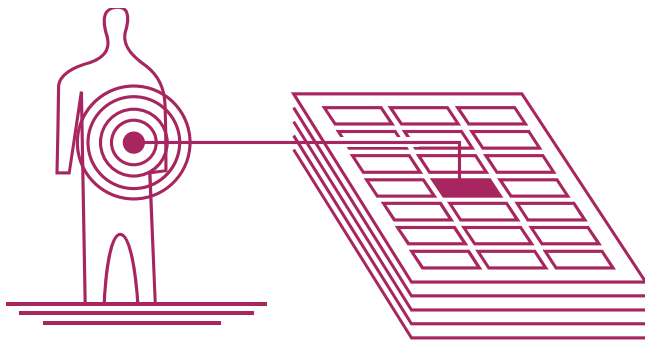




Canadian Blood Services
it's in you to give

*Donation and Transplantation
Canadian Eye and Tissue Banking Statistics
January 1 to December 31, 2014*

A Report from the Canadian Eye and Tissue Data Committee



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Executive Summary

Canadian Blood Services, on behalf of the Eye and Tissue Data Committee (ETDC), receives quarterly 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 Eye and Tissue Data Committee. The purpose of this report is to provide information and insights into the Canadian supply of, and demand for, ocular and tissue allografts across Canada.

Prospective data collection was initiated in 2012. 2014 data was submitted from 16 eye and tissue banks representing a census of all Canadian eye and tissue banking activity. The only data set which is not a census of Canadian activity is approach and consent rate; analysis presented is based on the 11 programs which submitted this metric and provides visibility to the consent rate within those programs. Data on allografts imported by Canadian hospitals from the United States was not available.

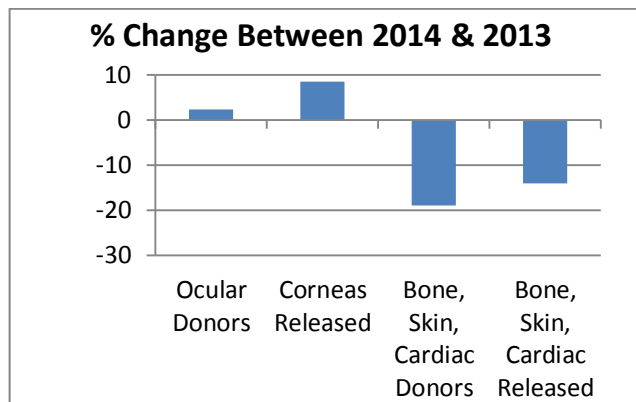
In 2014 Canadian Eye and Tissue Banks received 45,154 referrals for potential tissue donors. In those approached 48% consented to tissue donation. Tissue was recovered from 4,510 deceased donors and 681 living donors. These donations resulted in the production of 16,397 grafts which were released for transplantation; 5,591 ocular (cornea and sclera) and 10,806 tissue (bone, skin, cardiac, surgical bone and amnion).

There has been a 2.8% increase in deceased tissue donation between 2013 and 2014. There has been a continued decrease in living tissue donation with a 4.4% decrease in surgical bone donation between 2013 and 2014. There has been a 6.1% (n=1,067) decrease in the total

ocular and tissue grafts processed and released for transplantation between 2013 and 2014.

There has been a 2.4% increase in the number of donors where ocular tissue was recovered and an 8.5% increase in corneas produced and distributed by Canadian eye banks for transplantation (keratoplasty) between 2013 and 2014.

There has been a 5.1% increase in the yield of cornea grafts (# corneas released for transplant per donor) increasing from 0.97 to 1.02 per donor between 2013 and 2014.



Data indicates that in 2014, 49% of all cornea transplants (keratoplasty) performed in Canada were endothelial keratoplasty; requiring post recovery processing of the cornea prior to transplantation.

There has been a 18.8% decrease in the number of donors where musculoskeletal, skin and or cardiac tissue was recovered and a corresponding 14% decrease in the number of bone, cardiac and skin grafts processed and released for transplantation from deceased donors between 2013 and 2014 (n=1,588).

There has been a 203% increase in amnion production between 2013 and 2014; from 187 to 567 grafts.

This prospective data collection provides all jurisdictions with insight into tissue donation activity as well as to the Canadian production and supply of ocular and tissue grafts. Canadian eye and tissue programs are to be commended on their leadership and their contributions to this data analysis.

This report provides valued information documenting changes in system performance between 2013 and 2014 and provides insight into the current tissue environment.

Moving forward, Canadian Blood Services will continue to work with the Eye and Tissue

communities to advance and improve data collection and collation of performance data to support all programs and stakeholders in their valuable efforts to provide the donation and allograft services Canadians require.



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1.0 Introduction

Canadian eye and tissue programs, in collaboration with Canadian Blood Services, support the collection, collation and analysis of system performance data.

Data definitions are established (see Appendix A).

The Eye and Tissue Data Committee ETDC (see Appendix B) provides advice and collaboration on definitions, collection and analysis of data related to eye and tissue banking activity in Canada.

Canadian Blood Services is the repository for the data, supports data management and analytics, provides secretariat support and collaborates with the Eye and Tissue Data Committee in the analysis and presentation of data.

Prospective data collection was initiated in 2012. 2014 data was submitted from 16 eye and tissue banks (see Appendix C) representing a census of all Canadian eye and tissue banking activity.

In 2010 Canadian Blood Services published two reports, “Supply of Human Allograft Tissue in Canada” and “Demand for Ocular Tissue in Canada”, which detail the 2008 system performance activity of Canadian eye and tissue banks excluding Quebec.^{1,2} Héma-Québec published a 2008/2009 annual report detailing system performance activity for Quebec.³ These reports allow for an estimation of 2008

Canadian system performance activity which is presented in some instances for comparison.

The following reports on Canadian eye & tissue banking donation, production and distribution statistics for Canadian eye and tissue banks, for January 1 to December 31, 2014.

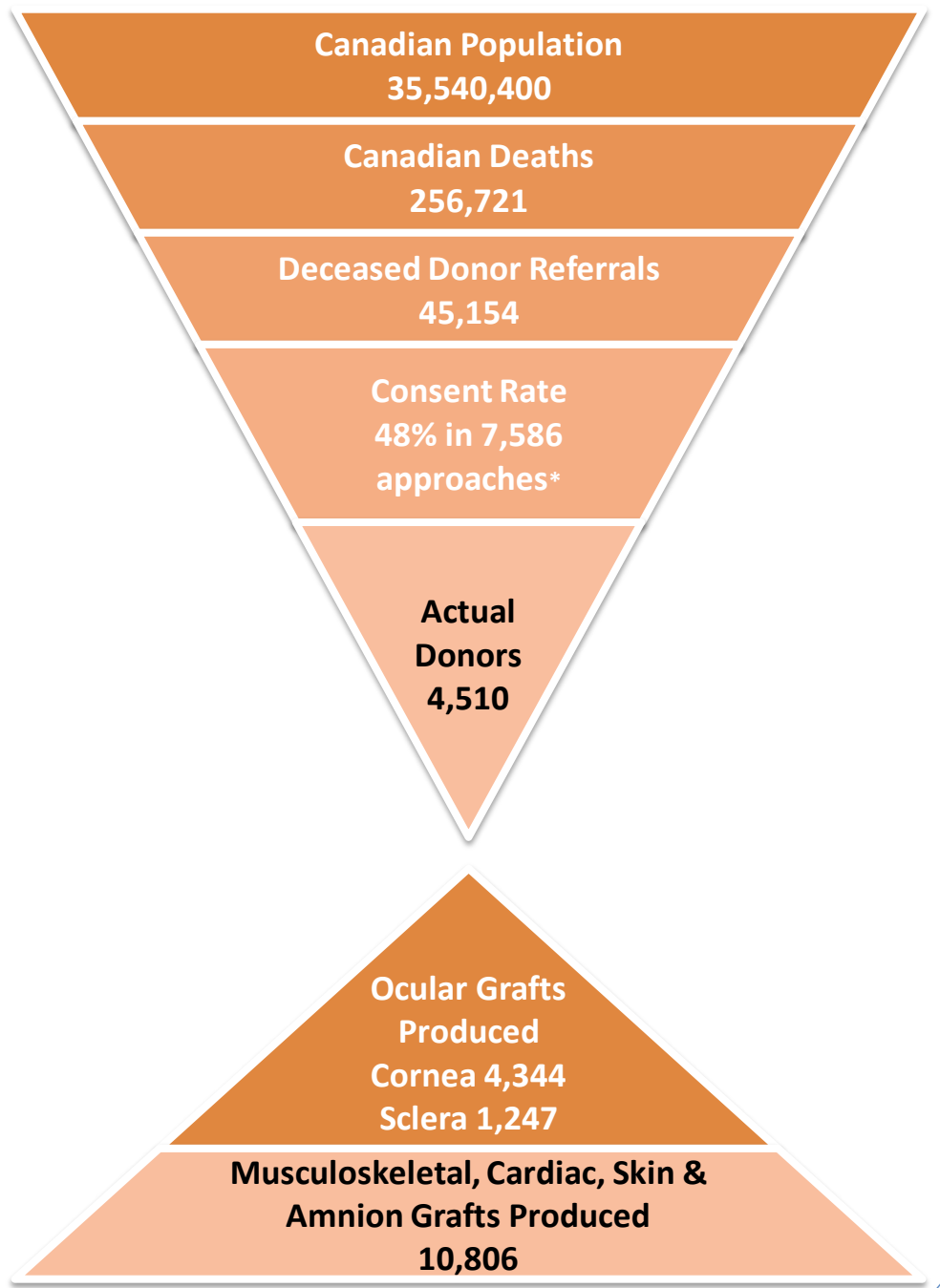
The following reports a comparative analysis of Canadian system performance 2013 to 2014.

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 Blood Services (2010). Supply of Human Allograft Tissue in Canada - Final Report 2010, www.organsandtissues.ca

² Canadian Blood Services (2010). Demand for Ocular Tissue in Canada - Final Report January 2010 www.organsandtissues.ca

³ Héma-Québec (2009). 2008-2009 Annual Report – March 2009 www.hema-quebec.ca



*11 programs collect data on the number of approaches and consent rate, this data documented a 48% consent rate. Population and death data sourced from Statistics Canada.

3.0 Comparative Analysis 2013 to 2014 Activity

3.1 Canadian Eye and Tissue Banks

Type of Bank	2008	2013	2014
Comprehensive Tissue Banks*	5	6	6
Eye Banks	7	4	4
Musculoskeletal Banks	4	3	3
Skin Banks	1	1	1
Cardiac Banks	1	1	1
Surgical Bone Banks	7	2	1
Total	25	17	16

*comprehensive is defined as recovering and/or processing more than one tissue type. A surgical bone bank is defined as a bank which recovers only surgical bone. Some musculoskeletal and comprehensive banks recover surgical bone.

3.2 Canadian Eye and Tissue Banking Activity

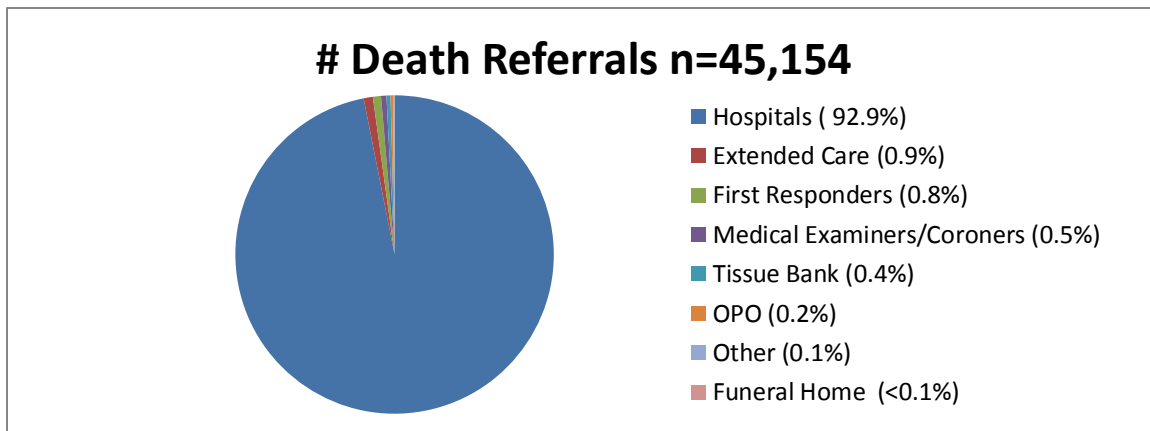
Total Canadian Activity	2013	2014	% Change
Deceased donor referrals	41,594	45,154	8.6%
Total deceased donors	4,383	4,510	2.8%
Donors where ocular tissue was retrieved	4,146	4,248	2.4%
Deceased donors where bone, cardiac and or skin was retrieved	772	627	-18.8%
Surgical bone donors	700	669	-4.4%
Corneas produced and released for transplant	4,004	4,344	8.5%
Corneas transplanted - keratoplasty*	3,284	3,259	0%
Cornea yield: Number of corneas processed/released per ocular donor	0.97	1.02	5.1%
Total tissue grafts processed and released for transplant (deceased & living donors - ocular, bone, skin, cardiac, surgical bone, amnion grafts)	17,464	16,397	-6.1%
Total bone, skin and cardiac grafts processed and released for transplant in deceased donors	11,297	9,709	-14.0%

* Data limitation: In 2014 an additional 632 corneas were distributed with the end use identified as "unknown" as compared to an additional 220 distributed to "unknown" use in 2013

4.0 2014 Canadian Eye & Tissue Banking Deceased Donation Activity

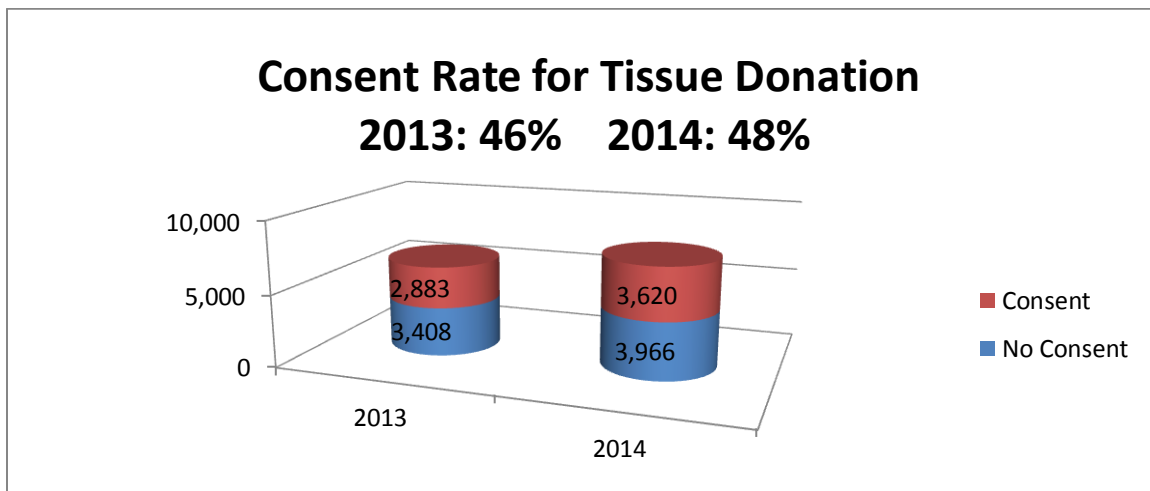
4.1 Total Donor Referrals

In 2014 45,154 deaths were identified and referred for initial screening/consideration of tissue donation potential, an increase of 8.6% (n3,560) from 2013 referrals. There was a 9% increase in referrals from hospitals from 2013 (n3,491). There was a 70% drop in donor referrals from OPOs 2013 (n361) to 2014 (n111) and a 45% drop in donor referrals from first responders; 2013 (n785) to 2014 (n356).



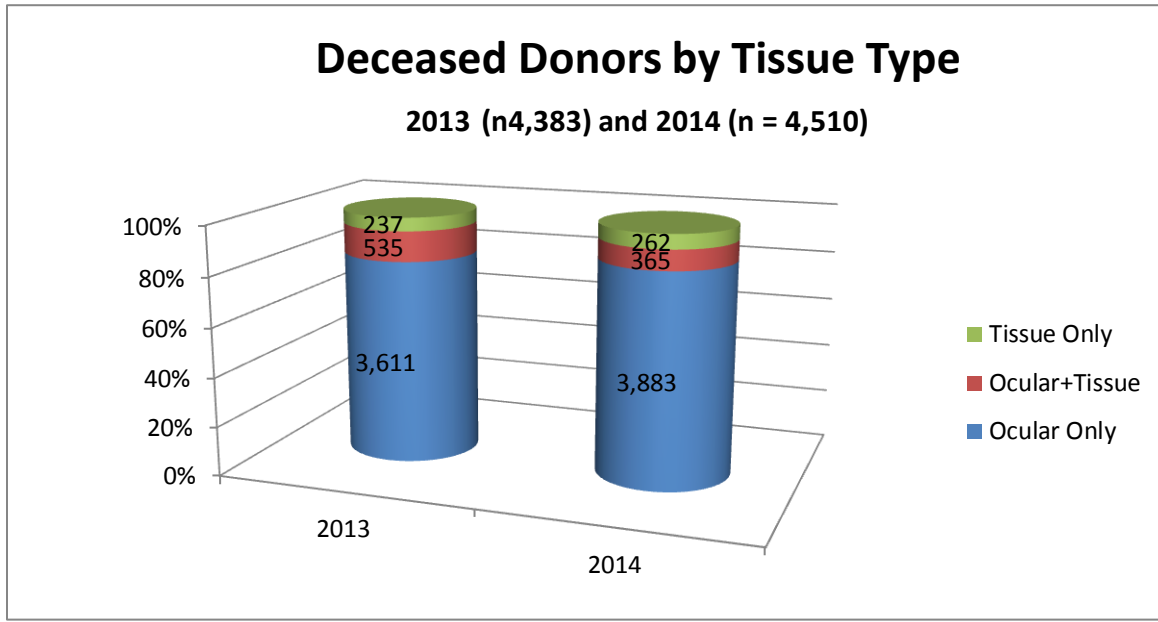
4.2 Consent Rate

In 2014, 11 programs were able to provide data on 7,586 approaches for deceased tissue donation. A consent rate of 48% was identified.



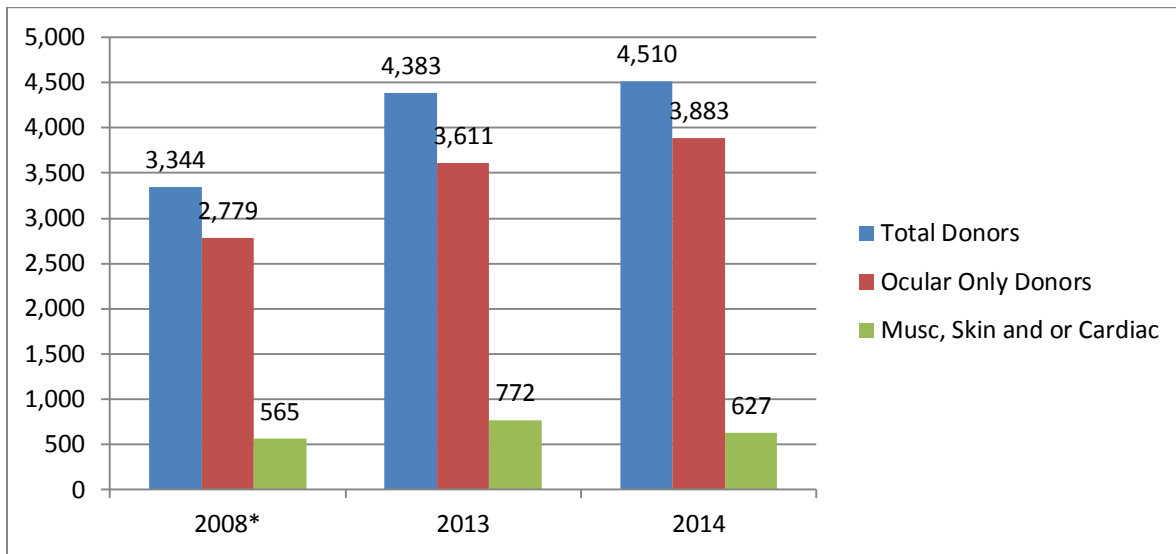
4.3 Deceased Donor Breakdown

In 2014 there were 4,510 deceased tissue donors in Canada. The vast majority of these donors (86%) were ocular only donors. As compared to 4,383 deceased donors in 2013 with 82% ocular only.



4.4 Deceased Donor Analysis

While the number of deceased donors increased in 2014 by 2.9% there was an 18.8% decrease in the number of donors where musculoskeletal, skin or cardiac tissue was recovered. The overall increase in deceased donors is attributed to a 7.5% increase in ocular only donors.

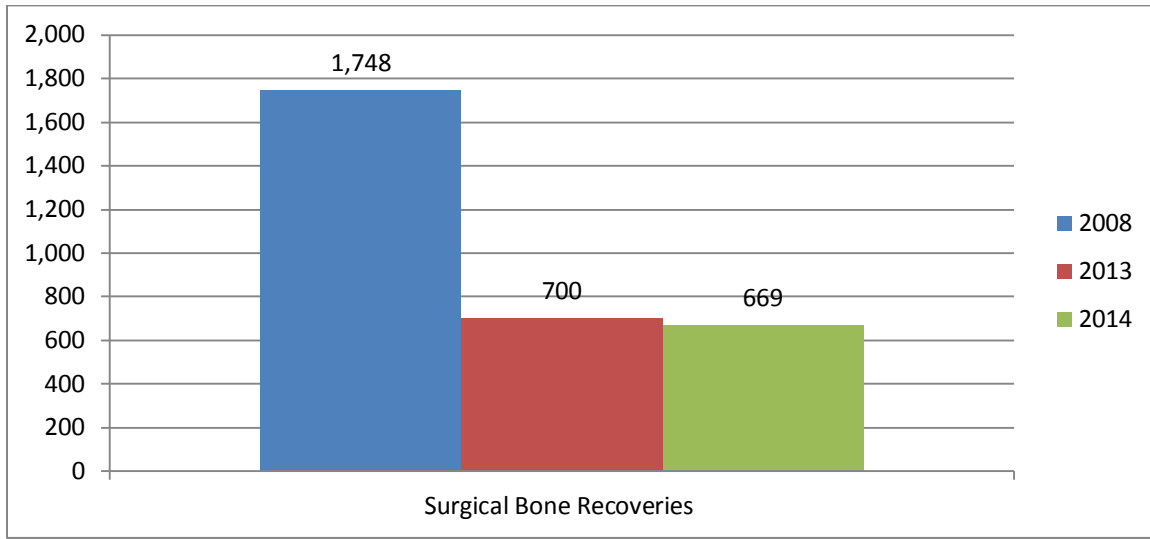


* 2008 data on tissue donors was estimated from best available data.

5.0 2014 Canadian Eye & Tissue Banking Living Donation Activity

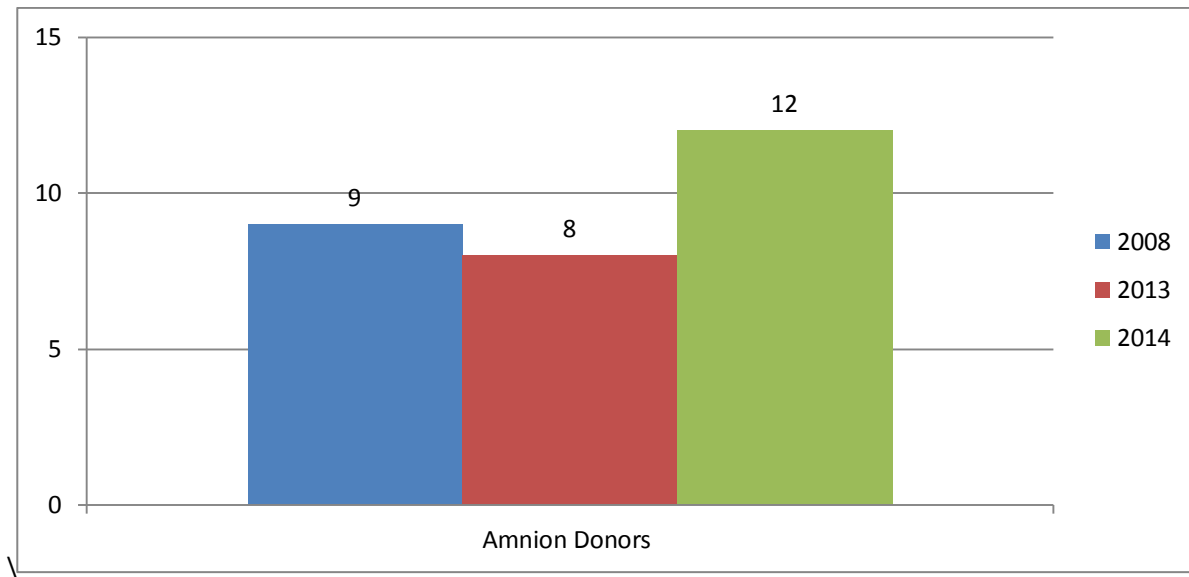
5.1 Living Donors – Surgical Bone

In 2014, five programs reported recovering bone from living donors; recovering femoral heads during total hip replacement surgery. There has been a 60% decrease in surgical bone donation between 2008 and 2013 (n=1,048) and a further 4.4% decrease in 2014 (n=31)

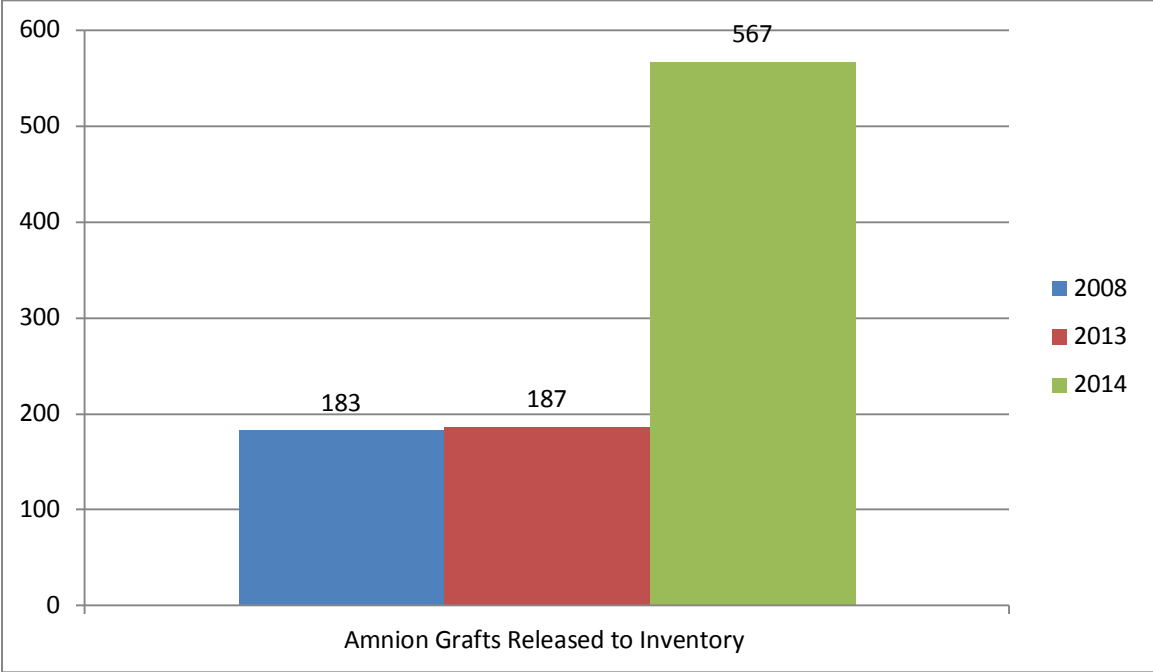


5.2 Living Donors – Amnion Donors

In 2013, two programs reported recovering amnion from living donors and produced 187 grafts. In 2014 there were three programs recovering amnion producing 567 grafts and increase of 203%.



5.3 Living Donors – Amnion Production



6.0 2013 Canadian Eye & Tissue Production and Distribution Activity

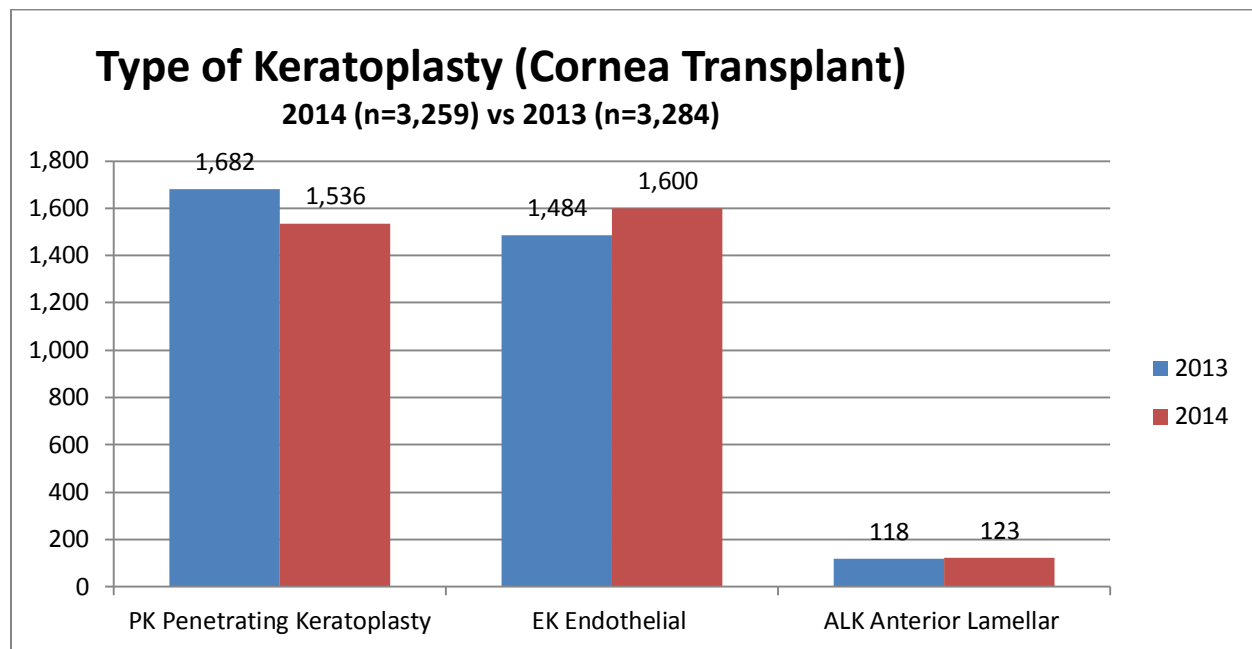
6.1 Total Corneas Distributed for Transplant

In 2014, Canadian eye banks produced/released 4,344 corneas for transplant, an 8.5% increase over 2013 production activity of 4,004 corneas. 4,201 corneas were documented as transplanted.

Of those 3,259 were distributed for keratoplasty, as compared with 3,284 in 2013. An additional 310 corneas were utilized in non-keratoplasty procedures including glaucoma shunt patch. A limitation in the data is corneas where the final use was detailed as “unknown” which included an additional 632 corneas in 2014 and an additional 220 in 2013. In addition the data does not detail the number of grafts distributed which were imported from outside of Canada for transplant.

49% of all cornea transplants performed in Canada in 2014 were endothelial keratoplasty EK as compared to 42% in 2013.

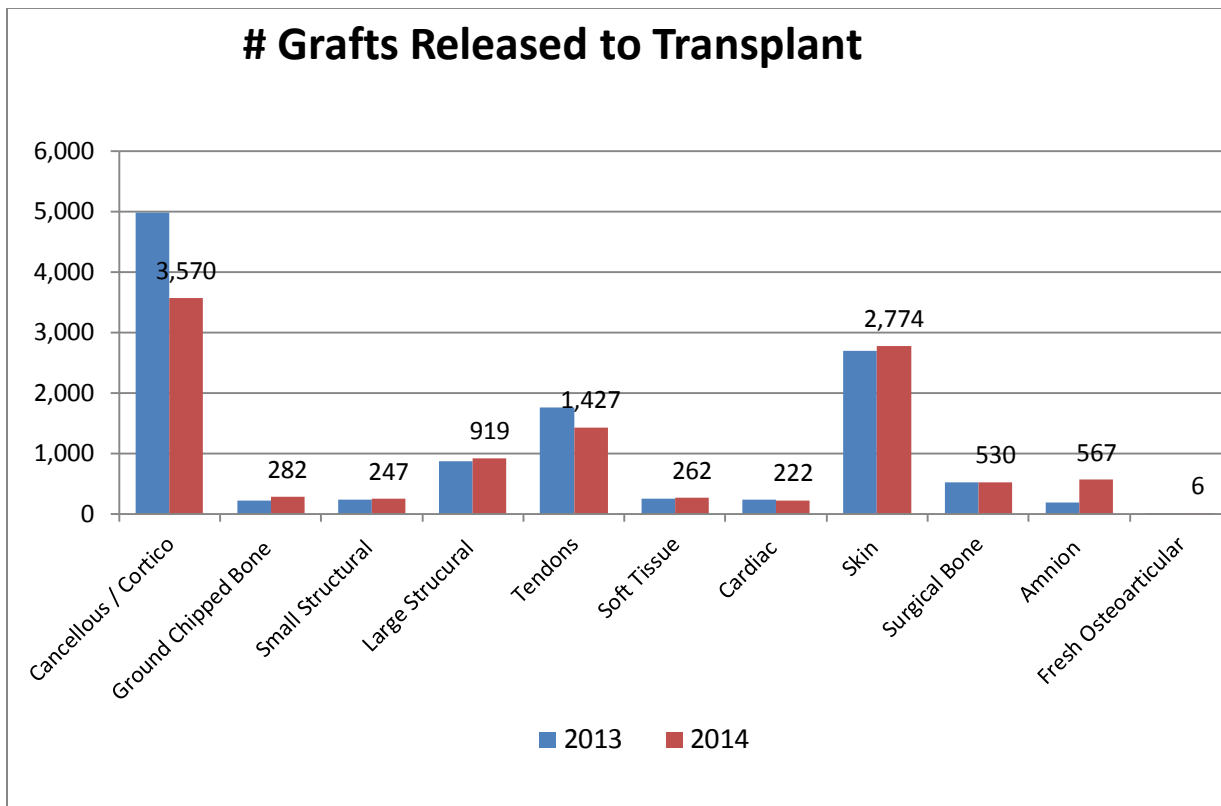
In 2014 three Canadian eye banks provided this processing service. In remaining regions the processing is completed by the surgeon in the operating room.



6.2 Tissue Grafts Processed and Released to Transplant: Type of Graft

In 2014, seven tissue banks processed and released 10,806 musculoskeletal, cardiac, skin and amnion grafts, from deceased and living donors for transplant; detailed as 33% cancellous bone products, 26% skin grafts, 13% tendons, 11% structural bone, 5% surgical bone and 2% cardiac grafts.

This represents a 10.1% decrease (n=1,223) below 2013 levels including a 28% decrease in the production of cancellous products (n=1,416) and a 19% decrease in the production of tendons (n=332). There was a 9.4% decrease in cardiac graft production (n=23) and a 2.8% increase in skin graft production (n=77) in 2014.



Conclusion

The prospective collection and collation of national eye and tissue bank activity provides insight into the Canadian supply and demand and as data accumulate more sophisticated trend analysis will help inform donation and production targets and strategies to better align supply with demand.

Appendix A: Definitions

Amniotic Membrane: Amniotic membrane is 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.

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: Is bone that has been processed into morsels which is used to pack bone voids in surgical repairs.

Consent Rate: Is the ratio of donors where consent for donation is obtained to the number of donor families approached for consent.

Deceased Donor: Refers to a donor where tissue is recovered following cardiac or neurological death.

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: Keratoplasty is a surgical procedure also known as corneal transplantation where the procedure is described as 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.

Penetrating Keratoplasty: Corneal transplant with replacement of all layers of the cornea, but retaining the peripheral cornea.

Endothelial Keratoplasty (EK): Endothelial keratoplasty is 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

Descemet’s Stripping (Automated) Endothelial Keratoplasty (DSAEK). The vast majority of EK today is DSAEK where the eye bank precuts the corneal tissue, or the surgeon precuts the corneal tissue in the operating room. The prepared (cut) graft is comprised of the donor tissue endothelium, Descemet’s membrane and a thin, partial layer of the donor tissue’s stroma.

Descemet’s Membrane Endothelial Keratoplasty (DMEK): DMEK involves the transplantation of only the Descemet’s membrane and endothelial layer of the cornea. 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.

Deep Anterior Lamellar Keratoplasty (DALK or ALK): Is 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.

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: Is a general term which refers to the tissues of the eye which include the cornea and the sclera.

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 orders. Fascia lata is processed into grafts for use in surgical repairs.

Structural Bone Grafts: These are bone grafts that are intended to support weight. They 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: Is a band of tough, inelastic fibrous tissue that connects a muscle with its boney attachment. Tendons commonly banked for use it sports medicine surgery include Achilles, Patellar and Tibialis.

Tissue: Tissue is a general term which refers to musculoskeletal (bone), cardiac and skin tissue (non-ocular tissues)

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
Brenda Weiss (Chair)	Patient Care Manager Ophthalmology Clinic, Misericordia Eye Bank	Misericordia Health Centre, Winnipeg, MB
Mike Bentley	Manager, Transplant Services	Comprehensive Tissue Centre, Edmonton, AB
Mary Gatien	Director NB Organ Donor Program, Director NB Eye and Tissue Bank	New Brunswick Eye and Tissue Bank, Saint John and Moncton, NB
Hugo Fournier	Directeur de l'exploitation des Tissus Humains	Héma-Québec, Québec City, QC
Ronn Ginther	Coordinator	Saskatchewan Transplant Program, Saskatoon, SK
Alison Halliday	Senior Technologist	Ontario Professional Firefighters' Skin Bank, Toronto, ON
Christine Humphreys	Provincial Resource Centre Manager – Tissue	Trillium Gift of Life Network, Toronto, ON
Cynthia Johnston	Quality Leader	Regional Tissue Bank, Halifax, NS
Mijani Ridic	Unit Manager, Lions Eye Bank	Southern Alberta Organ and Tissue Program, Calgary, AB
Gary Rockl	Senior Tissue Specialist	Southern Alberta Tissue Program Calgary, AB
Linda Sharpen	Manager	Eye Bank of Canada (Ontario Division), Toronto, ON
Chris Snow	Director	Tissue Bank Manitoba, Winnipeg, MB
Balram Sukhu	Manager	Mount Sinai Allograft Technologies, Toronto, ON
Ivan Yan	Head Technologist	Eye Bank of British Columbia, Vancouver, BC

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, 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

Quebec

- Héma-Québec, Saint Laurent

New Brunswick

- New Brunswick Eye and Tissue Bank, St. John and Moncton

Nova Scotia

- Regional Tissue Bank, Halifax