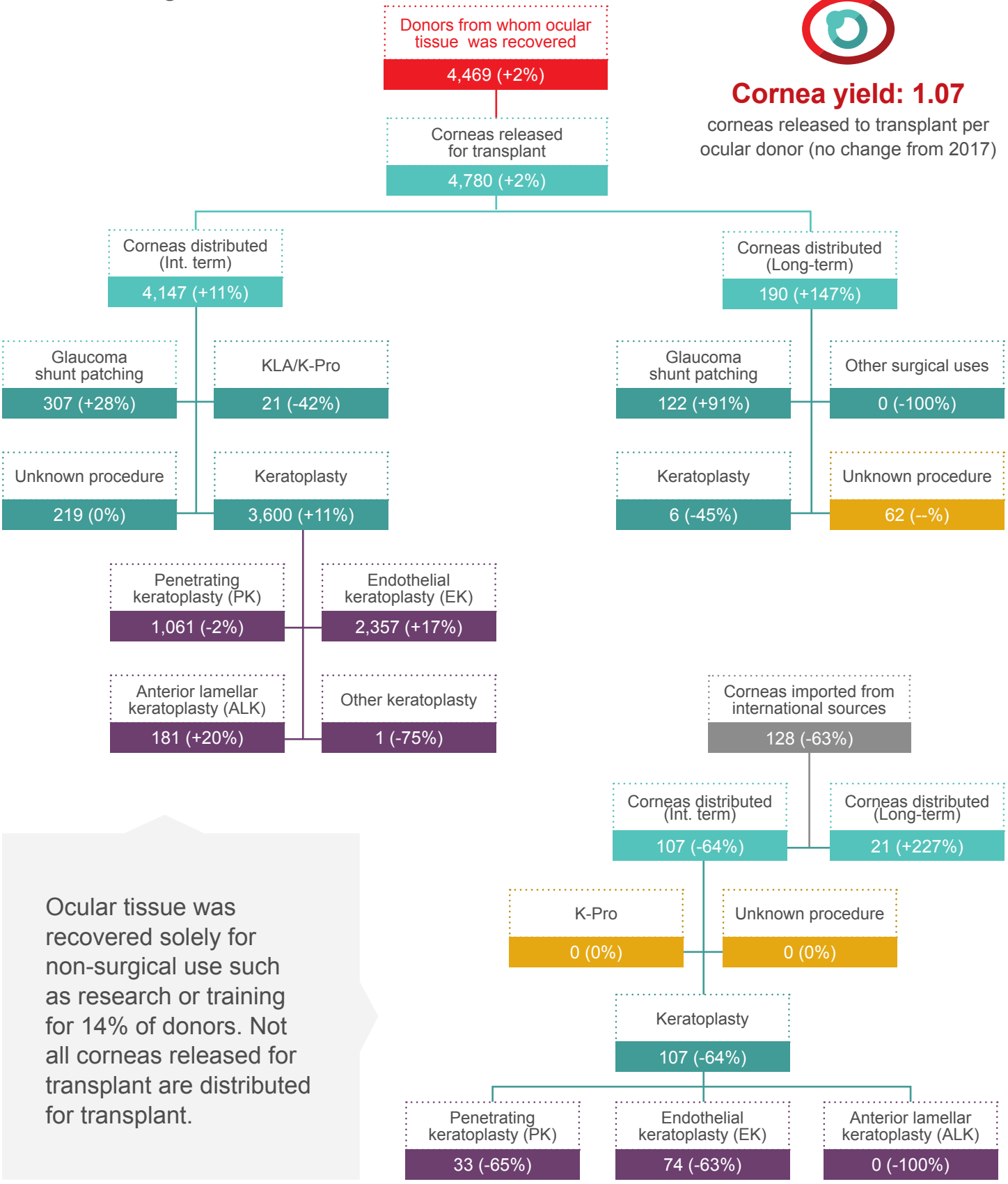
Canadian eye and tissue banking activity, 2013-2018

Total Canadian activity*	2013	2014	2015	2016	2017	2018	% Change (2017-2018)
Deceased donor referrals	41,594	45,154	46,381	45,609	50,506	53,925	+7%
Total deceased donors from whom tissue was recovered	4,383	4,510	4,473	4,418	4,521	4,627	+2%
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	+2%
Deceased donors where bone, cardiac and or skin was recovered	772	627	590	597	657	662	+1%
Surgical bone donors	700	669	549	456	379	186	-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%
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%
Musculoskeletal and amnion grafts processed and released into inventory from living donors	718	1024	822	1,050	896	768	-14%
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	+11%
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	+2%
Total: All eye and tissue grafts produced and released into inventory (deceased and living donors)	17,602	16,570	16,241	17,366	17,412	18,222	+5%
Total: All eye and tissue grafts distributed to transplantation (deceased and living donors)	17,820	17,131	16,595	18,650	18,327	18,973	+4%

*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=219 (2018); n=230 (2017); n=555 (2016); n=64 (2015); n=632 (2014); n=220 (2013).

Cornea processing and distribution in 2018, with % change from 2017



Cornea yield: 1.07

corneas released to transplant per ocular donor (no change from 2017)

Ocular tissue was recovered solely for non-surgical use such as research or training for 14% of donors. Not all corneas released for transplant are distributed for transplant.

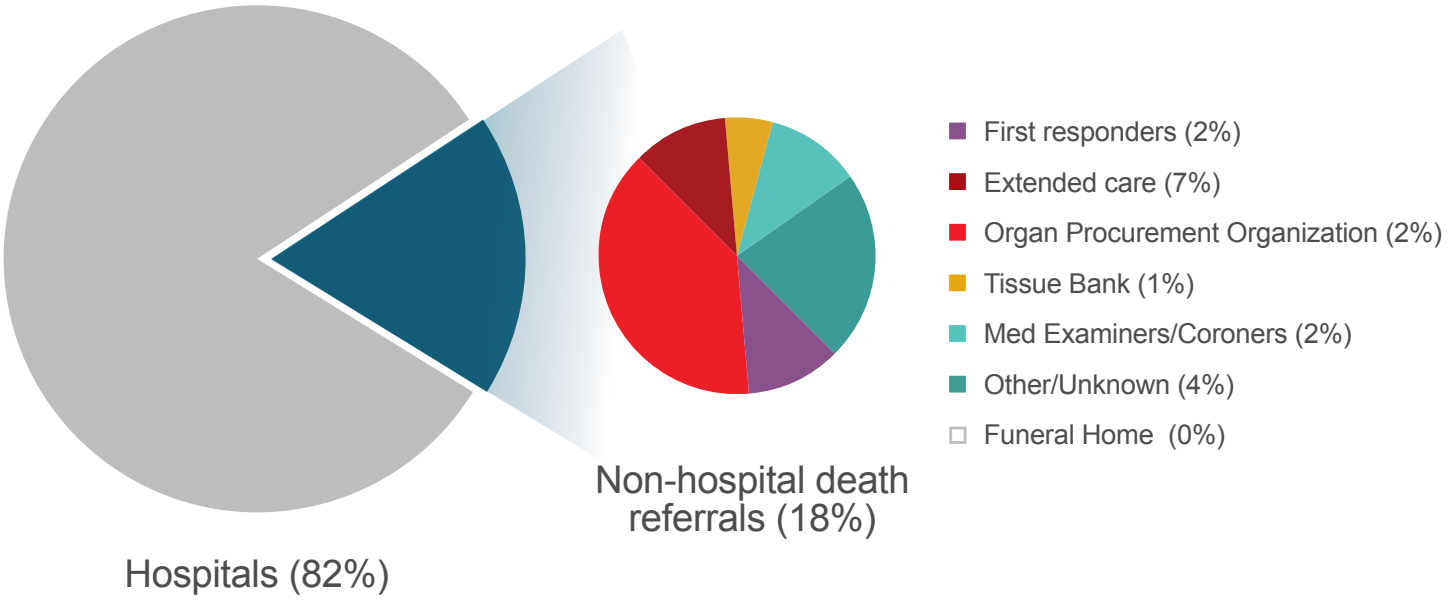
Deceased donation activity, 2018

Total donor referrals

A total of 53,925 deaths were identified and referred for initial screening and consideration of tissue donation potential in 2018, a 7% increase from 2017 (n=50,506) and an 18% increase from 2016 (n=45,609). Approximately one-fifth of realized donors in 2018 were non-hospital referrals, which is consistent with 2017 and 2016 results.

Actual donors by source, 2018

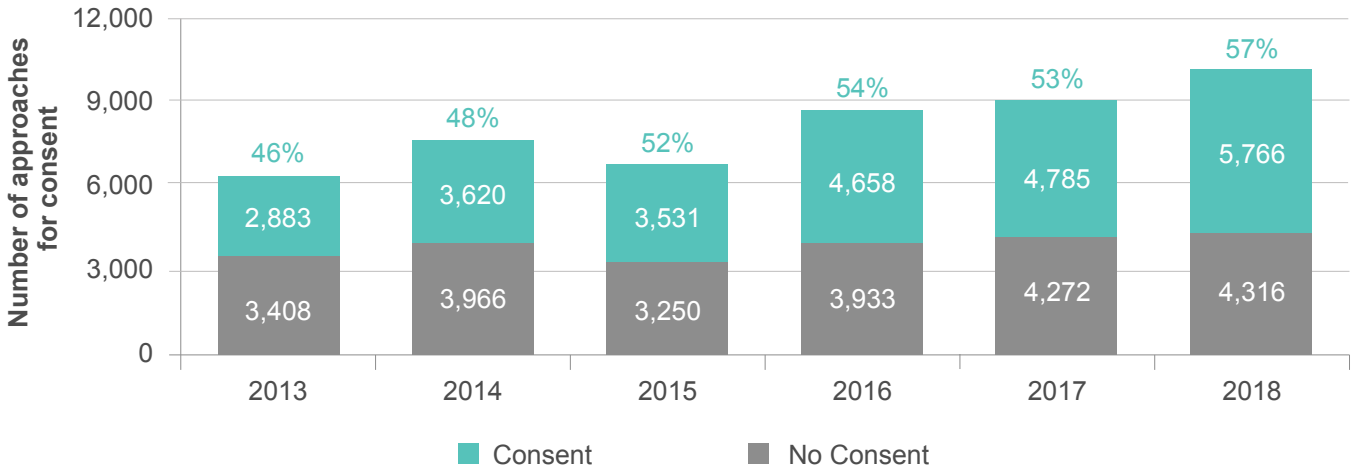
n=4,627



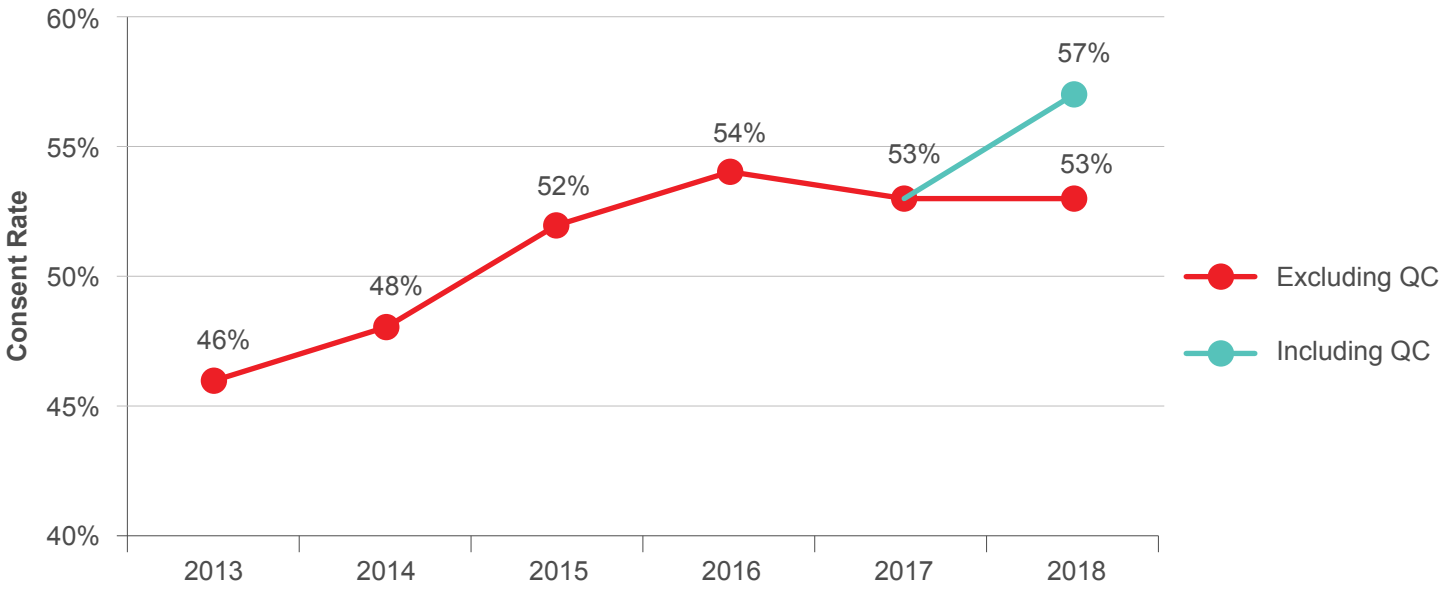
Consent rate

In 2018, 11 programs provided data on 10,082 approaches for deceased tissue donation. A consent rate of 57% was identified, which is the highest consent rate to date; the inclusion of Quebec's consent data for the first time was the cause of this increase.

Consent rate for tissue donation, 2013–2018



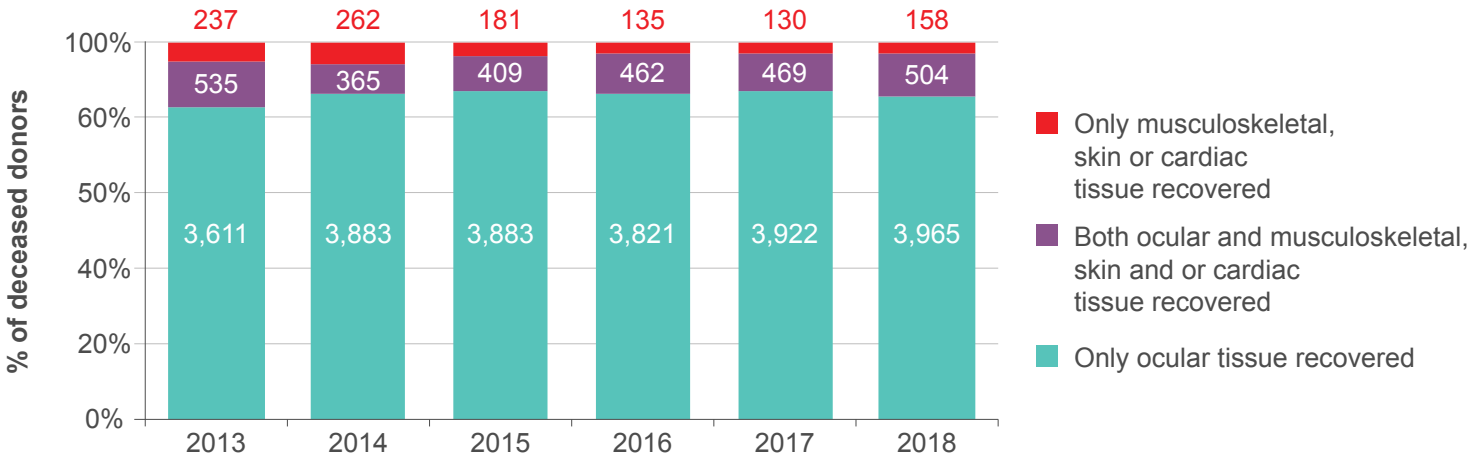
Consent rate for tissue donation: Quebec's addition, 2013–2018



Deceased donors: national analysis

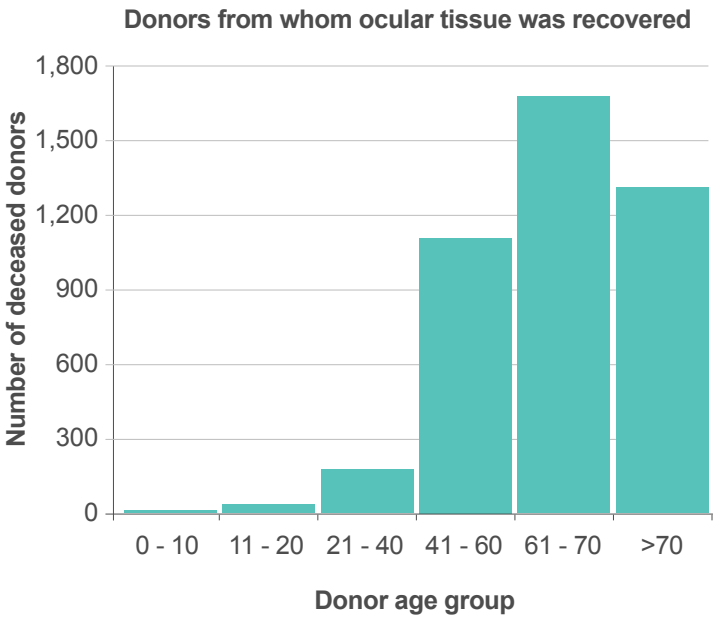
In 2018, there were 4,627 consented deceased donors from whom tissue was recovered in Canada, an increase of 2% from 2017 (n=4,521) and an increase of 5% from 2016 (n=4,418). Of these donors, 86% we ocular-only donors, as was the case in 2017 and 2016.

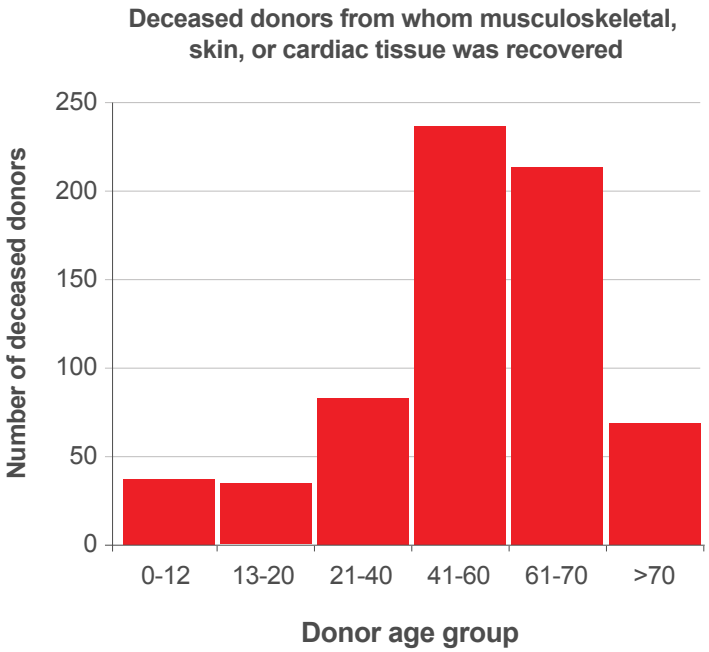
Deceased donors by tissue type recovered, 2013–2018



The 2018 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 six years, averaging 4,489 donors per year over this period, with each year's total being within 3% of the six-year average. The number of donors from whom ocular tissue is recovered has also remained within 4% of the average for the past six years (n=4,305).

Deceased eye and tissue donor age distribution, 2018



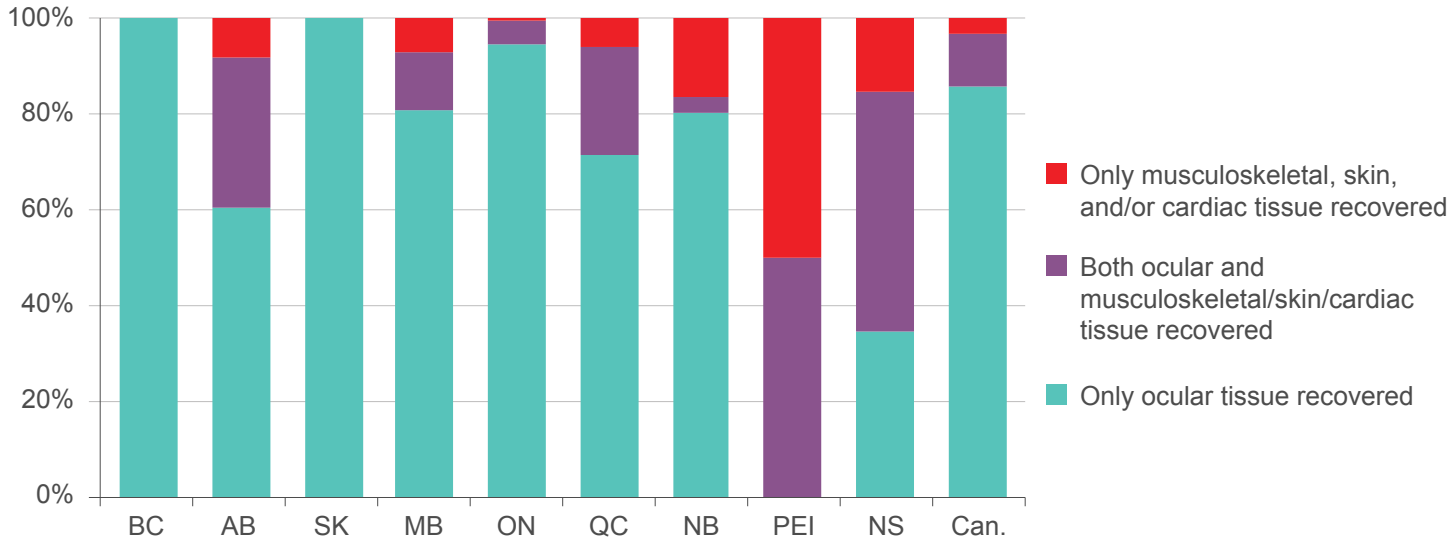


Age data available for 4,523 deceased donors (98% of total)

The age distributions for deceased donors in 2018 are essentially equivalent to the respective age distributions in the previous year.

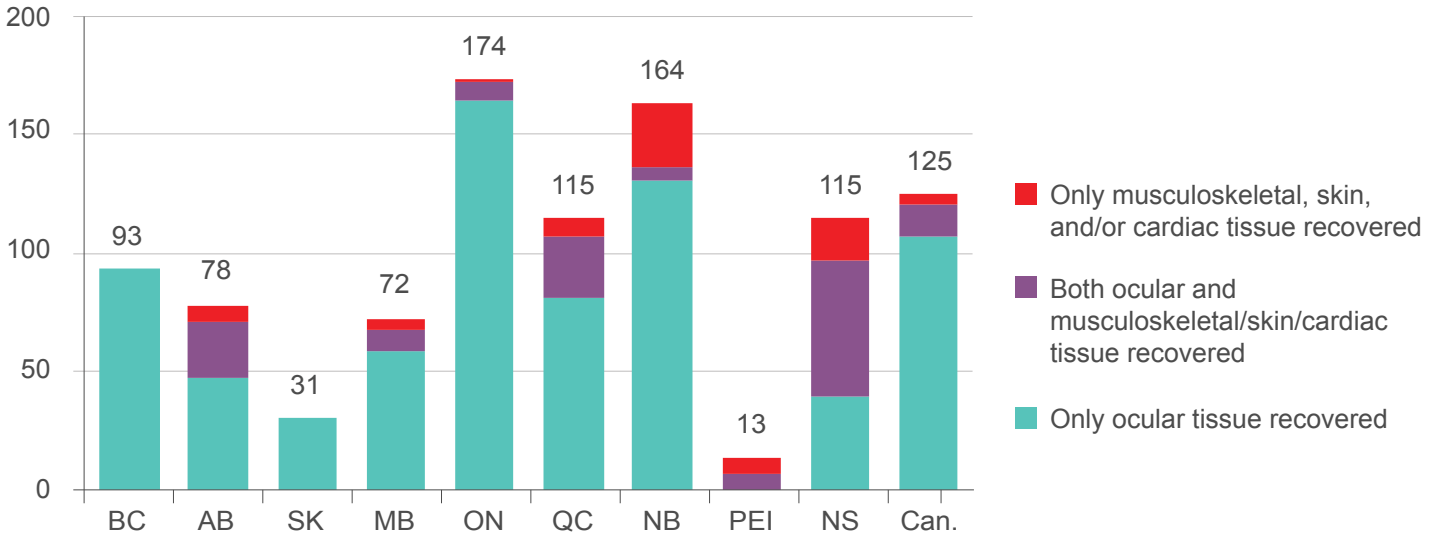
Deceased donors: provincial analysis

Deceased donors by tissue type recovered, 2018



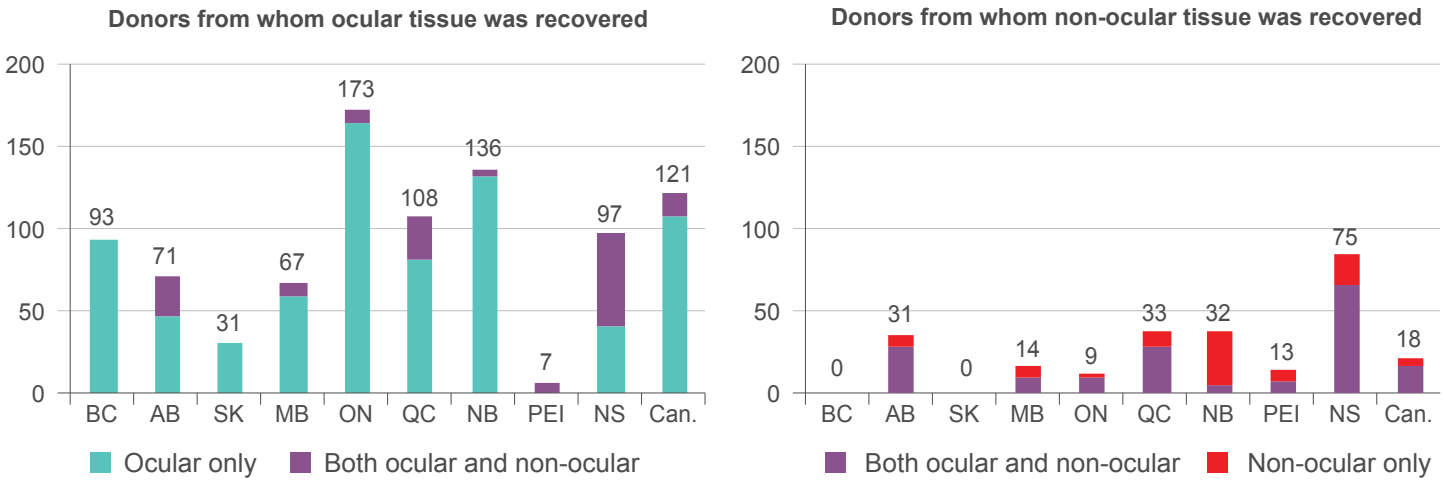
PEI results reflect PEI donors whose recoveries were performed by the NS program. NB donors whose recoveries were performed by the NS program are included in NB results.

Total deceased tissue donors, 2018
Results per million population (PMP)



Musculoskeletal, cardiac, and skin tissue is not recovered in BC or NL. Per million population rates based on Statistics Canada population estimates by province as of July 1, 2018 (Table 17-10-0134-01). PEI results reflect PEI 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, 2018
Results per million population (PMP)



Musculoskeletal, cardiac, and skin tissue is not recovered in BC or NL. Per million population rates based on Statistics Canada population estimates by province as of July 1, 2018 (Table 17-10-0134-01). NB donors whose recoveries were performed by the NS program are included in NB results. National rates are based on the entire national population.

Living donation activity

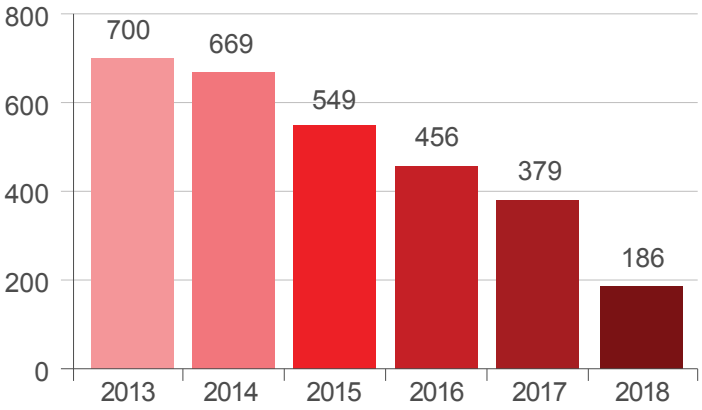
Surgical bone donation

In 2018, four programs reported recovering bone from living donors; this involves recovering femoral heads during total hip replacement surgery. Results from 2018 suggest the ongoing trend of decreasing living donor bone recovery, with a corresponding decrease in the number of surgical bone grafts released.

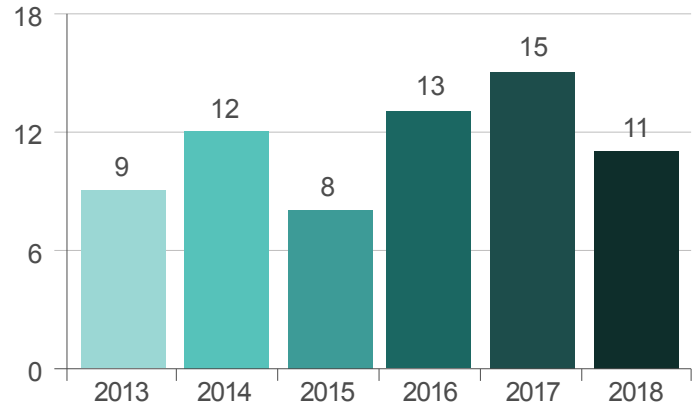
Amnion donation

In 2018, amnion living donation and production activity is similar to that seen over the past six years. Distribution of amnion has increased relative to 2017, reaching the highest recorded level to date.

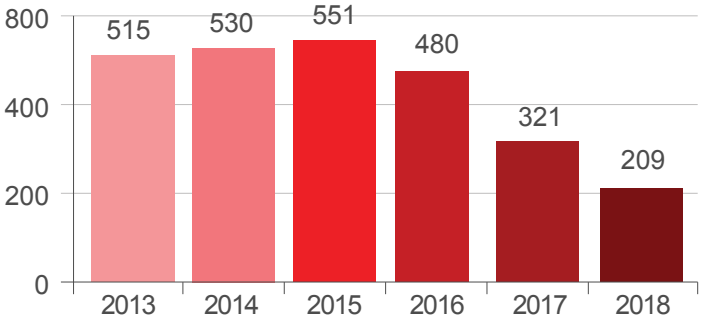
Surgical bone recoveries (donors)



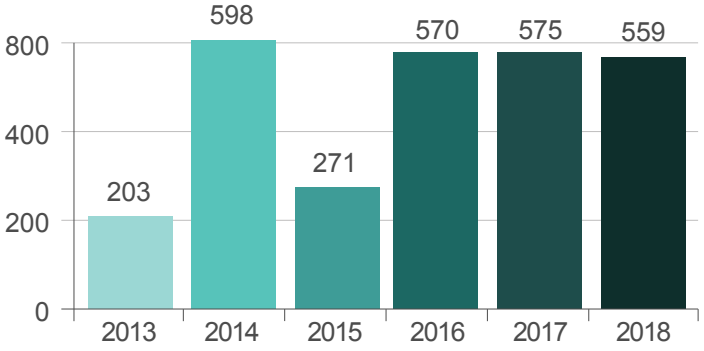
Amnion donors



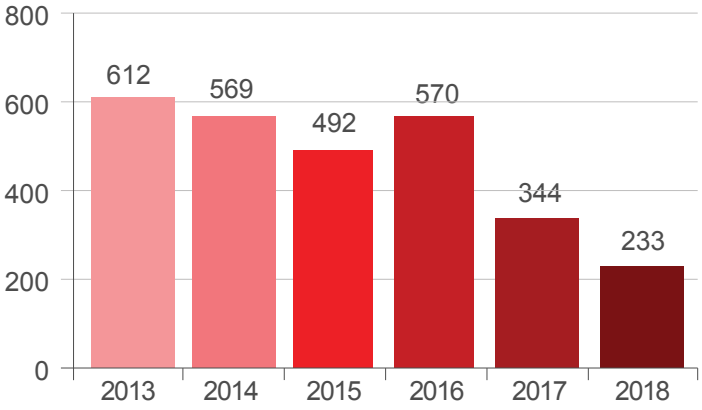
Surgical bone released into inventory



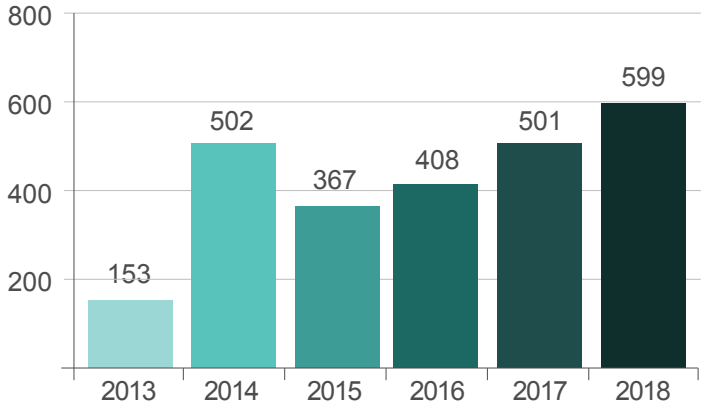
Amnion released into inventory



Surgical bone distributed

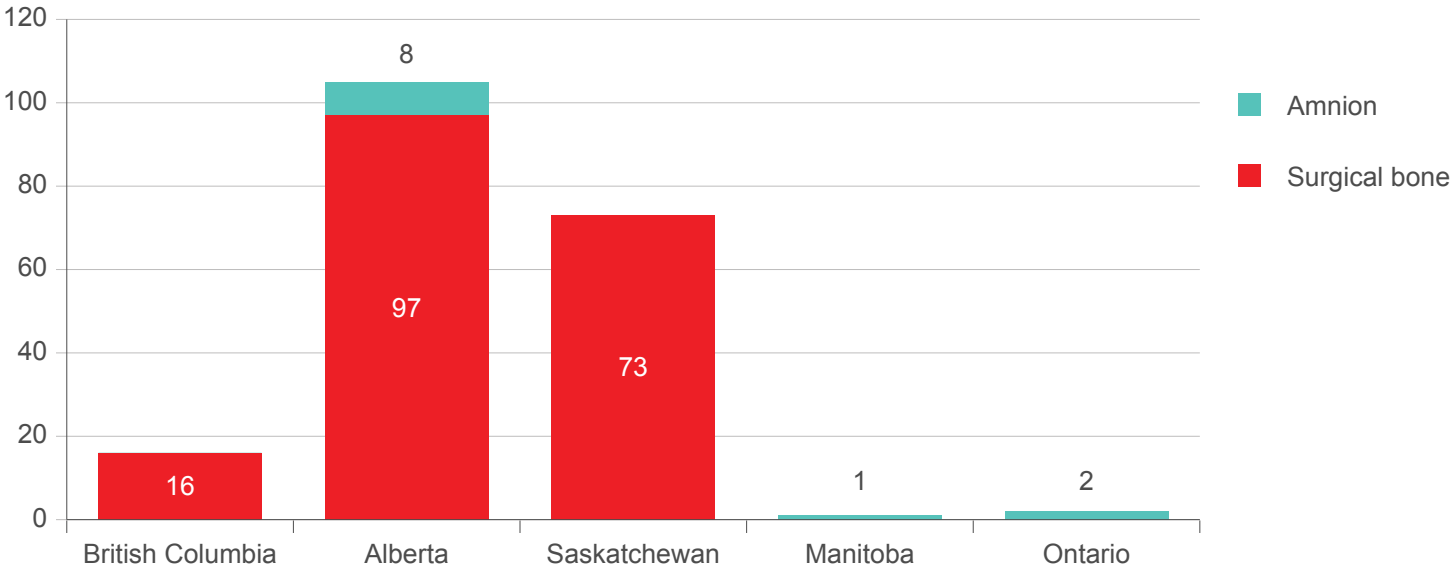


Amnion distributed

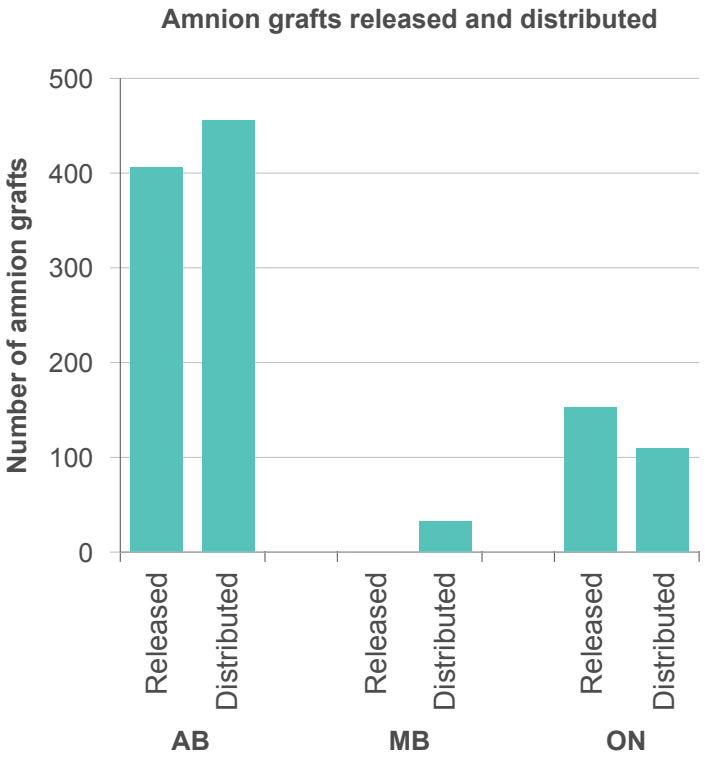


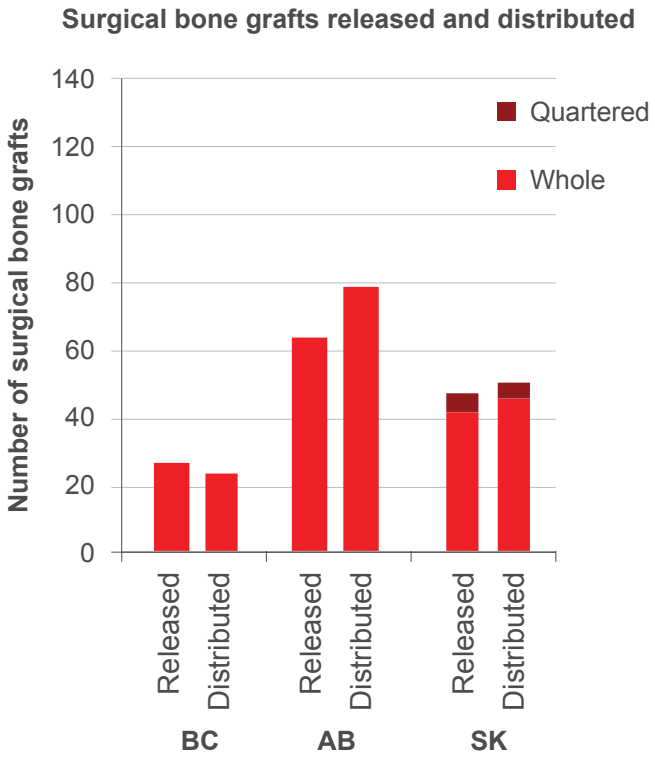
Living donation: provincial analysis

Living donors from whom tissue was recovered, 2018



Living donor surgical bone and amnion released and distributed, 2018





Production and distribution activity

Total corneas distributed for transplant

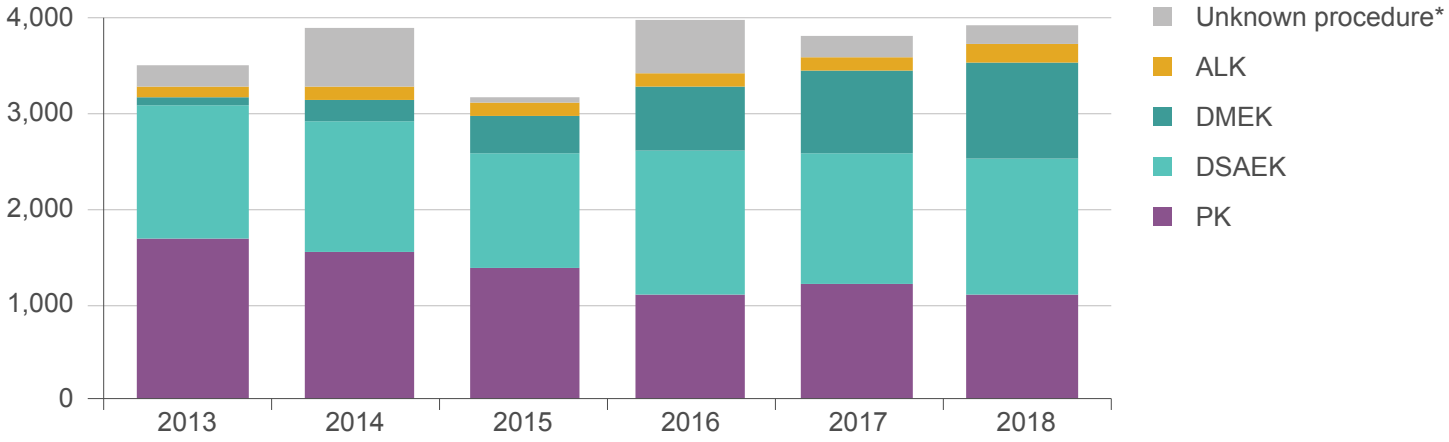
In 2018, Canadian eye banks distributed 4,498 corneas for surgical use, including 4,254 intermediate-term preserved corneas of which 3,706 were known to have been utilized for penetrating, endothelial, or anterior lamellar keratoplasty. This represents a 4% increase from the 3,550 corneas distributed for these types of keratoplasty in 2017.

One cornea was distributed for a keratoplasty procedure other than PK, EK, or ALK in 2018. In addition, six 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 219 corneas in 2018, similar to what was seen in 2017 (n=220). It is likely that these were used for keratoplasty, but the procedure type was not recorded.

In 2018, 328 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, 2013–2018



* 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.

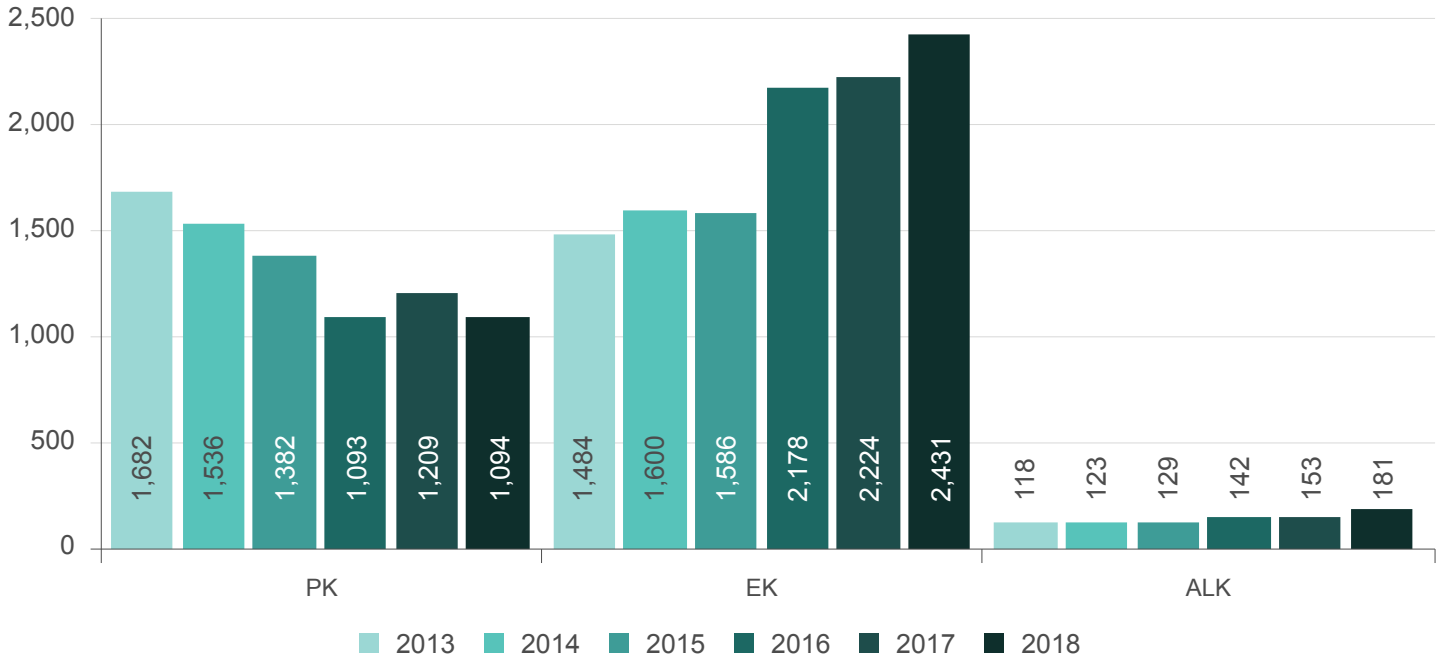
2017: Five corneas distributed for keratoplasty other than PK, DMEK, DSAEK, or ALK, including one case in which the cornea was distributed for an EK procedure other than DMEK/DSAEK.

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 2018 for which the keratoplasty type could be determined, 66% were for EK, which is slightly higher than the proportion in 2017 (62%) and 2016 (64%).

In 2018, six Canadian eye banks (Eye Bank of British Columbia, Comprehensive Tissue Centre in Alberta, Eye Bank of Ontario, Héma-Québec's Banque d'yeux du Québec and Banque d'yeux du CUO, Nova Scotia's Regional Tissue Bank, and the Lion's Eye Bank in Alberta) provided processing service, with all six providing pre-cutting service for DSAEK. Four centres, the Comprehensive Tissue Centre in Alberta, the Eye Bank of Ontario, Regional Tissue Bank of Nova Scotia, and the Banque d'yeux du Québec and 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, 2013-2018



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%. Since then it has continued to rise by an average rate of 6% per year. Intermediate-term preserved corneas distributed for ALK has remained relatively stable between 2013 to 2018.

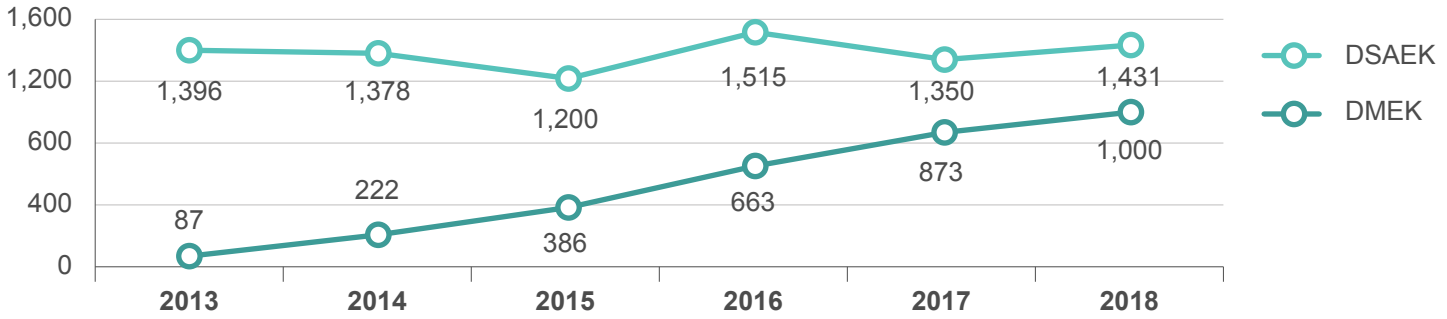
Types of endothelial keratoplasty

In endothelial keratoplasty (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 15% in 2018. In 2018, 41% of corneas known to have been used for EK procedures were used for DMEK.

Types of endothelial keratoplasty, 2013–2018

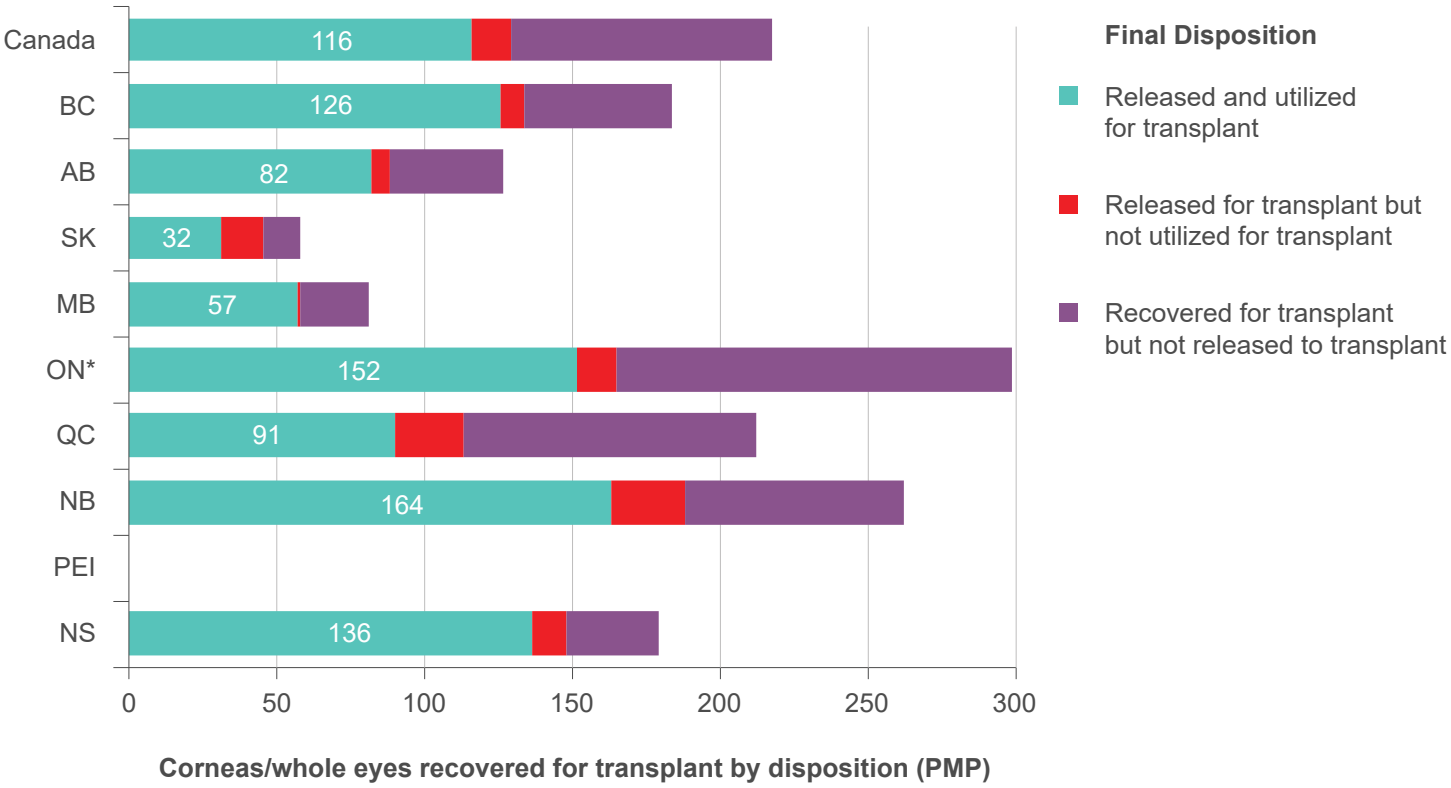


Not shown: one cornea distributed for EK for which specific procedure type could not be determined (2013). In 2017, 230 intermediate-term corneas were distributed with the end use identified as "unknown" compared to 555 in 2016, 64 in 2015, 632 in 2014, and 220 in 2013. The high number of unknowns impacts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

Ocular tissue production and distribution: provincial analysis of transplant

Corneas/whole globes recovered with the intention for transplant, 2018

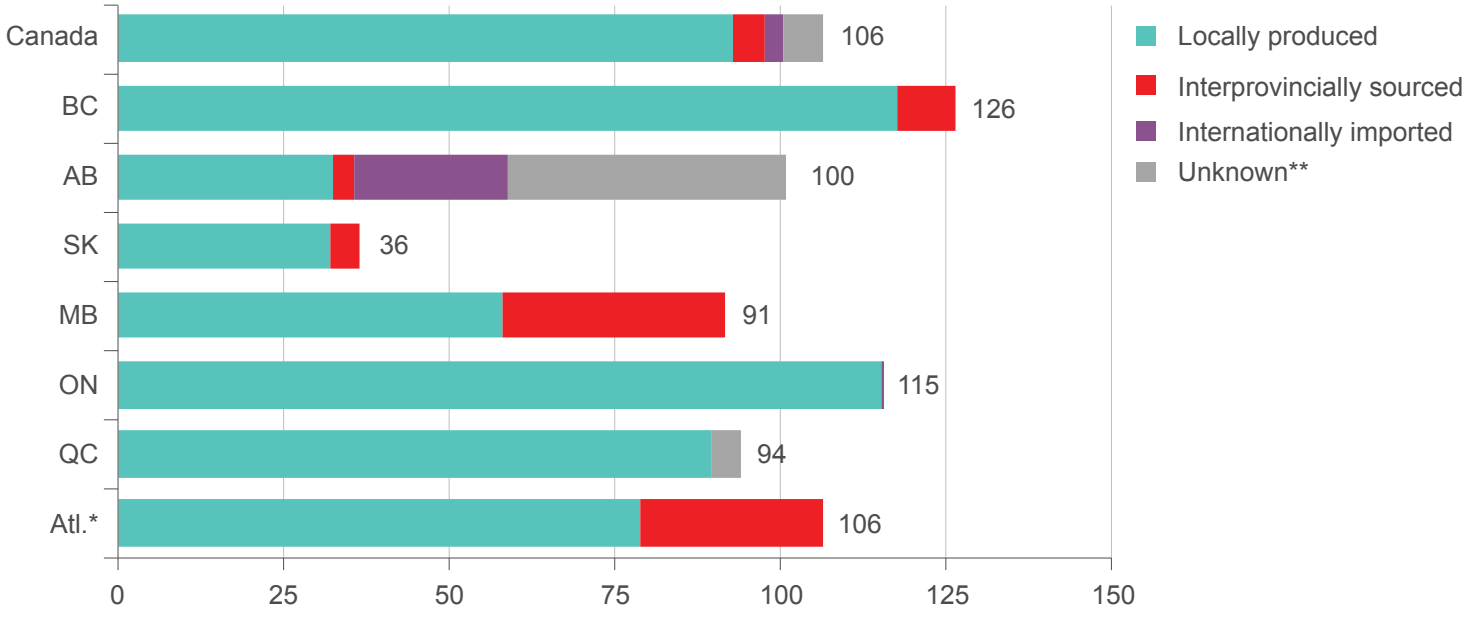
Results per million population (PMP)



* 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, at the time of this report, NL was no longer recovering ocular tissue. As such, the NL population is not included in the NB recovery rate. PEI results reflect PEI 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, 2018 (Table 17-10-0134-01). National rate is based on the entire national population, including NL, YT, NT, and NU.

Intermediate-term preserved corneas distributed for keratoplasty, 2018
Results per million population (PMP)

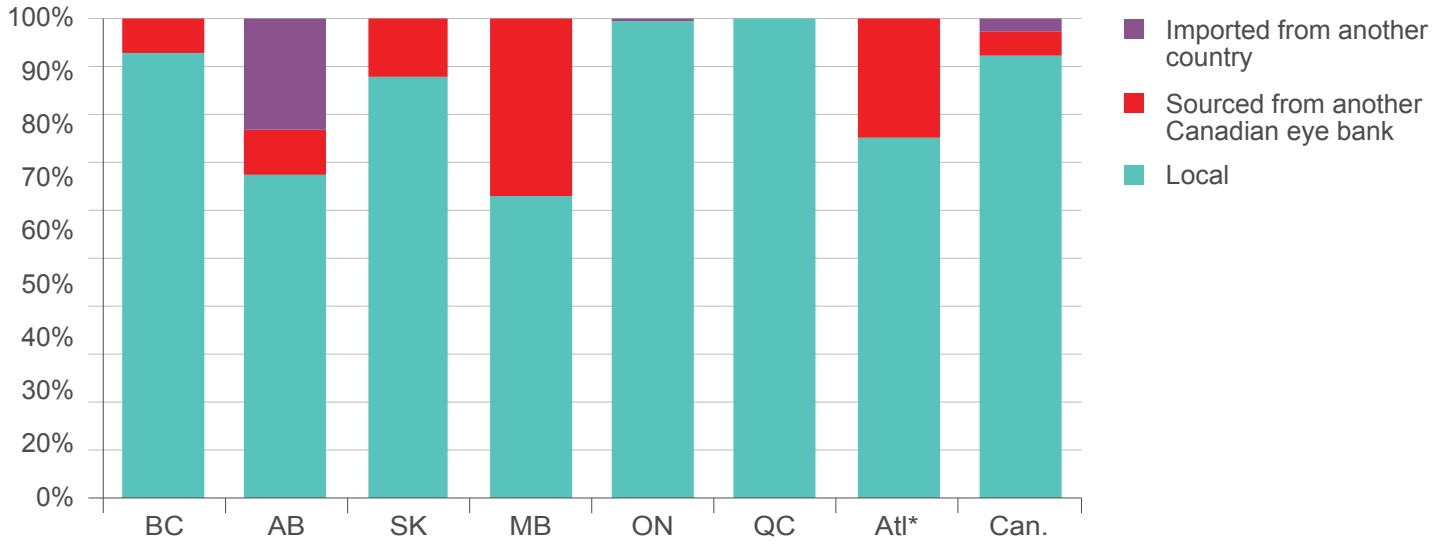


*Atlantic patients are transplanted in Nova Scotia; rate calculation includes populations of all Atlantic provinces (NS, NB, PEI, and NL).

**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, 2018 (Table 17-10-0134-01). National rate is based on the entire national population, including NL, YT, NT, and NU.

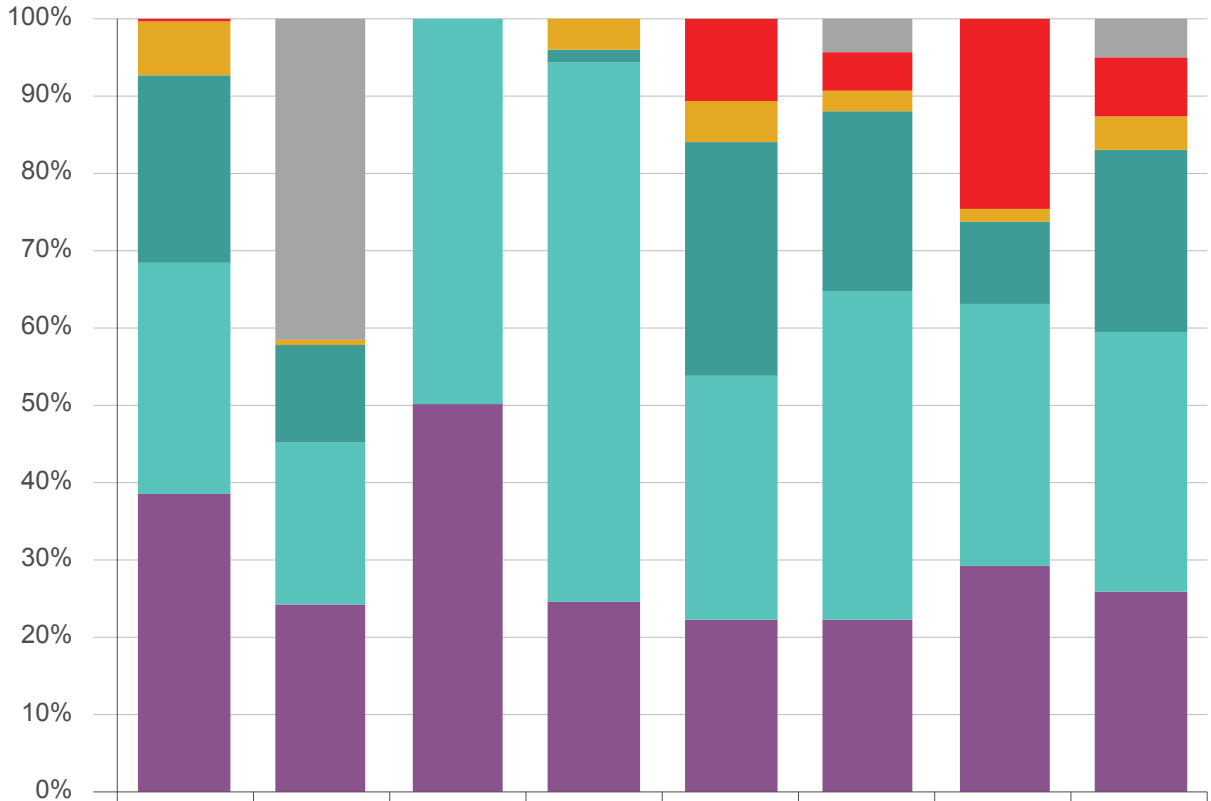
Source of intermediate-term preserved corneas distributed for surgical use, 2018



* Atlantic patients are transplanted in Nova Scotia (corneas are transferred from NB to NS programs).

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, 2018



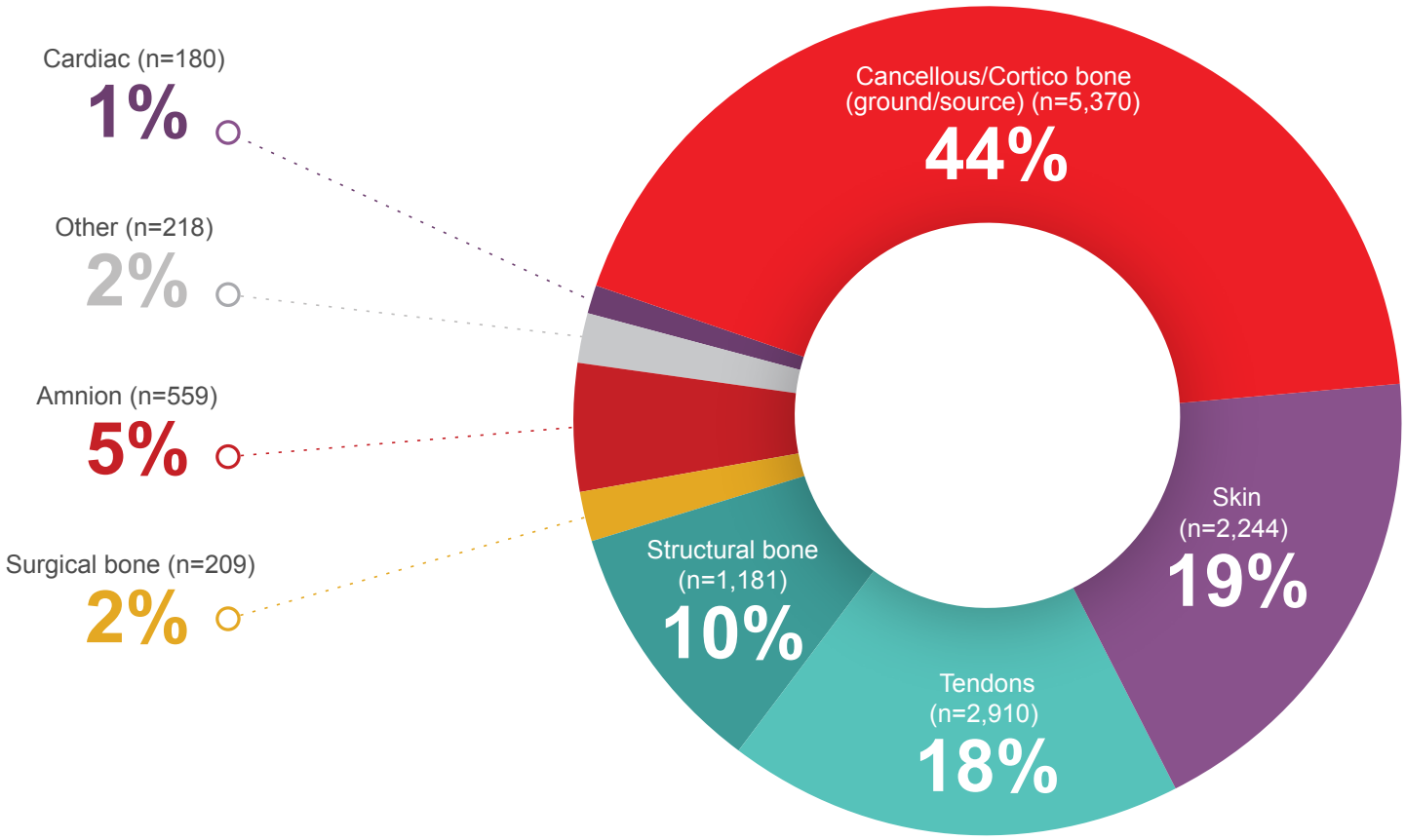
	BC	AB	SK	MB	ON	QC	ATL*	Can.
Unknown/Unspecified	0	182	0	0	0	37	0	219
Other**	3	0	0	0	202	40	84	329
ALK	44	3	0	5	99	24	6	181
DMEK	155	55	0	2	560	192	36	1,000
DSAEK	190	91	21	86	580	349	114	1,431
PK	244	105	21	30	412	182	99	1,094

*Atlantic patients are transplanted in NS (corneas are transferred from NB to NS programs).
**Includes K-Pro, KLA, glaucoma shunt patching, and other surgeries.

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

In 2018, ten tissue banks[1] processed and released 12,096 musculoskeletal, cardiac, skin, and amnion grafts from deceased and living donors into inventory for transplant.

Grafts processed and released to inventory, 2018



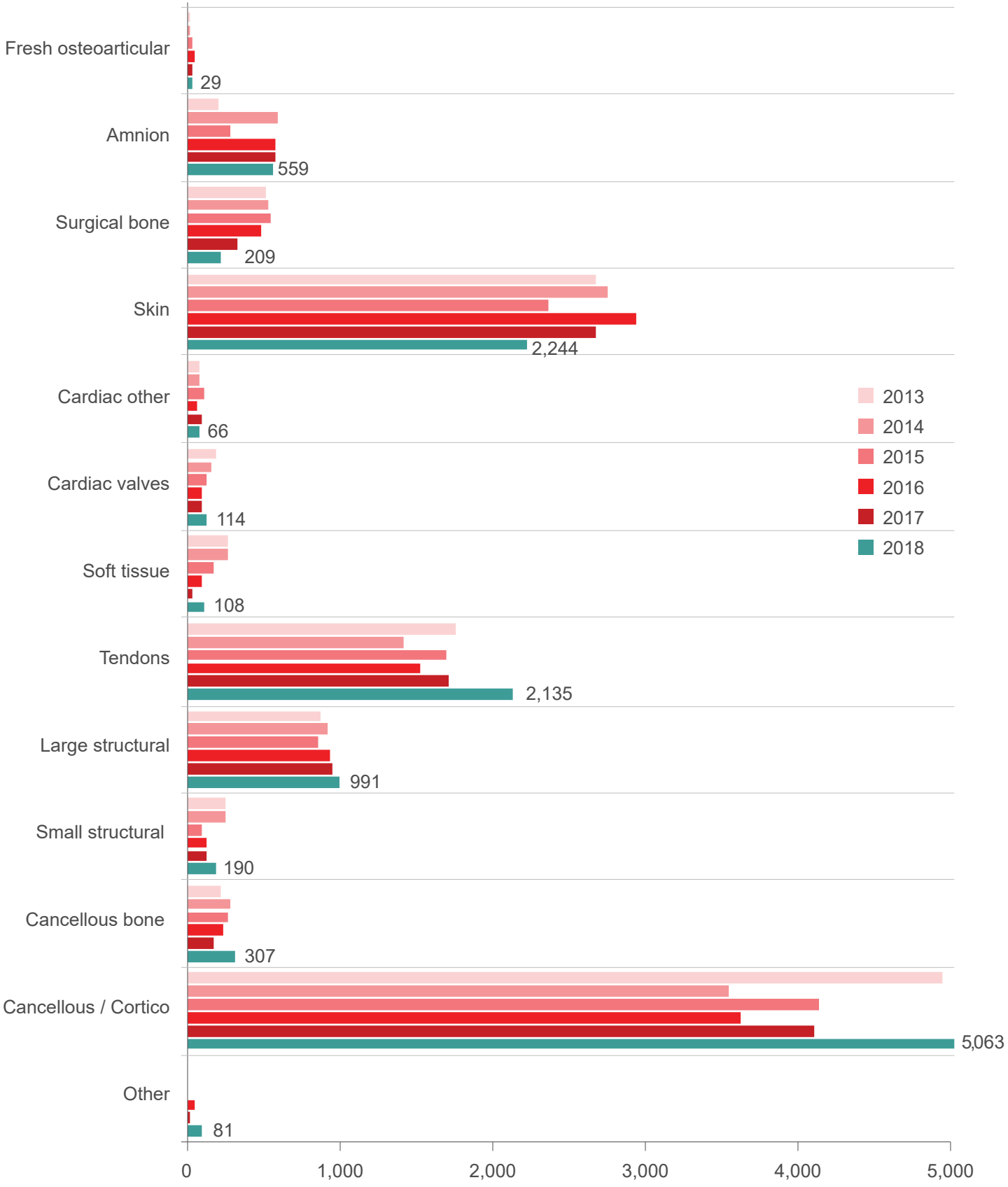
Total production in 2018 increased by 9% from the previous year (n=10,928).

Production and release of musculoskeletal grafts from deceased donors has increased from 2017, with cancellous/cortico bone increasing by 25% and structural bone increasing by 11%. This is countered by a decrease in the production and release of surgical bone from living donors, which lowered by 35% between 2017 and 2018.

There was an increase in the production and release of tendons in 2018 by 24% while the production and release of skin decreased by 17%.

[1] There are four banks in Ontario producing musculoskeletal, skin, cardiac, and/or amnion tissue; those banks submit program data to the Trillium Gift of Life Network.

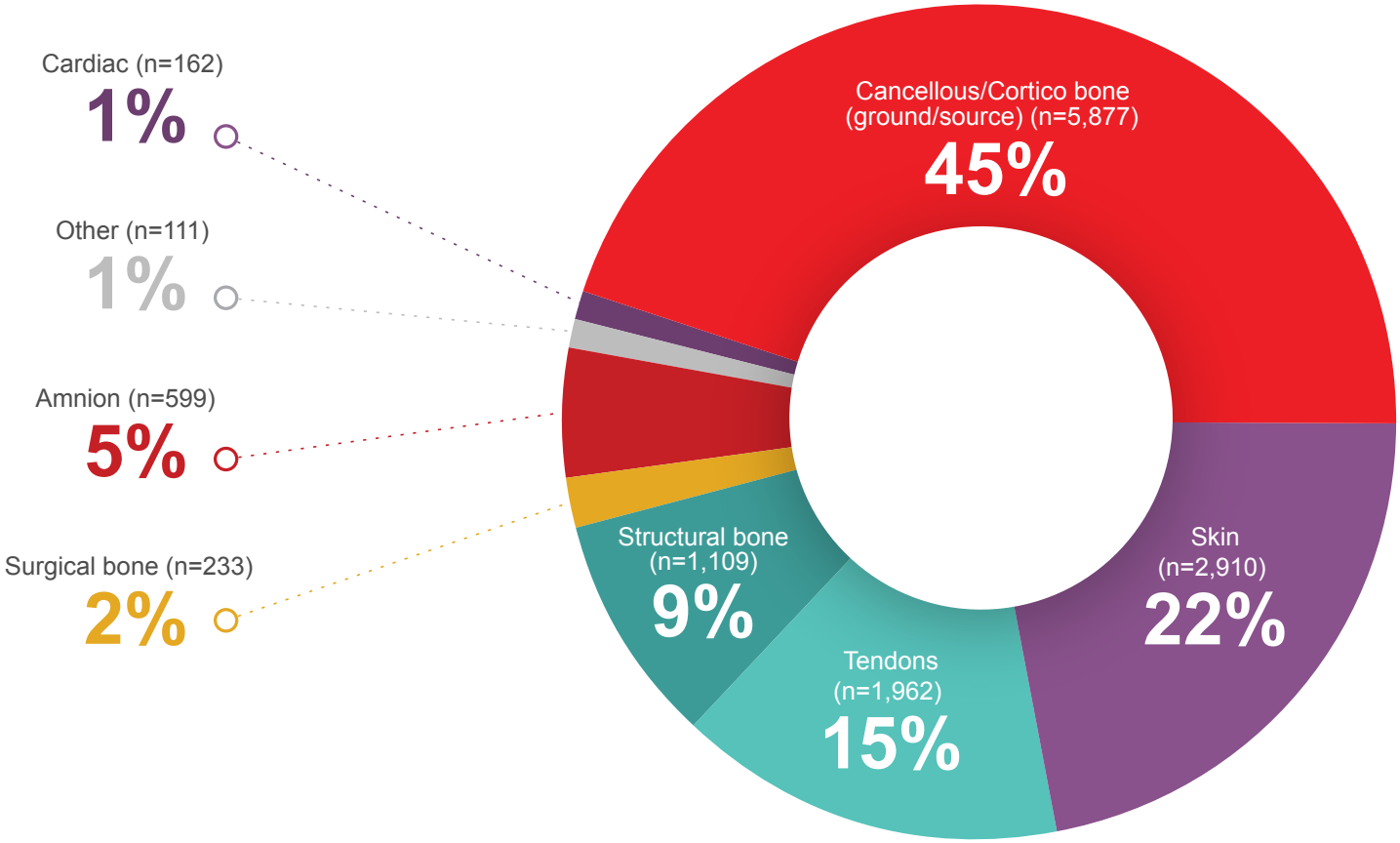
Number of grafts processed and released to inventory, 2013-2018



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

In 2018, 11 tissue banks distributed 12,963 musculoskeletal, skin, cardiac, and amnion grafts to transplantation, reflecting slightly more graft distribution than what was seen in 2016 (n=12,632) and 2017 (n=12,652). While ten banks produce allografts, one has a relationship with American processors who produce allografts from donors recovered by that bank and return them for distribution.

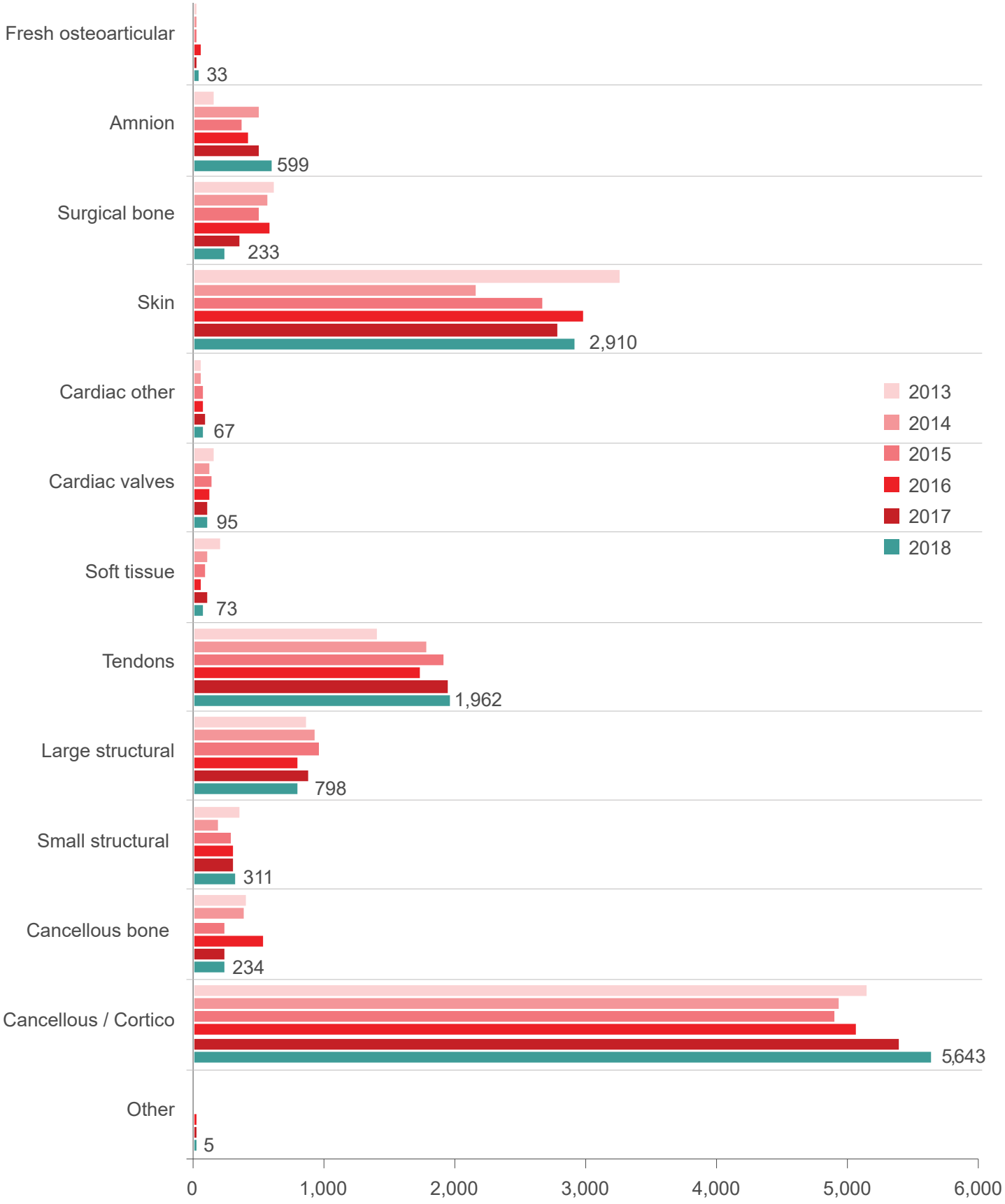
Grafts distributed to transplant, 2018



Distribution of musculoskeletal grafts from deceased donors has remained relatively unchanged between 2017 to 2018, with the percent change within 10%. There was a decrease in the distribution of surgical bone from living donors, which lowered by 32% between 2017 and 2018.

The number of tendons and skin distributed has also remained relatively unchanged between 2017 and 2018.

Number of grafts distributed to transplant, 2018

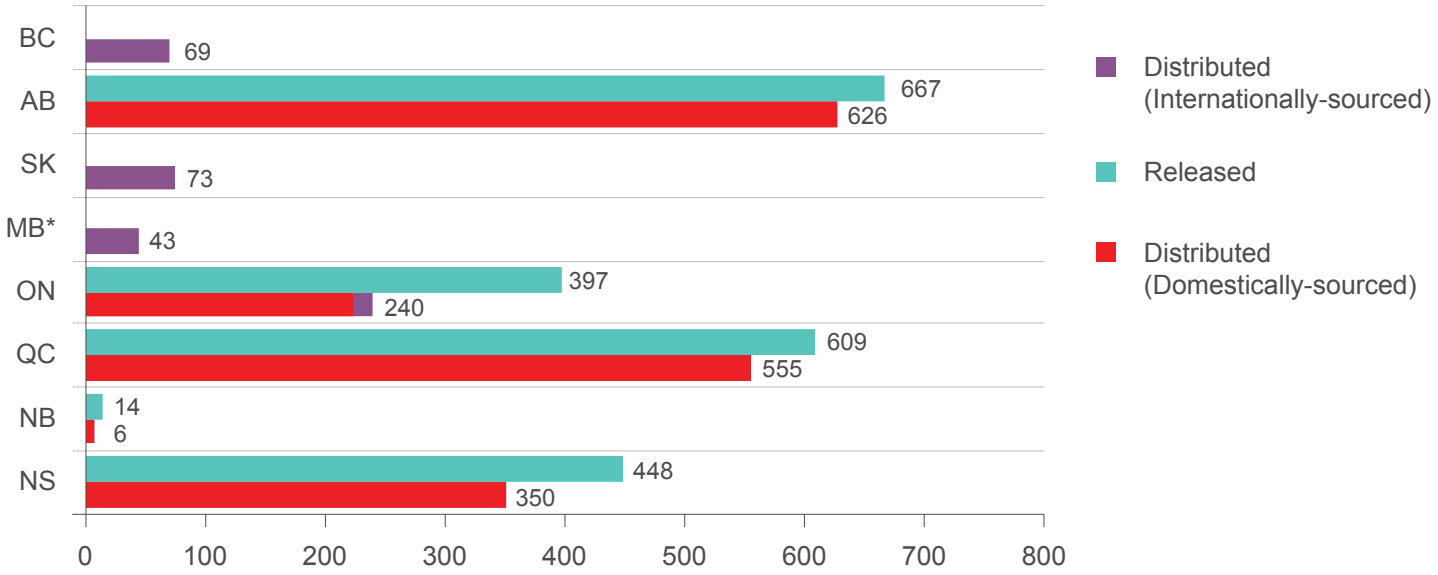


Deceased donor musculoskeletal, skin, and cardiac tissue: provincial analysis

Musculoskeletal grafts released and/or distributed for transplant, 2018

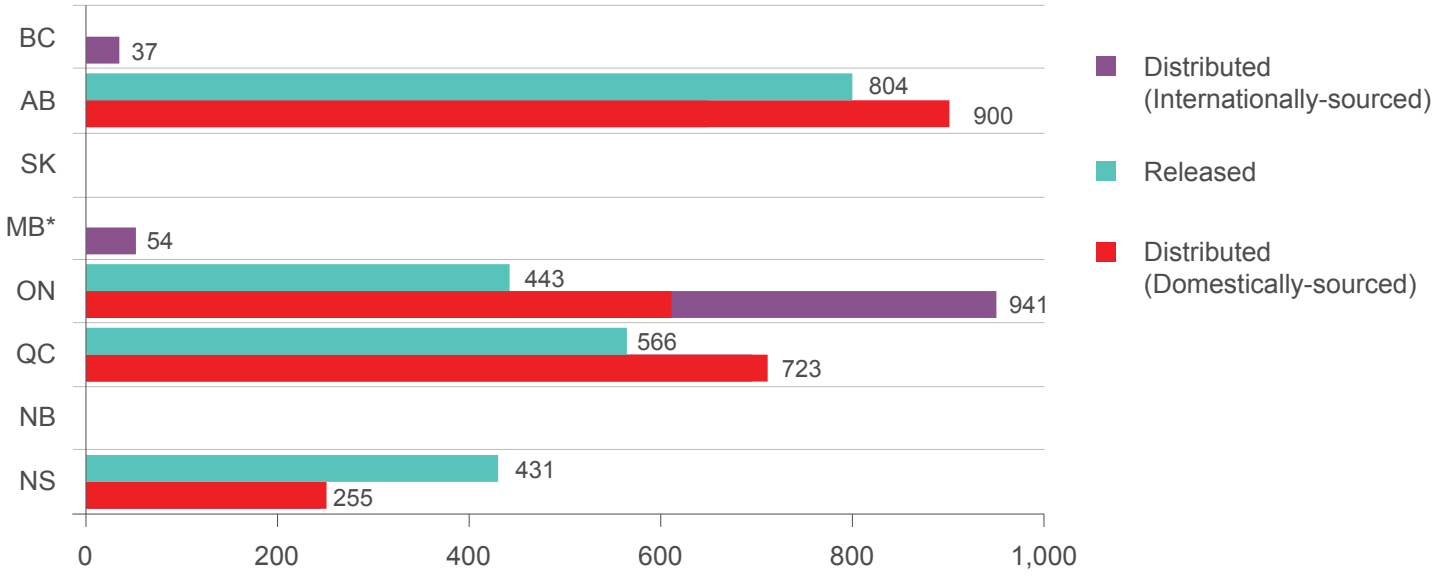
* Tissue Bank Manitoba is a recovery organization that sends tissues to a U.S. partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

Tendon grafts released and/or distributed for transplant, 2018



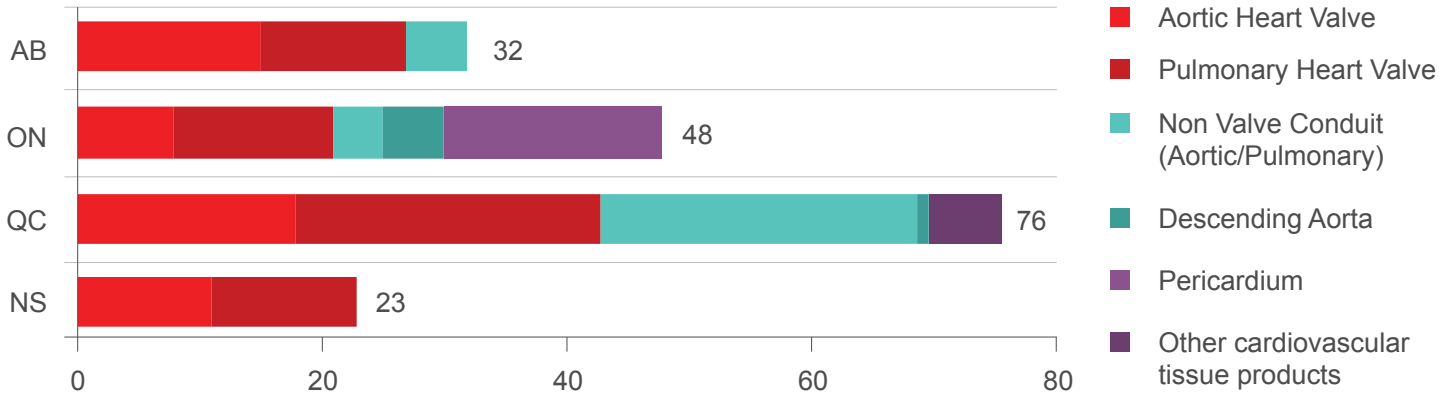
* Tissue Bank Manitoba is a recovery organization that sends tissues to a U.S. partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

Skin grafts released and/or distributed for transplant, 2018

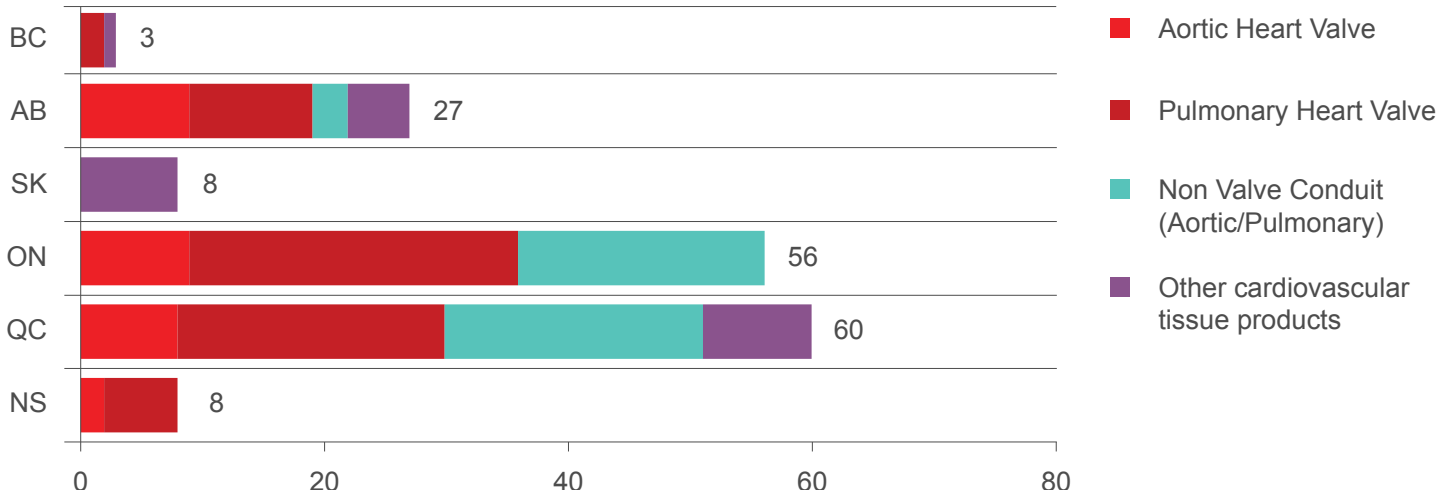


* Tissue Bank Manitoba is a recovery organization that sends tissues to a U.S. partner organization for processing and receives a proportional quantity of tissue grafts in return for distribution in their province.

Cardiac grafts processed and released for transplant, 2018



Cardiac grafts distributed for transplant, 2018



Conclusion

The Eye and Tissue Data Committee continues to refine minimal data sets, data definitions, data collection and quality assurance processes, conducting analysis and reporting on system activity and performance.

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 displays data to help inform the operational capacity of individual eye and tissue banks, as well as providing insight about patterns and trends to inform both national and regional strategy, planning and policy development.

Six years of sequential data analysis has provided insight into emerging national trends and will continue to inform individual tissue banks about operations and strategy goals for the future. Recent insights identified for consideration in operational planning and policy development include:

A lack of growth in Canada's tissue donation, allograft production and product development

Statistics Canada estimated that Canada's population increased by more than 530,000 people from mid-2018 to mid-2019, representing the highest annual increase ever observed, with the proportion of Canadians aged 65 or older continuing to increase and currently making up more than 17% of Canadians.[2] This would suggest an increasing demand for tissue products, especially in relation to the incidence of orthopedic surgery in an aging population; however, tissue donation and allograft production has remained relatively unchanged in the six years we have been tracking activity, which may suggest surgeons are importing more product to bridge the gap between Canadian supply and demand. This is an area which warrants consideration and further evaluation.

The number of deceased donors from which tissue was recovered increased less than 1% annually (5.6%) from 2013 to 2018 while the number of Canadians aged 65 or older increased 18.7% over the same period[3]. Domestic tissue production has shown very little change, with total Canadian graft production increasing only 3.5% since 2013, and with Canadian production focused to the most basic of tissue products. In contrast, from 2013 to 2018, the number of deceased organ donors in Canada increased 38% representing a rate of increase that exceeds the growth in the Canadian population.

With the exception of corneal DSEAK and DMEK processing, there has been no significant product development or enhancement in the six years that data tracking of Canadian production and distribution activity has occurred. Despite significant demand for advanced musculoskeletal products such as demineralized bone, bone putties, acellular dermal matrix and other highly processed products, Canadian banks have failed to initiate production. Canadian surgeons depend 100% on importation to supply the high demand for these products.

This disparity between the changing Canadian population, the static tissue donation and production activity and the lack of new product development warrants attention. If these trends were to continue, an increasing divergence in demand for tissue relative to tissue donation and production could represent a challenge in meeting Canadian health care needs and may present a security of supply risk.

Continued growth in the demand for DMEK

Canadian ocular activity overall, including ocular donors, ocular production, and ocular distribution, remains relatively consistent with last year. However, the demand for endothelial keratoplasty (cornea transplant) continues to increase; with the demand for DMEK procedures continuing to grow, with 41% of all endothelial keratoplasty's requiring DMEK processing in 2018. While DMEK demand continues to grow the increase in 2018 was less than trends established over the previous five years.

Adoption of new practices has historically followed the implementation and development in the U.S. prior to dissemination to Canada. The growing demand for pre-rolled DMEK products in the U.S. indicates that Canadian eye banks should be evaluating the potential impact of this emerging product on the Canadian system.

[2] Statistics Canada. The Daily: Canada's population estimates: Age and sex, July 1, 2019. Released 30 September 2019. Available online at https://www150.statcan.gc.ca/n1/daily-quotidien/190930/dq190930a-eng.htm

[3] Statistics Canada. Table 17-10-0005-01 Population estimates on July 1st, by age and sex. Data retrieved 11 November 2019. Accessible online at https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=1710000501

Conclusion (cont.)

Continued provincial variance in corneal donation and transplantation rates

There remains significant variance in the corneal donation and corneal transplantation rate per million population between provinces, with the pattern in this disparity being generally consistent from year to year. This variance of donation and transplantation rate requires consideration, as it may be an indicator of inequitable access to ocular care between jurisdictions. Data on access, specifically waiting lists and waiting time for corneal transplantation, is not currently available and represents a gap in system metrics.

In response to the variance in cornea donation and transplantation rates, Canadian Blood Services, in partnership with the Canadian Ophthalmological Society will be convening a consensus forum in February of 2020 to develop guidance and priorities for system performance improvement.

System efficiency: Interprovincial communication and coordination

Data indicates that there is opportunity for more robust supply-demand alignment across provincial boundaries. We have identified occurrences when one province cannot meet its demand while another province has an over-supply and limits production.

As an illustration, although Quebec does not over-produce tissue as a matter of policy (instead balancing their production to demand within the province), they currently have a surplus of skin grafts relative to their needs. At the same time, 30% of the skin grafts distributed in Ontario and 100% of all skin grafts distributed in British Columbia in 2018 were sourced internationally. Further discussion is warranted about how to improve coordination, supply-demand alignment and interprovincial tissue distribution.

There is currently no national forum for the tissue community to engage, share best practices and expertise, identify challenges, and present collaboration opportunities or system improvement priorities. Communication channels are limited and largely informal. The Eye and Tissue Data Committee, having acknowledged the need for national communication strategies, is currently exploring options with Canadian Blood Services for the advancement of a tissue community network.

The Eye and Tissue Data Committee is currently conducting limited investigations into the use of fresh osteochondral tissue grafts among Canadian banks and orthopedic surgeons which may identify opportunities for interprovincial collaboration.

Summation

The prospective collection and collation of national eye and tissue bank activity provides insight into the Canadian supply and demand. As data accumulates, more sophisticated trend analysis will help inform recovery and production targets and methodologies. Nationwide strategies to better align supply with demand can be developed using the collected data as a guide. The data collected also has the potential to inform further research in the ocular and tissue transplantation world, as a significant starting point for most research requires a broad tablet of basic data. Similarly, interprovincial comparisons offer insight into areas of potential resource and knowledge sharing, while providing a more nuanced understanding of provincial demand and reliance on internationally sourced grafts.

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.

Appendix A: (cont.)

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 cornea. 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 I 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
Cynthia Johnston (Chair)	Quality Leader	Regional Tissue Bank, Halifax, NS
Mike Bentley	Manager, Transplant Services	Comprehensive Tissue Centre, Edmonton, AB
Kimberly Dodds	Director	Tissue Bank Manitoba, Winnipeg, MB
Ryan Funk	Senior Tissue Specialist	Southern Alberta Tissue Program, Calgary, AB
Christine Humphreys	Director, Eye Bank of Canada (Ontario)	Trillium Gift of Life Network, Toronto, ON
Debbie Jefferson	Interim Director	New Brunswick Organ and Tissue Program, Saint John and Moncton, NB
Mijana Ridic	Manager, Lions Eye Bank	Southern Alberta Organ and Tissue Program, Calgary, AB
Gary Rockl	Tissue Innovation Specialist	Héma-Québec, Québec City, QC
Natalie Smigielski	Clinical Specialist, Tissue Program	Trillium Gift of Life Network, Toronto, ON
Ellen Sokol	Deceased Donation Coordinator	Saskatchewan Transplant Program, Saskatoon, SK
Balram Sukhu	Director	Mount Sinai Allograft Technologies, Toronto, ON
Brenda Weiss	Executive Director	Misericordia Eye Bank, Winnipeg, MB
Ivan Yan	Head Technologist	Eye Bank of British Columbia, Vancouver, BC

Canadian Blood Services members

Jim Mohr
Associate Director, Deceased Donation

Kyle Maru
Sr. Data Analyst, Information Management

Katie Sullivan
Data Analyst, Information 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 Transplant 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
- The Hospital for Sick Children Tissue Laboratory, Toronto
- Ontario Professional Fire Fighters Skin Bank, Toronto
- Mount Sinai Allograft Technologies, Toronto
- Lake Superior Centre for Regenerative Medicine, Thunder Bay
- 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: Products produced by program*

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

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	N	N	N	N	N	N	N
Southern Alberta Tissue Program	Y	Y	Y	Y	Y	Y	N	Y
Comprehensive Tissue Centre (AB)	Y	Y	Y	Y	N	Y	Y	Y
Saskatchewan Transplant	Y	Y	N	Y	N	N	N	N
Tissue Bank Manitoba**	Y	Y	Y	Y	N	Y	Y	Y
RegenMed (ON)	Y	Y	N	Y	N	N	N	N
Mount Sinai Allograft Technologies (ON)	Y	Y	N	Y	Y	N	N	N
Hospital for Sick Children, Tissue (ON)	N	N	N	N	N	N	Y	N
Ontario Professional Firefighters Skin Bank	N	N	N	N	N	N	N	Y
Héma-Québec	Y	Y	N	Y	N	N	Y	Y
New Brunswick Organ and Tissue	Y	Y	N	Y	N	N	N	N
Regional Tissue Bank (NS)	Y	Y	N	Y	Y	Y	Y	Y

* as of time of publication

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