EBAA
MEDICAL ADVISORY BOARD AGENDA BOOK

November 2, 2023 | San Francisco, California

EYE BANK ASSOCIATION OF AMERICA®

Welcome and Introductions	Winston Chamberlain, MD, PhD
Approval of Minutes	Winston Chamberlain, MD, PhD
Reports	
Medical Review Subcommittee	Elmer Tu, MD
Policy & Position Review Subcommittee	Asim Farooq, MD
Accreditation Board	Lisa Brooks / Bennie Jeng, MD
Certification Board	Adam Stockman
Technician Education Committee	Ingrid Schunder
Technical Procedures Manual Subcommittee	Vicki Adler
Old Business	
Data Integrity Subcommittee Report	Brian Philippy
Indications for Keratoplasty	Brian Philippy
E1.200 Processing and Preservation	Adam Stockman
New Business	
Revision to F1.300 and Glossary for PDEK	Jennifer DeMatteo
January-June 2023 Statistical Report	Jennifer DeMatteo
Late Additions	
For Information and Review	
Important Information for Human Cell, Tissue and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Tuberculosis Outbreaks Linked to a Bone Matrix Product	

APPROVAL OF MINUTES

Medical Advisory Board Meeting Minutes
Regency Ballroom - Fairmont Dallas Hotel
June 23, 2023

Dr. Winston Chamberlain called the meeting to order at 1:00pm. The following Board members were in attendance:

Winston Chamberlain, MD, PhD	MAB Chair
Shahzad Mian, MD	MAB Vice Chair
Victoria Adler, RN, BSN, CEBT	Technical Procedures Manual Subcommittee Chair
Alan Blake, CEBT, CTBS	
Lisa Brooks, CEBT, CTBS	Accreditation Board Co-Chair
Jason Brosious, RN, CEBT, CTBS	
Brychan Clark, MD	FDA Liaison, Ex-Officio
Kevin Corcoran, CAE	President & CEO
Maria Cortina, MD	
Andrea Crosson, CEBT	
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards, Ex-Officio
Marcella Dimond, CEBT, CTBS	
Donna Drury, CEBT, CTBS	
Asim Farooq, MD	Policy & Position Research Subcommittee Chair, Ex-Officio
Jennifer Li, MD	EBAA Chair, Ex-Officio
Amy Lin, MD	
John Lohmeier, CEBT	
Kristin Mathes, MS, MA	Ex-Officio Member
Kristen McCoy, CEBT, CTBS	
Eric Meinecke, CEBT	Medical Advisory Board Secretary
Brian Philippy, CEBT	
Edwin Roberts, MPA, CEBT	
Christopher Sales, MD, MPH	
Ingrid Schunder, CEBT	Technician Education Committee Chair
Adam Stockman, CEBT	Certification Board Chair
Chris Stoeger, CEBT, CTBS	Ex-Officio Member
Michael Tramber, CEBT, CTBS	

Concetta Triglia, CEBT	
Elmer Tu, MD	Medical Review Subcommittee Chair, Ex-Officio
Woodford Van Meter, MD	Ex-Officio Member
David Verdier, MD	Ex-Officio Member
William Waldrop, MD	

A motion was made and seconded to approve the minutes from the November 2, 2022 meeting. The minutes were approved.

Dr. Elmer Tu presented the Medical Review Subcommittee Report. The Medical Review Subcommittee (MRS) proposed multiple changes to the OARRS system including:

- Requiring the Donation Identification Number (DIN) and Product Code instead of the source and distributing bank tissue ID number, to be consistent with ISBT 128 required coding and labeling
- Adding Kerasave and Cornisol to the list of preservation methods
- The addition of numerous pathogens to the dropdown list
- Adding additional antifungal supplementation questions, including the drug, concentration, form (tablet or liquid), and whether this was done at recovery or processing.
- In January 2024, the OARRS system will need to be updated to the new listing of surgical indications.

Dr. Elmer Tu commented that adverse events have remained relatively stable over the last few years. Reported Primary Graft Failures (PGF) related to DSAEK and DMEK have decreased, but PGFs related to PK procedures have been increasing since 2018. The MRS also noted that the number of reported PGFs from tissue that had antifungal supplementation is increasing. Infections have been relatively stable for the last several years.

A motion was made and seconded to approve the changes to the OARRS system. The motion passed.

Dr. Asim Farooq presented the Policy and Position Review Subcommittee (PPRS) Report. The PPRS released a Mpox statement in July 2022. The statement was updated in September. A statement from PPRS on HTLV was released in February 2023. A COVID-19 survey was sent out in May 2023. PPRS is working on a manuscript related to HTLV, CMV, and EBV. Dr. Farooq also said that updated statements on Mpox and COVID-19 were in progress.

Lisa Brooks presented the Accreditation Board Report. During the spring inspection cycle, 16 banks were inspected. 15 banks received a 3-year accreditation, and 1 bank received a 1-year accreditation.

The Accreditation Board also had several proposed changes that were discussed and passed. The first change was to the Accreditation Inspection Confidentiality Agreement. The agreement will now include the statement: “Signature of the agreement does not preclude the Inspected

Bank from seeking remedy for harm caused by the Inspector." The next change was an addition to the Accreditation Inspector's Pledge. The new pledge reads, "I will delete, destroy, or return any information provided to me as part of the inspection within 10 business days of final resolution of Accreditation status.." On the same document the acknowledgment section was expanded and now reads: "I understand and agree that failure to honor this pledge could result in the removal from the Accreditation Board and in disciplinary action against my eye bank, as addressed in the Accreditation Board Policies and Procedures."

Related to the Accreditation Board Policy and Procedures, the AB voted and approved an addition to the D1.200, specifically:

"Accreditation status is contingent on payment in full of any financial obligations due to EBAA; failure to remit accreditation fees will result in revocation of accreditation status."

The long-term preservation subcommittee, which was formed in the fall to review the adequacy of the inspection process related to long term preserved corneas, recommended a change to PIQ Q37. PIQ Q37 specifically asks if a bank's policy and procedures meet the standards related to "long term tissue preservation". The subcommittee recommended changing PIQ Q37 to ask if the bank's policies and procedures meet the standards related to "Long term cornea preservation". The AB agreed that this change will guide inspectors to focus on the processing, storage, and release of long-term preserved corneas.

The AB had a request to clarify 1-C on the PIQ worksheet that instructs the applying bank to submit non-employee documentation of training, certification, and annual review. Question 1-C has an associated example that has caused confusion to the applying banks. The AB approved the removal of the example.

Due to increases in travel expenses, the AB voted to increase the accreditation inspection fee from $3500 to $4000. The increase will take effect with the Spring 2024 inspection cycle.

Adam Stockman gave the Certification Board Report. The Fall 2022 CEBT Exam took place October 8-22, 2022, in the US, Canada, Saudi Arabia, and Hong Kong. Out of the 25 candidates who took the exam, a total of 21 individuals passed, resulting in an 84% passing rate. Julie Shepard from New Brunswick Organ and Tissue Program received the highest score during this exam cycle. The Spring 2023 CEBT Exam took place April 8 -22, 2023, in the US and Canada. Out of the 32 candidates who took the exam, a total of 20 individuals passed, resulting in an 62.5% passing rate. Jany Fradette from Banque d'yeux du CUO received the highest score. The fall exam is scheduled to take place October 7 – 21, 2023, and the application is available on the EBAA website. The Exam Committee is hosting the webinar, "The CEBT Exam – What You Need to Know", on July 27. The session is free and registration is open on eyeLEARN.

The Exam Committee recently released an updated study guide for the CEBT Exam. This document is available on the EBAA website on the CEBT exam page.

Ingrid Schunder gave the Technician Education Committee Report. The Technician Education Committee has been very productive this year. Ingrid thanked the committee for their hard work and their many contributions to the technical education of the EBAA membership. The Technician Education Seminar was held virtually January 27 through February 17 and there were 80 attendees from the US, Canada, Australia, and Germany. The course featured 28 on-demand presentations and 4 live workshops.

In December, the Tech Ed Committee hosted a webinar session on DMEK corneal tissue processing basics. The speakers were Chelsea Green, Chris Conwell, Paul Graves, Darrell Lee, Nick Hicks, and Alyson Ronan.

In May, Tech Ed hosted the webinar, Infectious Disease: Overview and Updates, presented by Dr. Beverly Forsyth. Dr. Forsyth went over the basics of infection and disease and discussed the relevance to eye banking.

On August 10, Tech Ed will host the webinar, “Hosting a Wet Lab: What You Need to Know!” The session features Caithlin Lopes, Darrell Lee, and Dr. Lorenzo Cervantes. Registration is open on eyeLEARN.

The Technician Education Committee hosted a Community Chat on viewing chambers on April 26. The chat was well attended and there was a lot of productive conversation around issues concerning viewing chambers. While all on the call, the committee gathered important insight and feedback which was then sent to B&L.

The Technician Education Committee was very busy preparing for the Annual Meeting. The committee planned the Technical Skills Workshop as well as the following sessions:

- DSAEK Corneal Tissue Preparation Basics with Live Demo
- Handling Tissue with Care: Preventing Technician Induced Trauma
- Slit Lamp Microscopy Workshop: An Interactive Experience

Vicki Adler gave the Technical Procedures Manual Subcommittee Report.

<u>Medical Standard Changes</u>
1. C3.200 Equipment, Maintenance and Cleaning (page 11) - 3 years to 10 years
2. H1.000 Non-Surgical Donor Tissue (Biohazard and Biohazard Legend from Biohazardous)
3. Glossary (page 42) Intermediate Term Preservation – all media types added alphabetically

A motion was made and seconded to approve these changes to the medical standards. After a few brief questions, the MAB voted to approve the changes.

<u>Changes to Procedures</u>

1. E1.400 Long Term Preservation (LTP)
2. H1.000 Non-surgical Donor Tissue
3. J1.000 Labeling

A motion was made and seconded to approve the changes to the procedures. A question was raised regarding tissue reports forms and wet lab tissue. Kristin Mathes offered up some language to address the concern and provide clarity. The changes to the procedures, with Kristin's suggested revisions, were approved by the MAB.

Changes to Technical Procedures Manual C3.000 Facilities:

1. C3.100 Eye Bank Laboratory
2. C3.200 Equipment, Maintenance and Cleaning
3. C3.300 Instruments, Cleaning, Disinfection, Maintenance and Sterilization

A motion was made and seconded to approve the changes. Adam Stockman asked a question about C3.200. As written, C3.200 only covers BSC/Laminar Flow Hood and Clean Rooms. Adam pointed out that the Medical Standard E1.200 states, "Processing must be performed in a) a laminar air flow hood or cabinet which meets ISO Class 5 standards, b) in an accredited operating room, or **c) in another environment documented annually to have less than 25 colony forming units per 90 mm settle plate per one hour exposure."** Jennifer DeMatteo requested that a subcommittee be formed to review E1.200. Subcommittee members include: Jason Brosious, Dr. Win Chamberlain, Dr. Maria Cortina, Jennifer DeMatteo, John Lohmeier, Kristin Mathes, Eric Meinecke, Edwin Roberts, and Adam Stockman (Chair).

The MAB voted to approve the changes to C3.100, C3.200 and C3.300 of the Technical Procedures Manual (with language added to C3.200 that references Medical Standard E1.200).

Brian Philippy gave the Data Integrity Subcommittee Report. He briefly reviewed the goals and past actions of the subcommittee. Currently, the subcommittee is working on a best practices document for EBAA members as well as a guidance document for surgery schedulers. The subcommittee may recommend a revision to M1.600, should we not be able to significantly reduce the number of "unknown diagnosis" for domestic surgeries.

Brian reviewed the following best practices:

1. Ensure that eye bank staff thoroughly understand surgery types and the recipient diagnoses treated by each surgical type and apply surgical conscience principals to data.
2. Leverage technology to guide source data input.
3. Comb the data during entry (e.g., requests received by fax or email) or during approval (e.g., directly entered into database via portal).

4. Culture the information sources to submit high quality data. Provide on-going follow up with data sources as a form of continued education combined with live data clean-up.
5. Use verified recipient diagnosis information as a secondary selection variable during allocation.
6. When exporting tissue to another eye bank, request required data points, if available.
7. Recognize differences in partner models to guide follow up methods.
8. Seek reports from partners monthly or quarterly.
9. Set a goal of no more than 5% of domestic recipient diagnoses as “unknown”.
10. Programs that import large amounts of tissue can serve source partners by preparing reports monthly (best practice) or quarterly (upper limit of frequency).

Jennifer DeMatteo presented a request to revise Medical Standard B1.000. The Constitution and Bylaws Committee asked about conflicts in membership requirements between the Bylaws and Medical Standards while reviewing a new application for membership. The verbiage in MS B1.000 addresses Active (Accredited) Membership but does not address Associate (Unaccredited) Membership.

Jennifer proposed the following amendment to address this issue and clear up any confusion between these membership categories:

B1.000 Active Membership

In order for an eye bank to become an active (accredited) member of the Eye Bank Association of America (EBAA), it must comply with the EBAA Bylaws and the Following:

1. Demonstrate compliance with EBAA Medical Standards.
2. Maintain accreditation status by passing the site inspection as administered by the EBAA Accreditation Board.
3. Demonstrate proficiency in any aspect of eye banking including recovery, processing, tissue storage, evaluation, donor eligibility determination and distribution.
4. Proficiency shall be demonstrated by providing documentation, at the time of completing the application, of the handling of at least 25 surgical corneas for each eye bank function for which it is seeking accreditation.
5. Certify compliance with applicable Federal and State regulations.
6. Maintain registration with ICCBBA for a Facility Identification Number (FIN). This is required for all eye banks that assign a DIN or apply an ISBT 128 label to ocular tissue.

Once accredited, an eye bank must be inspected and reaccredited at least every three years to maintain active membership in the EBAA.

An associate (unaccredited) member of the EBAA meets all the criteria for membership except that it has not yet met or does not currently meet the Association’s requirements for accreditation.

A motion was made and seconded to approve the changes to B1.000. The motion passed.

Jennifer DeMatteo presented a proposed change to C3.310 Instruments:

To prevent contamination or cross-contamination, all surgical instruments that come in contact with eye tissue during recovery or processing, shall be properly cleaned, decontaminated, and sterilized prior to use and between different donors. The eye bank shall describe in their policy and procedures manual how these activities are performed and monitored. Adequate sterile instruments shall be available for sterile removal and processing of whole eyes and corneas. Instruments shall be inspected frequently to ensure that they function properly. The eye bank's policy and procedures shall also describe how these instruments are documented and tracked.

An eye bank that sterilizes its instruments, shall adhere to manufacturer and/or the eye bank's respective regulatory authority (e.g. current Association for the Advancement of Medical Instrumentation (ANSI/AAMI) Standard 79 " –Comprehensive guide to steam sterilization and sterility assurance in health care facilities"). The eye bank shall have documentation that shows that each load was properly sterilized. The sterilizer shall be appropriately qualified, and the sterilization process validated before use. The eye bank shall establish and define in their procedures the appropriate sterilization acceptance criteria. The calibration and preventive maintenance routine schedule shall be included in the eye bank's procedure manual.

If instruments are sterilized by a third party, the eye bank shall qualify the contractor performing the sterilization. The eye bank shall ensure through external audits, that the contractor's sterilization policies and procedures follow standards and applicable regulations.

The eye bank shall ensure that the qualified sterilizer is routinely calibrated and that the preventive maintenance activities are performed and documented according to manufacturer's recommendation. If the preventive maintenance is not defined by the manufacturer, then it should be performed annually. Sterilization records shall be maintained and readily available for a minimum of 3 years.

Prior to use, instruments shall be verified to be sterile, that the packaging integrity is intact, the applicable indicators (when available) are acceptable, and that the sterilization expiration dates, if applicable, are acceptable at the time of use.

A motion was made and seconded to approve the addition of "if applicable." The motion passed.

Kody Westrick requested that the Medical Advisory Board consider forming and distributing medical recommendations for donors with plasma cell neoplasms, most notably multiple myeloma and plasmacytoma. Dr. Asim Farooq agreed to take this to the PPRS.

Victoria Martin requested a revision to Medical Standard L1.100 Tissue Report Form. #9 would read, “Name and EBAA accreditation status (including accredited functions) of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, tissue storage, evaluation, donor eligibility determination, and final distribution.”

A motion was made and seconded to change L1.100. Brian asked about the scenario in which an eye bank sends its tissue to another eye bank for processing. How would the accreditation status (including functions) of the processing bank make it on the source eye bank tissue report form? Processing eye banks often just add a processing document, and don’t generate a different tissue report form. After several comments, Dr. Chamberlain asked that the Accreditation Board work on this.

Brian Ha updated the references for Appendix V - Accredited Eye Banks Not Located in the United States. A motion was made and seconded to approve the changes. The motion passed.

Janice Sedgwick and Maria Chelko gave a presentation to the MAB regarding eye care for vented/non-blinking patients. In the fall of 2022, the Donor, Partner and Community Relations Committee created a subcommittee to develop a guidance document and a citation list for eye banks to share with hospitals as Best Practice for non-blinking/vented patient eye care. The subcommittee reviewed past practices and recent studies on ICU eye care in creating an up-to-date Guidance Document.

Requests from hospitals for eye bank guidance regarding non-blinking and/or vented patient eye care are common. Hospital ICU staff also seek guidance regarding proper techniques for contact lens removal. There is no EBAA resource for member eye banks to use for reference when advising hospital staff. Janice and Maria both commented that there is often no standard eye care for ICU patients and sometimes patients endure prolonged lagophthalmos or have contact lenses in their eyes for weeks at a time.

The Donor, Partner and Community Relations Committee would like the MAB to endorse an EBAA Best Practice document on the subject, readily accessible for eye bankers to refer to and share with facilities. The document would serve to improve eye care for patients who recover and leave the hospital and would also contribute to improved transplant outcomes for those patients who become eye donors.

There were several comments in support of a guidance document. Some MAB members expressed concern about liability and whether or not it was appropriate for the MAB to issue ICU care policies or guidelines. Dr. Li and others suggested asking Dr. Barry Lee to help bring this topic to AAO and the Cornea Society. Dr. Van Meter voiced his strong support and Donna Drury commented that organ procurement organizations need this important information as well.

Jennifer DeMatteo briefly discussed the revisions made to the Guide to Medical Examiner &

Coroner Cases. The revision was a collaborative effort between EBAA, AATB and AOPO. A motion was made and seconded to add the Guide to Medical Examiner & Coroner Cases to the appendix of the EBAA Procedures Manual.

There were no late additions. Dr. Chamberlain thanked the Medical Advisory Board, and a motion was made and seconded to adjourn.

END

REPORTS

MEDICAL REVIEW SUBCOMMITTEE

EYE BANK ASSOCIATION OF AMERICA

OARRS
The Online Adverse Reaction Reporting System

Adverse Reactions Reasonably Likely/ Proven to be Due to Donor Tissue

Report generated 27 Sep 2023 4:51pm EDT

	2018	2019	2020	2021	2022	2023	Mean
Primary Graft Failure	**89**	**100**	**70**	**87**	**75**	**35**	**76**
Recipient's Age (mean)	68.95	69.41	67.18	66.37	64.58	69.02	67.69
Donor's Age (mean)	57.25	59.56	55.12	58.47	58.41	61.58	58.1
Donor Cause of Death							
Heart disease	28 (31%)	26 (26%)	16 (23%)	22 (25%)	21 (28%)	13 (37%)	21 (28%)
Cancer	14 (16%)	29 (29%)	19 (27%)	18 (21%)	13 (17%)	6 (17%)	16.5 (22%)
Cerebrovascular accident	10 (11%)	7 (7%)	12 (17%)	13 (15%)	10 (13%)	4 (11%)	9.33 (12%)
Respiratory disease	6 (7%)	6 (6%)	4 (6%)	9 (10%)	5 (7%)	2 (6%)	5.33 (7%)
Trauma	6 (7%)	7 (7%)	6 (9%)	4 (5%)	8 (11%)	1 (3%)	5.33 (7%)
Toxic / Accident	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)	1 (3%)	0.5 (1%)
Other	25 (28%)	24 (24%)	13 (19%)	21 (24%)	17 (23%)	8 (23%)	18 (24%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Procedure Type							
Penetrating keratoplasty (includes LAK/IEK)	10 (11%)	15 (15%)	13 (19%)	18 (21%)	25 (33%)	5 (14%)	14.33 (19%)
Anterior lamellar keratoplasty (includes ALK, DALK)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0.17 (0%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	57 (64%)	50 (50%)	32 (46%)	41 (47%)	28 (37%)	11 (31%)	36.5 (48%)
Endothelial keratoplasty: DMEK or DMAEK	22 (25%)	35 (35%)	24 (34%)	28 (32%)	22 (29%)	19 (54%)	25 (33%)
Source of Lamellar Cut							
N/A	1 (1%)	13 (13%)	14 (20%)	17 (20%)	26 (35%)	3 (9%)	12.33 (17%)
Surgeon	5 (6%)	13 (13%)	2 (3%)	2 (2%)	0 (0%)	2 (6%)	4 (5%)
Processing establishment - source eye bank	45 (56%)	53 (54%)	31 (44%)	38 (44%)	32 (43%)	12 (34%)	35.17 (47%)
Other processing establishment	29 (36%)	20 (20%)	23 (33%)	30 (34%)	17 (23%)	18 (51%)	22.83 (31%)
Type of Lamellar Cut							
N/A	1 (1%)	21 (21%)	15 (21%)	19 (22%)	26 (35%)	4 (11%)	14.33 (19%)
Microkeratome	61 (76%)	49 (49%)	31 (44%)	40 (46%)	24 (32%)	12 (34%)	36.17 (49%)
Laser	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0.17 (0%)
Manual Dissection	18 (23%)	29 (29%)	24 (34%)	27 (31%)	25 (33%)	19 (54%)	23.67 (32%)
Tissue Preloaded							
Yes	6 (7%)	24 (24%)	19 (27%)	21 (24%)	20 (27%)	13 (37%)	17.17 (23%)
No	83 (93%)	76 (76%)	51 (73%)	66 (76%)	55 (73%)	22 (63%)	58.83 (77%)
Location of Tissue Transplant							
United States	70 (79%)	64 (64%)	48 (69%)	70 (80%)	53 (71%)	23 (66%)	54.67 (72%)
International	19 (21%)	36 (36%)	22 (31%)	17 (20%)	22 (29%)	12 (34%)	21.33 (28%)
Preoperative Diagnosis							
A. Post-cataract surgery edema	13 (15%)	13 (13%)	13 (19%)	16 (18%)	9 (12%)	3 (9%)	11.17 (15%)
B. Keratoconus	2 (2%)	2 (2%)	3 (4%)	1 (1%)	10 (13%)	1 (3%)	3.17 (4%)
C. Fuchs' dystrophy	44 (49%)	43 (43%)	23 (33%)	33 (38%)	31 (41%)	21 (60%)	32.5 (43%)
D. Repeat corneal transplant	6 (7%)	9 (9%)	9 (13%)	11 (13%)	2 (3%)	2 (6%)	6.5 (9%)
E. Other degenerations or dystrophies	9 (10%)	7 (7%)	5 (7%)	1 (1%)	4 (5%)	1 (3%)	4.5 (6%)
G. Microbial changes	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (0%)
H. Mechanical or chemical trauma	0 (0%)	0 (0%)	0 (0%)	1 (1%)	2 (3%)	0 (0%)	0.5 (1%)
I. Congenital opacities	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	1 (3%)	0.33 (0%)

	2018	2019	2020	2021	2022	2023	Mean
K. Non-infectious ulcerative keratitis or perforation	0 (0%)	0 (0%)	0 (0%)	2 (2%)	1 (1%)	0 (0%)	0.5 (1%)
L. Other causes of corneal dysfunction or distortion (non-endothelial)	3 (3%)	2 (2%)	3 (4%)	1 (1%)	2 (3%)	1 (3%)	2 (3%)
M. Other causes of endothelial dysfunction	9 (10%)	16 (16%)	12 (17%)	17 (20%)	11 (15%)	5 (14%)	11.67 (15%)
Z. Unknown, unreported, or unspecified	3 (3%)	7 (7%)	2 (3%)	3 (3%)	3 (4%)	0 (0%)	3 (4%)
Endothelial Density (mean)	2904.22	2839.89	2873.9	2847.02	2841.07	2762.83	2853.31
Death to Cooling (mean hrs)	4.91	4.78	3.85	4.35	3.8	2.84	4.3
Range	0–21	0–20.6	0–15	0–19	1–18	0–8	0–21
Death to Preservation (mean hrs)	12.14	27.64	11.23	13.07	12.48	13.36	15.74
Range	3–24	3.8–1515	3–23	3–24	3.7–23	2.4–25	2.4–1515
Death to Surgery (mean days)	6.4	6.39	6.61	6.45	6.91	7.66	6.62
Range	2–14	2–15	3–13	2–10.6	2–12	3–12	2–15
Preservation Method							
Optisol-GS	77 (87%)	87 (87%)	63 (90%)	66 (76%)	58 (77%)	31 (89%)	63.67 (84%)
Life4C	9 (10%)	13 (13%)	7 (10%)	21 (24%)	5 (7%)	0 (0%)	9.17 (12%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (11%)	3 (9%)	1.83 (2%)
Cornea Cold®	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (0%)
Other	2 (2%)	0 (0%)	0 (0%)	0 (0%)	4 (5%)	1 (3%)	1.17 (2%)
Was storage solution changed after processing?							
No	27 (30%)	33 (33%)	22 (31%)	31 (36%)	32 (43%)	8 (23%)	25.5 (34%)
Yes	62 (70%)	67 (67%)	48 (69%)	56 (64%)	43 (57%)	27 (77%)	50.5 (66%)
Post-Processing Preservation Method							
Optisol-GS	37 (59%)	61 (91%)	40 (83%)	45 (80%)	32 (74%)	22 (81%)	39.5 (78%)
Life4C	7 (11%)	4 (6%)	6 (13%)	8 (14%)	2 (5%)	0 (0%)	4.5 (9%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (16%)	2 (7%)	1.5 (3%)
Cornea Cold®	9 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.5 (3%)
Other	10 (16%)	2 (3%)	2 (4%)	3 (5%)	2 (5%)	3 (11%)	3.67 (7%)
Antifungal Supplementation?							
No	61 (97%)	79 (87%)	55 (79%)	67 (77%)	59 (79%)	26 (74%)	57.83 (82%)
Yes	2 (3%)	12 (13%)	15 (21%)	20 (23%)	16 (21%)	9 (26%)	12.33 (18%)
Recovery Procedure							
In-situ corneal excision	88 (99%)	97 (97%)	67 (96%)	85 (98%)	74 (99%)	34 (97%)	74.17 (98%)
In-laboratory corneal and/or scleral excision after enucleation	1 (1%)	3 (3%)	3 (4%)	2 (2%)	1 (1%)	1 (3%)	1.83 (2%)
Donor Site Facility							
Hospital	45 (51%)	65 (65%)	48 (69%)	50 (57%)	43 (57%)	22 (63%)	45.5 (60%)
Medical examiner	7 (8%)	7 (7%)	4 (6%)	5 (6%)	5 (7%)	1 (3%)	4.83 (6%)
Funeral home or mortuary	12 (13%)	11 (11%)	5 (7%)	8 (9%)	1 (1%)	2 (6%)	6.5 (9%)
Other	25 (28%)	17 (17%)	13 (19%)	24 (28%)	26 (35%)	10 (29%)	19.17 (25%)
Early Regraft	**52**	**82**	**78**	**65**	**89**	**33**	**66.5**
Recipient's Age (mean)	66.63	66.98	66.22	67.37	69.89	72.36	67.86
Donor's Age (mean)	58.85	62.35	59.31	58.48	59.86	58.73	59.85
Donor Cause of Death							
Heart disease	13 (25%)	21 (26%)	20 (26%)	20 (31%)	27 (30%)	14 (42%)	19.17 (29%)
Cancer	8 (15%)	36 (44%)	20 (26%)	13 (20%)	20 (22%)	11 (33%)	18 (27%)
Cerebrovascular accident	10 (19%)	5 (6%)	9 (12%)	7 (11%)	5 (6%)	4 (12%)	6.67 (10%)
Respiratory disease	4 (8%)	6 (7%)	3 (4%)	8 (12%)	9 (10%)	0 (0%)	5 (8%)
Trauma	6 (12%)	4 (5%)	5 (6%)	6 (9%)	7 (8%)	1 (3%)	4.83 (7%)
Toxic / Accident	1 (2%)	0 (0%)	1 (1%)	1 (2%)	2 (2%)	0 (0%)	0.83 (1%)
Other	10 (19%)	10 (12%)	20 (26%)	10 (15%)	19 (21%)	3 (9%)	12 (18%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Procedure Type							

	2018	2019	2020	2021	2022	2023	Mean
Penetrating keratoplasty (includes LAK/IEK)	5 (10%)	2 (2%)	13 (17%)	7 (11%)	5 (6%)	0 (0%)	5.33 (8%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	25 (48%)	19 (23%)	25 (32%)	19 (29%)	20 (22%)	9 (27%)	19.5 (29%)
Endothelial keratoplasty: DMEK or DMAEK	22 (42%)	61 (74%)	40 (51%)	39 (60%)	64 (72%)	24 (73%)	41.67 (63%)
Source of Lamellar Cut							
N/A	0 (0%)	2 (2%)	9 (12%)	9 (14%)	9 (10%)	0 (0%)	4.83 (7%)
Surgeon	2 (4%)	4 (5%)	5 (6%)	1 (2%)	3 (3%)	1 (3%)	2.67 (4%)
Processing establishment - source eye bank	28 (60%)	53 (65%)	47 (60%)	29 (45%)	50 (56%)	25 (76%)	38.67 (59%)
Other processing establishment	17 (36%)	23 (28%)	17 (22%)	26 (40%)	27 (30%)	7 (21%)	19.5 (30%)
Type of Lamellar Cut							
N/A	0 (0%)	3 (4%)	13 (17%)	9 (14%)	9 (10%)	0 (0%)	5.67 (9%)
Microkeratome	26 (55%)	20 (24%)	25 (32%)	19 (29%)	18 (20%)	9 (27%)	19.5 (30%)
Laser	0 (0%)	0 (0%)	0 (0%)	1 (2%)	2 (2%)	0 (0%)	0.5 (1%)
Manual Dissection	21 (45%)	59 (72%)	40 (51%)	36 (55%)	60 (67%)	24 (73%)	40 (61%)
Tissue Preloaded							
Yes	14 (27%)	44 (54%)	28 (36%)	35 (54%)	50 (56%)	25 (76%)	32.67 (49%)
No	38 (73%)	38 (46%)	50 (64%)	30 (46%)	39 (44%)	8 (24%)	33.83 (51%)
Location of Tissue Transplant							
United States	51 (98%)	74 (90%)	64 (82%)	57 (88%)	82 (92%)	31 (94%)	59.83 (90%)
International	1 (2%)	8 (10%)	14 (18%)	8 (12%)	7 (8%)	2 (6%)	6.67 (10%)
Preoperative Diagnosis							
A. Post-cataract surgery edema	6 (12%)	3 (4%)	3 (4%)	4 (6%)	5 (6%)	2 (6%)	3.83 (6%)
B. Keratoconus	3 (6%)	0 (0%)	4 (5%)	0 (0%)	2 (2%)	0 (0%)	1.5 (2%)
C. Fuchs' dystrophy	30 (58%)	59 (72%)	39 (50%)	36 (55%)	63 (71%)	29 (88%)	42.67 (64%)
D. Repeat corneal transplant	4 (8%)	3 (4%)	12 (15%)	3 (5%)	4 (4%)	1 (3%)	4.5 (7%)
E. Other degenerations or dystrophies	5 (10%)	10 (12%)	9 (12%)	5 (8%)	5 (6%)	1 (3%)	5.83 (9%)
H. Mechanical or chemical trauma	0 (0%)	0 (0%)	1 (1%)	1 (2%)	1 (1%)	0 (0%)	0.5 (1%)
L. Other causes of corneal dysfunction or distortion (non-endothelial)	1 (2%)	1 (1%)	2 (3%)	2 (3%)	0 (0%)	0 (0%)	1 (2%)
M. Other causes of endothelial dysfunction	3 (6%)	4 (5%)	5 (6%)	11 (17%)	5 (6%)	0 (0%)	4.67 (7%)
Z. Unknown, unreported, or unspecified	0 (0%)	2 (2%)	3 (4%)	3 (5%)	4 (4%)	0 (0%)	2 (3%)
Endothelial Density (mean)	2857.19	2795.9	2783.15	2820.63	2829.56	2835.6	2816.04
Death to Cooling (mean hrs)	3.86	3.89	3.31	3.58	5.48	3.22	3.98
Range	0–13.4	0–13.6	0–10	0–11	0–39	1–11	0–39
Death to Preservation (mean hrs)	12.06	11.65	11.53	12.55	11.49	10.98	11.73
Range	1–24	1–23	3.2–23	3.1–24	2.8–23.5	3.46–24	1–24
Death to Surgery (mean days)	5.79	5.83	6.22	6.54	6.13	5.97	6.09
Range	2–13	2–13	1–12	3–10	2–11	2–10	1–13
Preservation Method							
Optisol-GS	45 (87%)	72 (88%)	68 (87%)	49 (75%)	65 (73%)	31 (94%)	55 (83%)
Life4C	7 (13%)	10 (12%)	10 (13%)	16 (25%)	12 (13%)	0 (0%)	9.17 (14%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	10 (11%)	1 (3%)	1.83 (3%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	1 (3%)	0.5 (1%)
Was storage solution changed after processing?							
No	14 (27%)	13 (16%)	18 (23%)	14 (22%)	30 (34%)	5 (15%)	15.67 (24%)
Yes	38 (73%)	69 (84%)	60 (77%)	51 (78%)	59 (66%)	28 (85%)	50.83 (76%)
Post-Processing Preservation Method							
Optisol-GS	23 (61%)	63 (91%)	50 (83%)	35 (69%)	37 (63%)	16 (57%)	37.33 (73%)
Life4C	8 (21%)	6 (9%)	8 (13%)	10 (20%)	6 (10%)	0 (0%)	6.33 (12%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (5%)	5 (18%)	1.33 (3%)
Cornea Cold®	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.33 (1%)

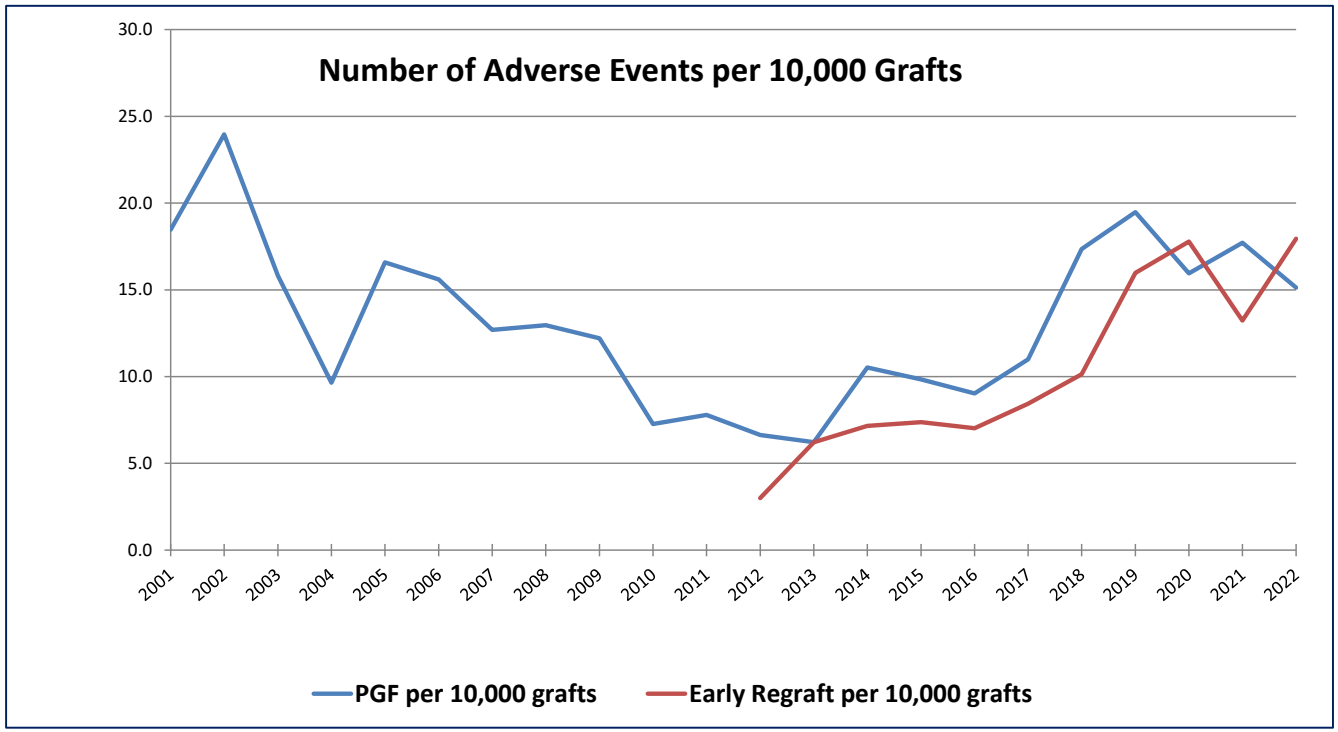
	2018	2019	2020	2021	2022	2023	Mean
Other	5 (13%)	0 (0%)	2 (3%)	6 (12%)	13 (22%)	7 (25%)	5.5 (11%)
Antifungal Supplementation?							
No	37 (97%)	58 (74%)	58 (74%)	45 (69%)	57 (64%)	22 (67%)	46.17 (73%)
Yes	1 (3%)	20 (26%)	20 (26%)	20 (31%)	32 (36%)	11 (33%)	17.33 (27%)
Recovery Procedure							
In-situ corneal excision	52 (100%)	82 (100%)	78 (100%)	62 (95%)	87 (98%)	33 (100%)	65.67 (99%)
In-laboratory corneal and/or scleral excision after enucleation	0 (0%)	0 (0%)	0 (0%)	3 (5%)	2 (2%)	0 (0%)	0.83 (1%)
Donor Site Facility							
Hospital	33 (63%)	47 (57%)	55 (71%)	36 (55%)	50 (56%)	20 (61%)	40.17 (60%)
Medical examiner	5 (10%)	7 (9%)	6 (8%)	8 (12%)	5 (6%)	2 (6%)	5.5 (8%)
Funeral home or mortuary	4 (8%)	16 (20%)	4 (5%)	5 (8%)	4 (4%)	3 (9%)	6 (9%)
Other	10 (19%)	12 (15%)	13 (17%)	16 (25%)	30 (34%)	8 (24%)	14.83 (22%)
Endophthalmitis	**13**	**10**	**13**	**9**	**11**	**10**	**11**
Recipient's Age (mean)	71.17	69.6	58.54	57.44	62.1	59.44	63.24
Donor's Age (mean)	58	63.3	61.69	46	54.8	50.6	56.26
Donor Cause of Death							
Heart disease	4 (31%)	4 (40%)	3 (23%)	1 (11%)	3 (27%)	3 (30%)	3 (27%)
Cancer	3 (23%)	3 (30%)	4 (31%)	2 (22%)	2 (18%)	2 (20%)	2.67 (24%)
Cerebrovascular accident	2 (15%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.33 (3%)
Respiratory disease	1 (8%)	0 (0%)	4 (31%)	1 (11%)	0 (0%)	2 (20%)	1.33 (12%)
Trauma	1 (8%)	0 (0%)	0 (0%)	0 (0%)	1 (9%)	3 (30%)	0.83 (8%)
Toxic / Accident	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Other	2 (15%)	3 (30%)	1 (8%)	5 (56%)	5 (45%)	0 (0%)	2.67 (24%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0.17 (2%)
Procedure Type							
Penetrating keratoplasty (includes LAK/IEK)	4 (31%)	2 (20%)	3 (23%)	5 (56%)	3 (27%)	5 (50%)	3.67 (33%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	7 (54%)	3 (30%)	4 (31%)	1 (11%)	5 (45%)	3 (30%)	3.83 (35%)
Endothelial keratoplasty: DMEK or DMAEK	2 (15%)	5 (50%)	5 (38%)	3 (33%)	3 (27%)	2 (20%)	3.33 (30%)
Keratoprosthesis (K-Pro)	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Source of Lamellar Cut							
N/A	0 (0%)	2 (20%)	4 (31%)	5 (56%)	3 (27%)	4 (40%)	3 (29%)
Surgeon	0 (0%)	0 (0%)	2 (15%)	0 (0%)	1 (9%)	0 (0%)	0.5 (5%)
Processing establishment - source eye bank	5 (56%)	4 (40%)	4 (31%)	4 (44%)	6 (55%)	5 (50%)	4.67 (45%)
Other processing establishment	4 (44%)	4 (40%)	3 (23%)	0 (0%)	1 (9%)	1 (10%)	2.17 (21%)
Type of Lamellar Cut							
N/A	0 (0%)	2 (20%)	4 (31%)	5 (56%)	3 (27%)	5 (50%)	3.17 (31%)
Microkeratome	7 (78%)	3 (30%)	4 (31%)	1 (11%)	5 (45%)	3 (30%)	3.83 (37%)
Manual Dissection	2 (22%)	5 (50%)	5 (38%)	3 (33%)	3 (27%)	2 (20%)	3.33 (32%)
Tissue Preloaded							
Yes	1 (8%)	3 (30%)	4 (31%)	2 (22%)	5 (45%)	3 (30%)	3 (27%)
No	12 (92%)	7 (70%)	9 (69%)	7 (78%)	6 (55%)	7 (70%)	8 (73%)
Location of Tissue Transplant							
United States	10 (77%)	9 (90%)	12 (92%)	8 (89%)	10 (91%)	8 (80%)	9.5 (86%)
International	3 (23%)	1 (10%)	1 (8%)	1 (11%)	1 (9%)	2 (20%)	1.5 (14%)
Concordant Positive Cultures	5 (38%)	5 (50%)	1 (8%)	1 (11%)	1 (9%)	2 (20%)	2.5 (23%)
Recipient Culture Results							
Candida albicans	1 (9%)	1 (9%)	1 (8%)	1 (13%)	0 (0%)	1 (11%)	0.83 (8%)
Candida glabrata	1 (9%)	6 (55%)	3 (23%)	2 (25%)	0 (0%)	0 (0%)	2 (19%)
Candida other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0.17 (2%)
Candida parapsilosis	1 (9%)	0 (0%)	1 (8%)	1 (13%)	0 (0%)	0 (0%)	0.5 (5%)

	2018	2019	2020	2021	2022	2023	Mean
Candida tropicalis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0.17 (2%)
Candida unspecified	0 (0%)	0 (0%)	1 (8%)	0 (0%)	1 (8%)	0 (0%)	0.33 (3%)
Clostridium perfringens	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Enterobacter spp.	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Enterococcus faecalis	1 (9%)	2 (18%)	1 (8%)	0 (0%)	1 (8%)	1 (11%)	1 (9%)
Pseudomonas aeruginosa	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Staphylococcus aureus	0 (0%)	0 (0%)	0 (0%)	1 (13%)	1 (8%)	0 (0%)	0.33 (3%)
Viridans streptococci (alpha hemolytic)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Yeast - non-specified	1 (9%)	0 (0%)	1 (8%)	0 (0%)	1 (8%)	0 (0%)	0.5 (5%)
Other Organism	0 (0%)	0 (0%)	0 (0%)	1 (13%)	1 (8%)	1 (11%)	0.5 (5%)
Not done	4 (36%)	1 (9%)	2 (15%)	1 (13%)	2 (17%)	3 (33%)	2.17 (20%)
No growth	0 (0%)	0 (0%)	2 (15%)	1 (13%)	3 (25%)	3 (33%)	1.5 (14%)
Death to Cooling (mean hrs)	3.6	4.3	4.42	4.81	3.66	4	4.1
Range	1.5–10.5	1–8	1.5–15	1.5–11	1.7–7	0–9	0–15
Death to Preservation (mean hrs)	10.93	11.39	14.23	11.76	14.73	14.15	12.88
Range	4–23.83	6.8–21	5–20	6–23	7–21	6–22	4–23.83
Death to Surgery (mean days)	7.08	5.9	5.77	7.11	5.91	6.6	6.38
Range	2–13	3–8	4–10	3–13	3–9	3–10	2–13
Preservation Method							
Optisol-GS	13 (100%)	7 (70%)	8 (62%)	5 (56%)	7 (64%)	8 (80%)	8 (73%)
Life4C	0 (0%)	3 (30%)	5 (38%)	4 (44%)	1 (9%)	0 (0%)	2.17 (20%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (18%)	2 (20%)	0.67 (6%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0.17 (2%)
Was storage solution changed after processing?							
No	7 (54%)	4 (40%)	4 (31%)	5 (56%)	6 (55%)	6 (60%)	5.33 (48%)
Yes	6 (46%)	6 (60%)	9 (69%)	4 (44%)	5 (45%)	4 (40%)	5.67 (52%)
Post-Processing Preservation Method							
Optisol-GS	5 (83%)	5 (83%)	7 (78%)	3 (75%)	3 (60%)	3 (75%)	4.33 (76%)
Life4C	0 (0%)	0 (0%)	2 (22%)	1 (25%)	0 (0%)	0 (0%)	0.5 (9%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	0.17 (3%)
Other	1 (17%)	1 (17%)	0 (0%)	0 (0%)	1 (20%)	1 (25%)	0.67 (12%)
Antifungal Supplementation?							
No	5 (83%)	7 (88%)	13 (100%)	9 (100%)	11 (100%)	10 (100%)	9.17 (96%)
Yes	1 (17%)	1 (13%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.33 (4%)
Recovery Procedure							
In-situ corneal excision	13 (100%)	10 (100%)	13 (100%)	9 (100%)	11 (100%)	10 (100%)	11 (100%)
Donor Site Facility							
Hospital	9 (69%)	6 (60%)	6 (46%)	8 (89%)	7 (64%)	7 (70%)	7.17 (65%)
Medical examiner	0 (0%)	1 (10%)	3 (23%)	0 (0%)	1 (9%)	2 (20%)	1.17 (11%)
Funeral home or mortuary	1 (8%)	0 (0%)	0 (0%)	1 (11%)	0 (0%)	1 (10%)	0.5 (5%)
Other	3 (23%)	3 (30%)	4 (31%)	0 (0%)	3 (27%)	0 (0%)	2.17 (20%)
Infectious Keratitis	**14**	**6**	**8**	**19**	**16**	**4**	**11.17**
Recipient's Age (mean)	70.69	62.33	43.57	61.25	65.13	57.25	62.03
Donor's Age (mean)	59.14	49.83	47.71	54.94	49.87	56	53.44
Donor Cause of Death							
Heart disease	7 (50%)	1 (17%)	2 (25%)	4 (21%)	4 (25%)	0 (0%)	3 (27%)
Cancer	0 (0%)	1 (17%)	0 (0%)	1 (5%)	1 (6%)	2 (50%)	0.83 (7%)
Cerebrovascular accident	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (1%)
Respiratory disease	1 (7%)	1 (17%)	1 (13%)	5 (26%)	2 (13%)	0 (0%)	1.67 (15%)

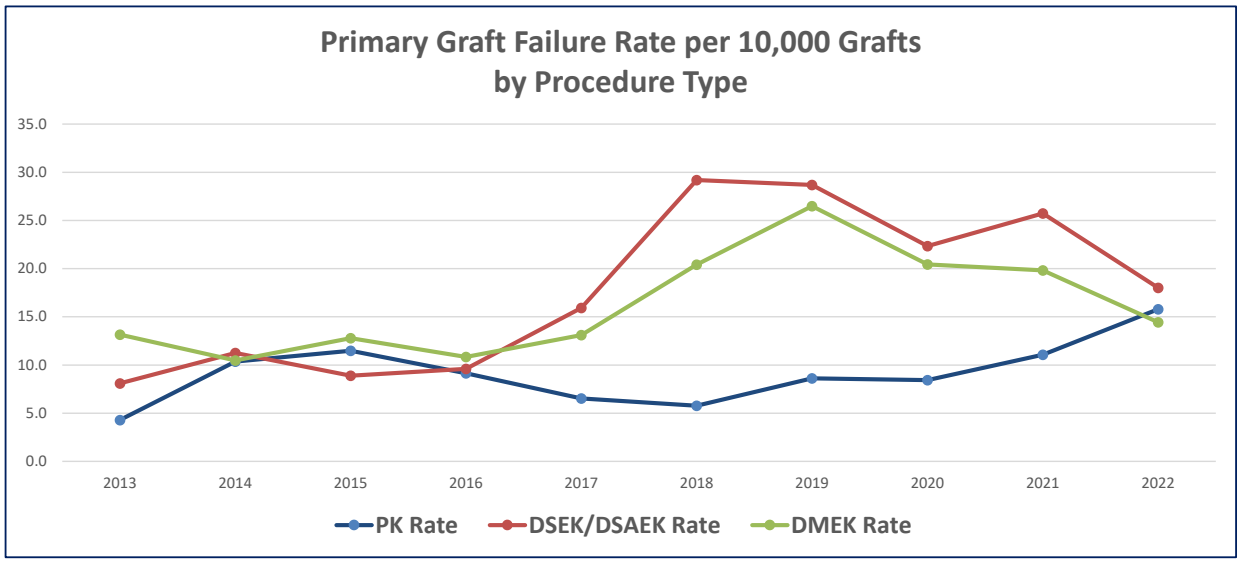
	2018	2019	2020	2021	2022	2023	Mean
Trauma	0 (0%)	0 (0%)	2 (25%)	2 (11%)	4 (25%)	1 (25%)	1.5 (13%)
Toxic / Accident	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (1%)
Other	6 (43%)	3 (50%)	3 (38%)	5 (26%)	5 (31%)	1 (25%)	3.83 (34%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	1 (5%)	1 (6%)	0 (0%)	0.33 (3%)
Procedure Type							
Penetrating keratoplasty (includes LAK/IEK)	3 (21%)	2 (33%)	2 (25%)	7 (37%)	2 (13%)	1 (25%)	2.83 (25%)
Anterior lamellar keratoplasty (includes ALK, DALK)	0 (0%)	0 (0%)	0 (0%)	2 (11%)	1 (6%)	0 (0%)	0.5 (4%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	9 (64%)	0 (0%)	6 (75%)	4 (21%)	9 (56%)	1 (25%)	4.83 (43%)
Endothelial keratoplasty: DMEK or DMAEK	2 (14%)	4 (67%)	0 (0%)	5 (26%)	4 (25%)	2 (50%)	2.83 (25%)
Keratoprosthesis (K-Pro)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (1%)
Source of Lamellar Cut							
N/A	0 (0%)	2 (33%)	2 (25%)	9 (47%)	2 (13%)	1 (25%)	2.67 (25%)
Surgeon	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Processing establishment - source eye bank	8 (73%)	2 (33%)	5 (63%)	6 (32%)	11 (69%)	3 (75%)	5.83 (55%)
Other processing establishment	3 (27%)	1 (17%)	1 (13%)	4 (21%)	3 (19%)	0 (0%)	2 (19%)
Type of Lamellar Cut							
N/A	0 (0%)	2 (33%)	2 (25%)	9 (47%)	2 (13%)	1 (25%)	2.67 (25%)
Microkeratome	9 (82%)	0 (0%)	6 (75%)	5 (26%)	8 (50%)	0 (0%)	4.67 (44%)
Manual Dissection	2 (18%)	4 (67%)	0 (0%)	5 (26%)	6 (38%)	3 (75%)	3.33 (31%)
Tissue Preloaded							
Yes	1 (7%)	2 (33%)	0 (0%)	5 (26%)	4 (25%)	1 (25%)	2.17 (19%)
No	13 (93%)	4 (67%)	8 (100%)	14 (74%)	12 (75%)	3 (75%)	9 (81%)
Location of Tissue Transplant							
United States	10 (71%)	6 (100%)	5 (63%)	17 (89%)	14 (88%)	3 (75%)	9.17 (82%)
International	4 (29%)	0 (0%)	3 (38%)	2 (11%)	2 (13%)	1 (25%)	2 (18%)
Concordant Positive Cultures	1 (7%)	2 (33%)	1 (13%)	5 (26%)	1 (6%)	0 (0%)	1.67 (15%)
Recipient Culture Results							
Candida albicans	2 (17%)	0 (0%)	2 (25%)	3 (16%)	3 (19%)	1 (25%)	1.83 (17%)
Candida glabrata	2 (17%)	1 (17%)	0 (0%)	3 (16%)	1 (6%)	0 (0%)	1.17 (11%)
Candida tropicalis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	0.17 (2%)
Candida unspecified	1 (8%)	0 (0%)	0 (0%)	3 (16%)	1 (6%)	0 (0%)	0.83 (8%)
Enterococcus faecalis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	0.17 (2%)
Herpes simplex	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Propionibacterium spp.	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (2%)
Staphylococcus epidermidis / coagulase negative	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (2%)
Streptococcus agalactiae (Group B Strep)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Streptococcus unspecified	0 (0%)	0 (0%)	1 (13%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Viridans streptococci (alpha hemolytic)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0.17 (2%)
Yeast - non-specified	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.17 (2%)
Other Organism	0 (0%)	0 (0%)	2 (25%)	1 (5%)	1 (6%)	0 (0%)	0.67 (6%)
Not done	7 (58%)	0 (0%)	2 (25%)	2 (11%)	5 (31%)	3 (75%)	3.17 (29%)
No growth	0 (0%)	2 (33%)	1 (13%)	4 (21%)	3 (19%)	0 (0%)	1.67 (15%)
Death to Cooling (mean hrs)	4.53	3.25	6.94	4.41	3.1	3.67	4.35
Range	2–13	2–6	2–11.51	1–13	1–11.5	2–6	1–13
Death to Preservation (mean hrs)	11.89	13.24	17.39	14.02	13.81	10.75	13.66
Range	5–23.83	6.57–23.85	10.75–23	5–21	7.35–22.5	6–13	5–23.85
Death to Surgery (mean days)	6.64	4.83	7.81	7	5.75	7.5	6.56
Range	2–12	2–7	2–14	2–13.5	2–9	5–11	2–14
Preservation Method							

	2018	2019	2020	2021	2022	2023	Mean
Optisol-GS	12 (86%)	5 (83%)	6 (75%)	12 (63%)	8 (50%)	4 (100%)	7.83 (70%)
Life4C	2 (14%)	1 (17%)	2 (25%)	7 (37%)	5 (31%)	0 (0%)	2.83 (25%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (13%)	0 (0%)	0.33 (3%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	0.17 (1%)
Was storage solution changed after processing?							
No	6 (43%)	3 (50%)	6 (75%)	9 (47%)	3 (19%)	1 (25%)	4.67 (42%)
Yes	8 (57%)	3 (50%)	2 (25%)	10 (53%)	13 (81%)	3 (75%)	6.5 (58%)
Post-Processing Preservation Method							
Optisol-GS	5 (63%)	3 (100%)	2 (100%)	7 (70%)	9 (69%)	1 (33%)	4.5 (69%)
Life4C	0 (0%)	0 (0%)	0 (0%)	3 (30%)	3 (23%)	0 (0%)	1 (15%)
Eusol-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8%)	2 (67%)	0.5 (8%)
Other	3 (38%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.5 (8%)
Antifungal Supplementation?							
No	8 (100%)	4 (80%)	8 (100%)	17 (89%)	13 (81%)	4 (100%)	9 (90%)
Yes	0 (0%)	1 (20%)	0 (0%)	2 (11%)	3 (19%)	0 (0%)	1 (10%)
Recovery Procedure							
In-situ corneal excision	14 (100%)	6 (100%)	8 (100%)	19 (100%)	16 (100%)	4 (100%)	11.17 (100%)
Donor Site Facility							
Hospital	9 (64%)	3 (50%)	2 (25%)	9 (47%)	8 (50%)	1 (25%)	5.33 (48%)
Medical examiner	0 (0%)	0 (0%)	1 (13%)	3 (16%)	5 (31%)	1 (25%)	1.67 (15%)
Funeral home or mortuary	1 (7%)	0 (0%)	3 (38%)	1 (5%)	0 (0%)	1 (25%)	1 (9%)
Other	4 (29%)	3 (50%)	2 (25%)	6 (32%)	3 (19%)	1 (25%)	3.17 (28%)
Scleral Graft Infection							
Donor Corneal Dystrophy or Degeneration	**1**	**0**	**0**	**1**	**2**	**0**	**0.67**
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Donor Corneal Refractive Surgery							
Donor-to-host Transmission of Systemic Infection	**1**	**2**	**1**	**0**	**0**	**0**	**0.67**
Malignancy							
Other (or Multiple)	**1**	**0**	**1**	**0**	**3**	**1**	**1**

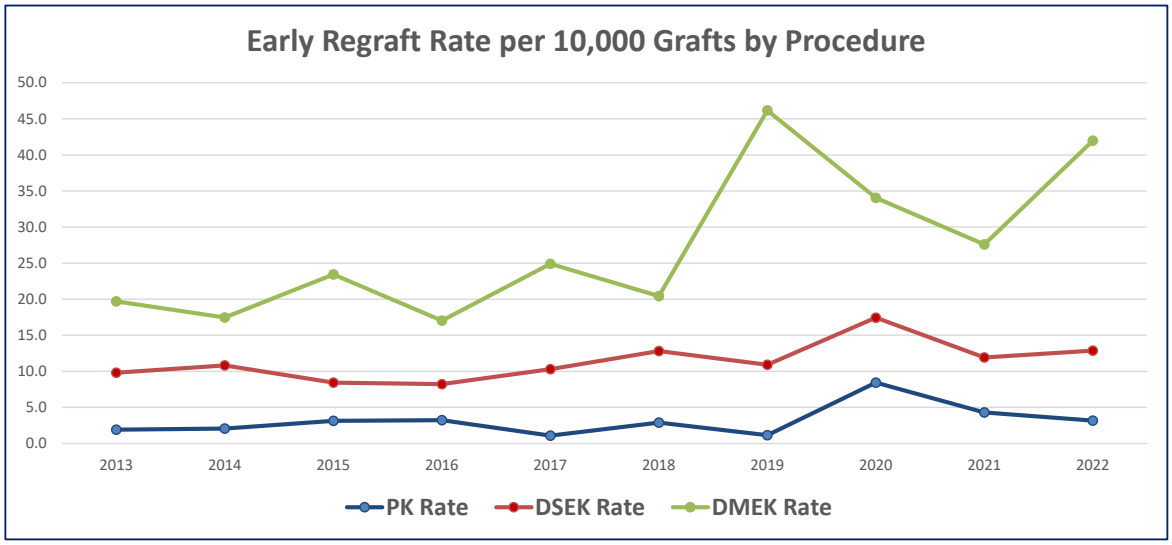
YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
PGF	61	78	51	31	53	53	50	54	52	31	36	31	30	50	48	45	56	89	100	70	87	75
Early Regraft												14	30	34	36	35	43	52	82	78	65	89
No. Corneal Grafts performed in U.S.	33035	32559	32240	32106	31952	33962	39391	41652	42606	42642	46196	46,684	48,229	47,530	48,792	49,869	50,934	51,294	51,336	43,873	49,110	49,597
PGF per 10,000 grafts	18.47	23.96	15.82	9.66	16.59	15.61	12.69	12.96	12.20	7.27	7.79	6.64	6.22	10.52	9.84	9.02	10.99	17.35	19.48	15.96	17.72	15.12
Early Regraft per 10,000 grafts												3.00	6.22	7.15	7.38	7.02	8.44	10.14	15.97	17.78	13.24	17.94



Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
PGF following PK	9	20	22	17	12	10	15	13	18	25
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402	16,269	15,835
PGF rate per 10,000 PK	**4.30**	**10.37**	**11.48**	**9.15**	**6.54**	**5.76**	**8.62**	**8.44**	**11.06**	**15.79**
PGF following DSEK	19	26	20	21	34	57	50	32	41	28
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331	15,935	15,544
PGF rate per 10,000 DSEK	**8.10**	**11.26**	**8.88**	**9.60**	**15.93**	**29.19**	**28.69**	**22.33**	**25.73**	**18.01**
PGF following DMEK	2	3	6	7	10	22	35	24	28	22
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749	14,128	15,248
PGF rate per 10,000 DMEK	**13.14**	**10.47**	**12.78**	**10.84**	**13.11**	**20.42**	**26.49**	**20.43**	**19.82**	**14.43**



Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Early Regraft following PK	4	4	6	6	2	5	2	13	7	5
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402	16,269	15,835
Early regraft rate per 10,000 PK	**1.91**	**2.07**	**3.13**	**3.23**	**1.09**	**2.88**	**1.15**	**8.44**	**4.30**	**3.16**
Early Regraft following DSEK	23	25	19	18	22	25	19	25	19	20
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331	15,935	15,544
Early Regraft rate per 10,000 DSEK	**9.80**	**10.82**	**8.44**	**8.23**	**10.31**	**12.80**	**10.90**	**17.44**	**11.92**	**12.87**
Early regraft following DMEK	3	5	11	11	19	22	61	40	39	64
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749	14,128	15,248
Early regraft rate per 10,000 DMEK	**19.71**	**17.45**	**23.43**	**17.03**	**24.91**	**20.42**	**46.16**	**34.05**	**27.60**	**41.97**



Graft Failures with Antifungal Supplementation

PGF	2018	2019	2020	2021	2022
PK	0	2	2	4	7
DSEK	2	5	6	10	5
DMEK	0	5	7	6	4
TOTAL	**2**	**12**	**15**	**20**	**16**

Early Regraft	2018	2019	2020	2021	2022
PK	0	0	1	2	1
DSEK	1	0	8	5	8
DMEK	0	20	11	13	23
TOTAL	**1**	**20**	**20**	**20**	**32**

PGF & Early Regraft Combined	2018	2019	2020	2021	2022
PK	0	2	3	6	8
DSEK	3	5	14	15	13
DMEK	0	25	18	19	27
TOTAL	**3**	**32**	**35**	**40**	**48**

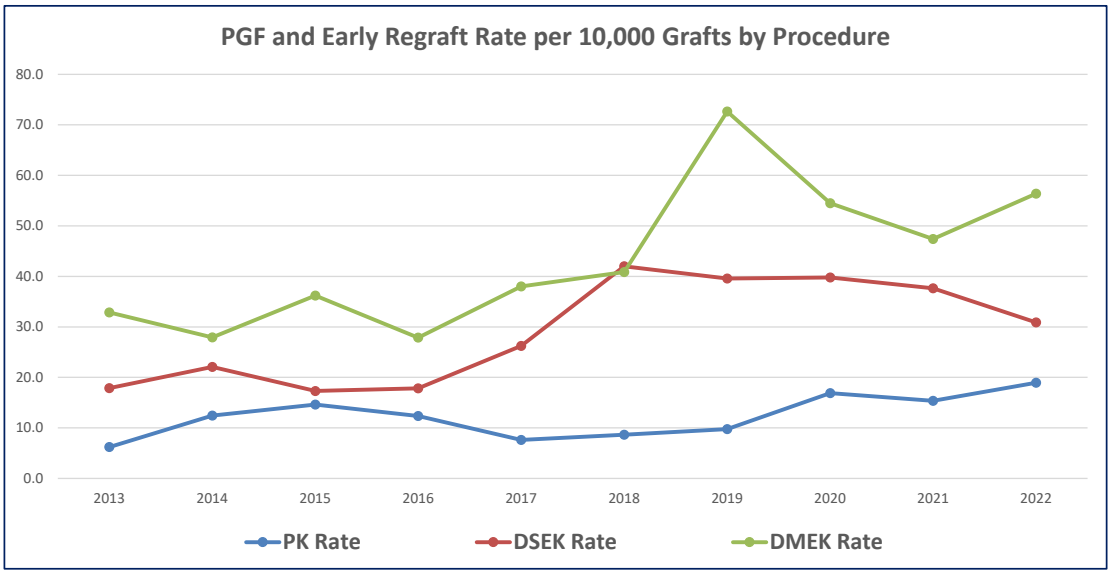
Percent of Graft Failures with Antifungal Supplementation	2018	2019	2020	2021	2022
PK	0.0%	11.8%	11.5%	24.0%	26.7%
DSEK	3.7%	7.2%	24.6%	25.0%	27.1%
DMEK	0.0%	26.0%	28.1%	28.4%	31.4%
TOTAL	**2.1%**	**17.6%**	**23.6%**	**26.3%**	**29.3%**

Endophthalmitis & Infectious Keratitis Infections with Antifungal Supplementation

# Infections with Antifungal Supplementation	2018	2019	2020	2021	2022
PK	0	0	0	1	0
ALK	0	0	0	1	0
DSEK	1	1	0	0	3
DMEK	0	1	0	0	0
TOTAL	**1**	**2**	**0**	**2**	**3**

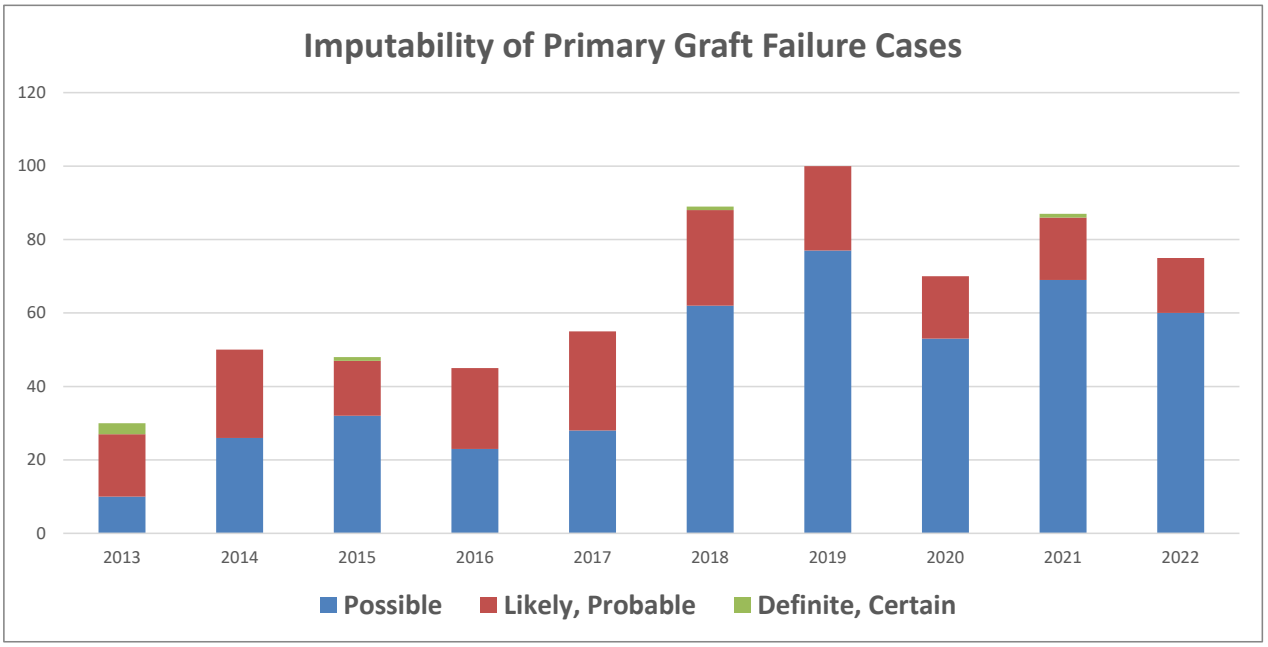
Percent of Infections with Antifungal Supplementation	2018	2019	2020	2021	2022
PK	0.0%	0.0%	0.0%	8.3%	0.0%
ALK	0.0%	0.0%	0.0%	50.0%	0.0%
DSEK	6.3%	9.1%	0.0%	0.0%	21.4%
DMEK	0.0%	11.1%	0.0%	0.0%	0.0%
TOTAL	**3.7%**	**12.5%**	**0.0%**	**7.1%**	**11.1%**

Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
PGF + Early Regaft following PK	13	24	28	23	14	15	17	26	25	30
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402	16,269	15,835
PGF + Early Regraft Rate per 10,000 PK	**6.20**	**12.44**	**14.61**	**12.38**	**7.63**	**8.65**	**9.77**	**16.88**	**15.37**	**18.95**
PGF+ Early Regraft following DSEK	42	51	39	39	56	82	69	57	60	48
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331	15,935	15,544
PGF+ Early Regraft Rate per 10,000 DSEK	**17.90**	**22.08**	**17.32**	**17.83**	**26.25**	**42.00**	**39.59**	**39.77**	**37.65**	**30.88**
PGF+ Early Regraft following DMEK	5	8	17	18	29	44	96	64	67	86
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749	14,128	15,248
PGF+ Early Regraft Rate per 10,000 DMEK	**32.85**	**27.92**	**36.22**	**27.87**	**38.02**	**40.84**	**72.64**	**54.47**	**47.42**	**56.40**



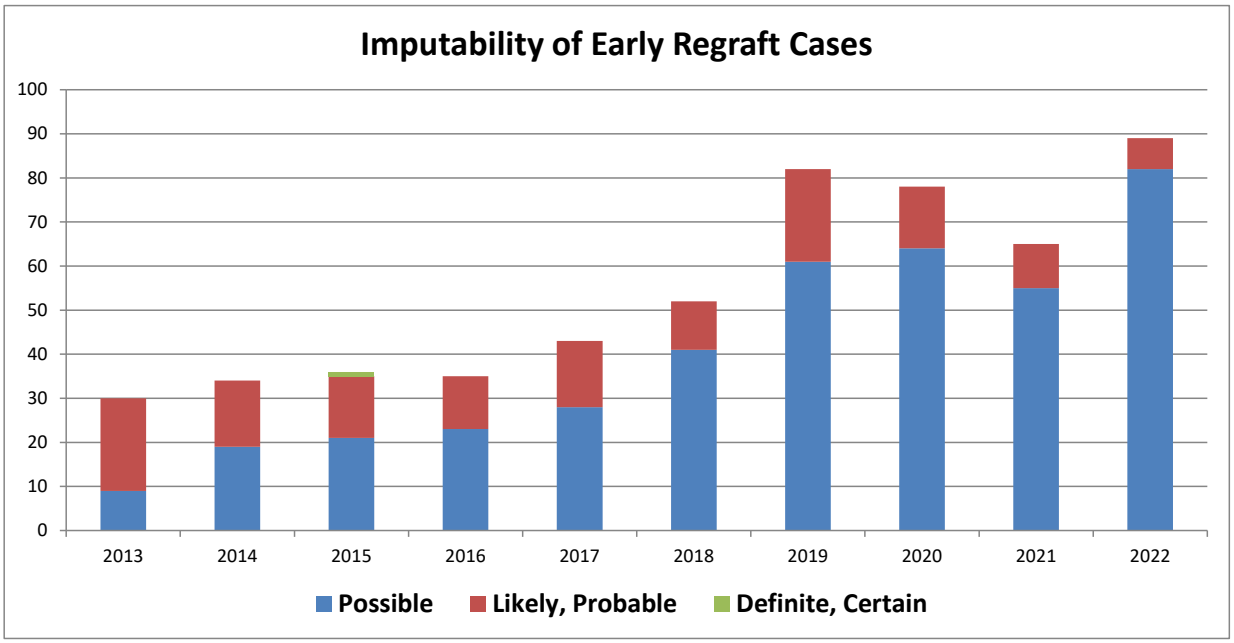
Imputability of PGF

PGF	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Possible	10	26	32	23	28	62	77	53	69	60
Likely, Probable	17	24	15	22	27	26	23	17	17	15
Definite, Certain	3	0	1	0	0	1	0	0	1	0
Total Reported	**30**	**50**	**48**	**45**	**56**	**89**	**100**	**70**	**87**	**75**

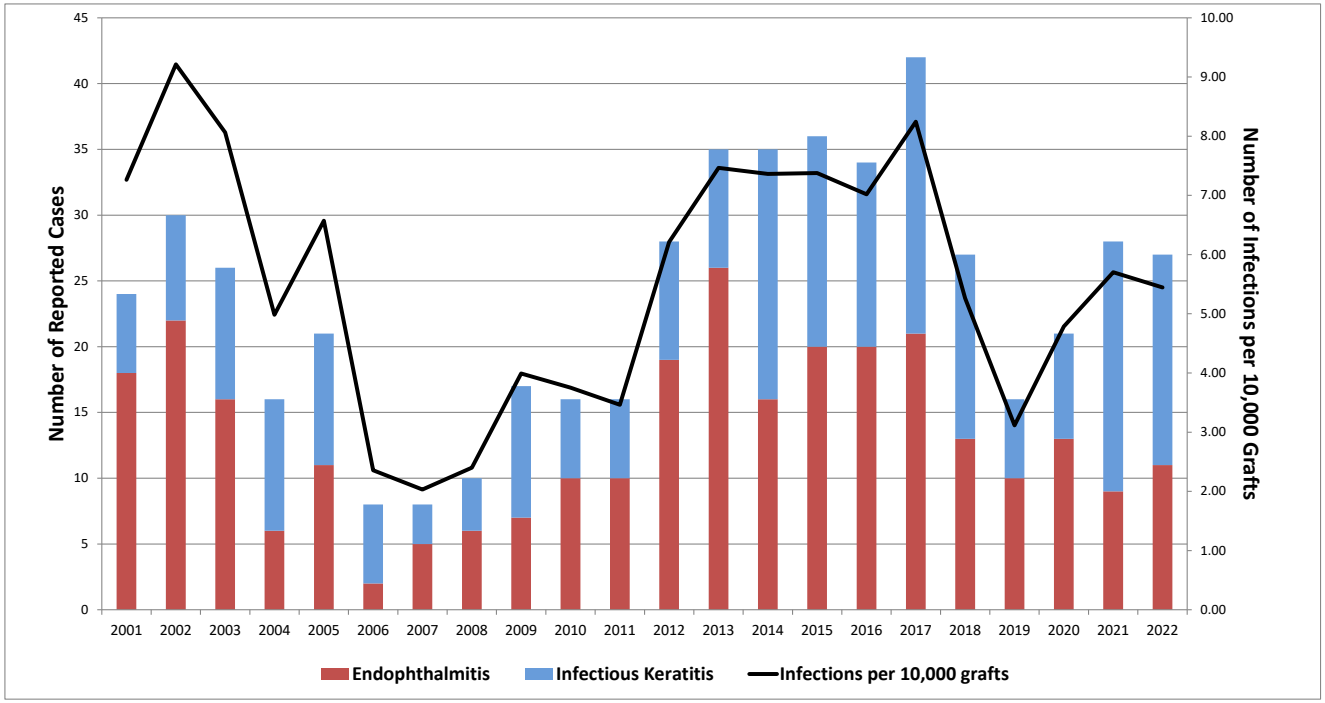


Imputability of Early Regraft

Early Regraft	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Possible	9	19	21	23	28	41	61	64	55	82
Likely, Probable	21	15	14	12	15	11	21	14	10	7
Definite, Certain	0	0	1	0	0	0	0	0	0	0
Total Reported	**30**	**34**	**36**	**35**	**43**	**52**	**82**	**78**	**65**	**89**

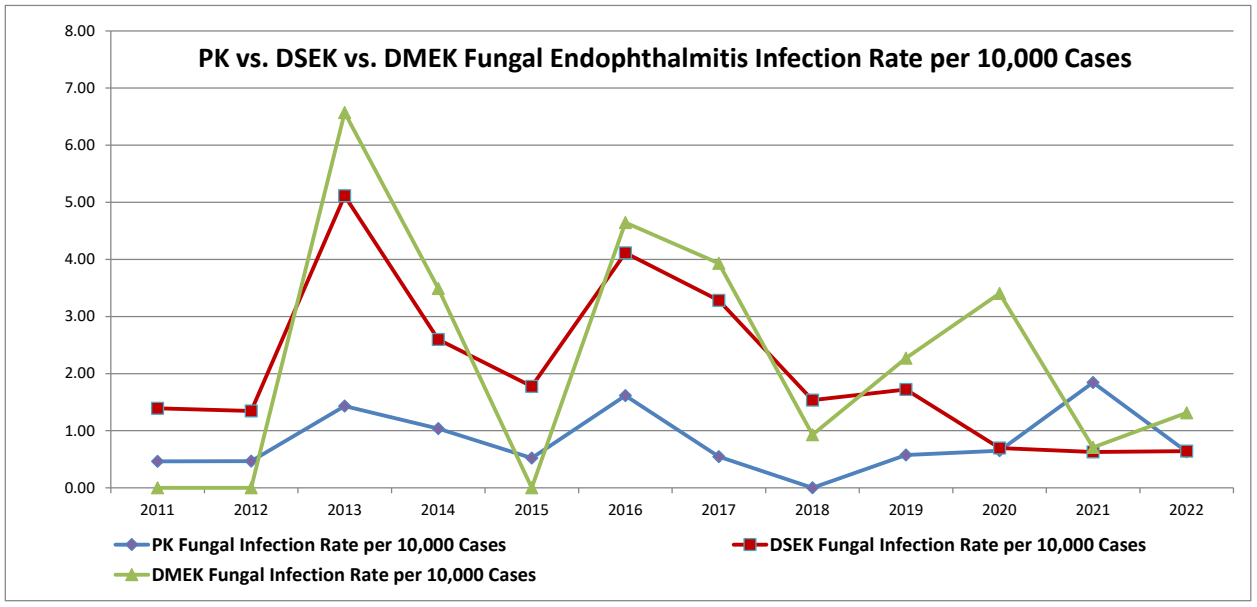


YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Endophthalmitis	18	22	16	6	11	2	5	6	7	10	10	19	26	16	20	20	21	13	10	13	9	11
Infectious Keratitis	6	8	10	10	10	6	3	4	10	6	6	9	9	19	16	14	21	14	6	8	19	16
Total Infections*	24	30	26	16	21	8	8	10	17	16	16	29	36	35	36	35	42	27	16	21	28	27
No. Corneal Grafts performed in U.S.	33035	32559	32240	32106	31952	33962	39391	41652	42606	42642	46196	46,684	48,229	47,530	48792	49,869	50,934	51,294	51,336	43,873	49,110	49,597
Infections per 10,000 grafts	7.27	9.21	8.06	4.98	6.57	2.36	2.03	2.40	3.99	3.75	3.46	6.21	7.46	7.36	7.38	7.02	8.25	5.26	3.12	4.79	5.70	5.44



Year	Total Endophthalmitis Cases	Fungal Endophthalmitis Cases	PK Fungal Cases	DSEK Fungal Cases	DMEK Fungal Cases	Total Domestic PK Procedures	Total Domestic DSEK Procedures	Total Domestic DMEK Procedures	PK Fungal Infection Rate per 10,000 Cases	DSEK Fungal Infection Rate per 10,000 Cases	DMEK Fungal Infection Rate per 10,000 Cases
2011	10	4	1	3	0	21,620	21,555	344	0.46	1.39	0.00
2012	19	4	1	3	0	21,422	22,301	748	0.47	1.35	0.00
2013	26	16	3	12	1	20,954	23,465	1,522	1.43	5.11	6.57
2014	16	9	2	6	1	19,294	23,100	2,865	1.04	2.60	3.49
2015	20	5	1	4	0	19,160	22,514	4,694	0.52	1.78	0.00
2016	21	15	3	9	3	18,579	21,868	6,459	1.61	4.12	4.64
2017	21	11	1	7	3	18,346	21,337	7,628	0.55	3.28	3.93
2018	13	4	0	3	1	17,347	19,526	10,773	0.00	1.54	0.93
2019	10	7	1	3	3	17,409	17,428	13,215	0.57	1.72	2.27
2020	13	7*	1	1	4	15,402	14,391	11,749	0.65	0.69	3.40
2021	9	5	3	1	1	16,269	15,935	14,128	1.84	0.63	0.71
2022	11	4	1	1	2	15,835	15,544	15,248	0.63	0.64	1.31

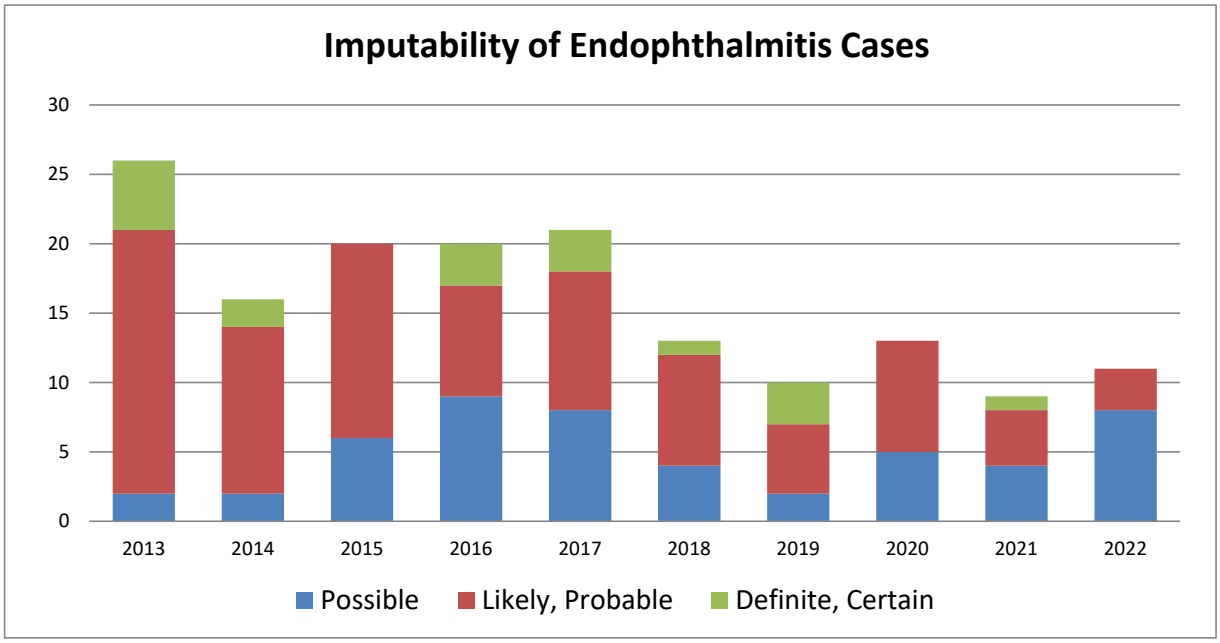
* Includes one fungal KPRO case

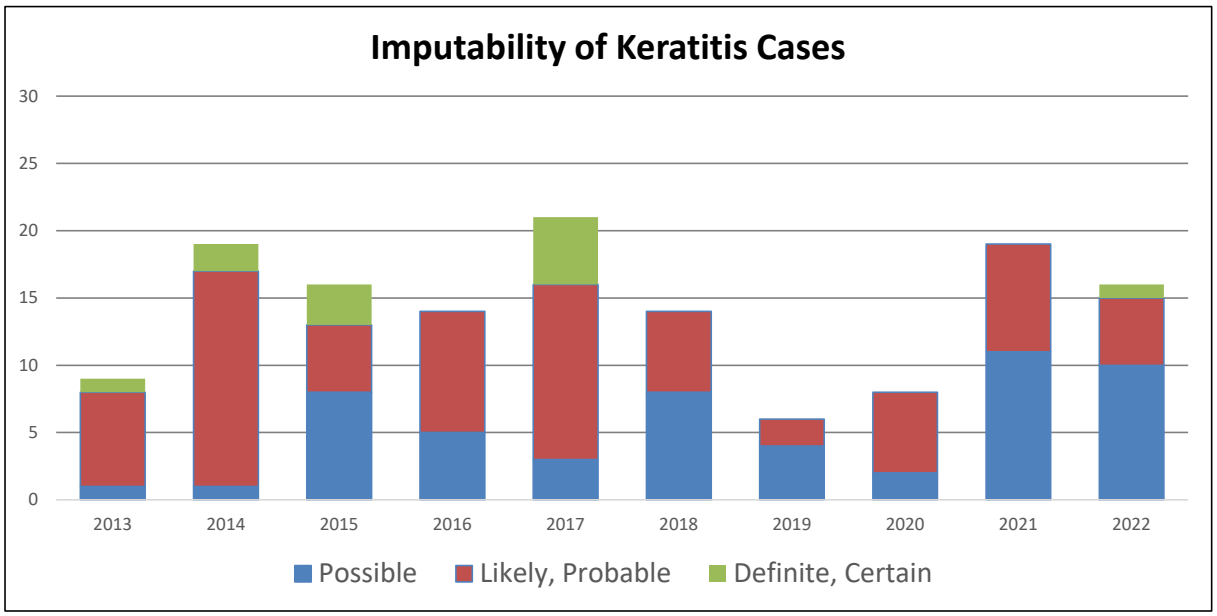


Imputability of Endophthalmitis and Infectious Keratitis

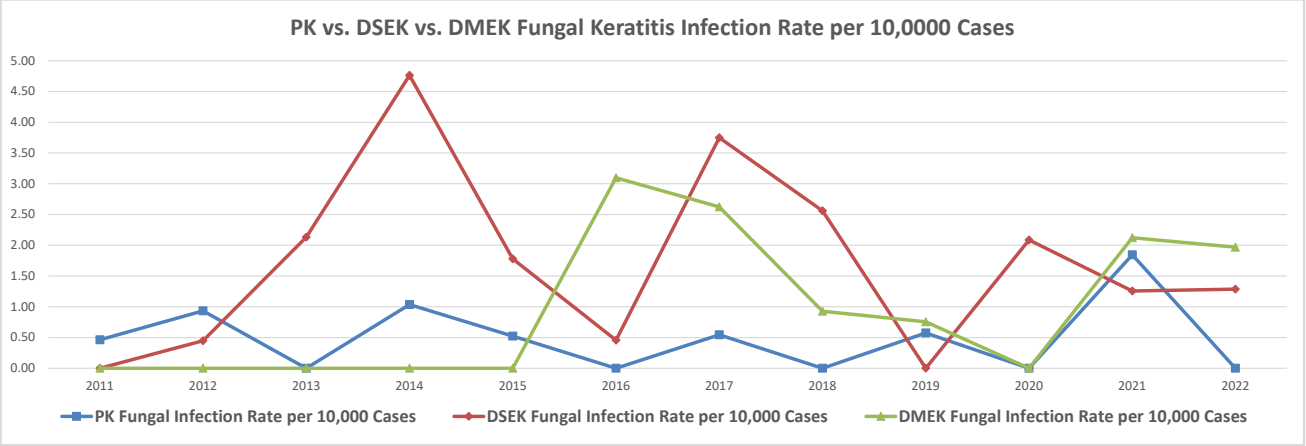
Endophthalmitis	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Possible	2	2	6	9	8	4	2	5	4	8
Likely, Probable	19	12	14	8	10	8	5	8	4	3
Definite, Certain	5	2	0	3	3	1	3	0	1	0
Total Reported	**26**	**16**	**20**	**20**	**21**	**13**	**10**	**13**	**9**	**11**

Keratitis	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Possible	1	1	8	5	3	8	4	2	11	10
Likely, Probable	7	16	5	9	13	6	2	6	8	5
Definite, Certain	1	2	3	0	5	0	0	0	0	1
Total Reported	**9**	**19**	**16**	**14**	**21**	**14**	**6**	**8**	**19**	**16**

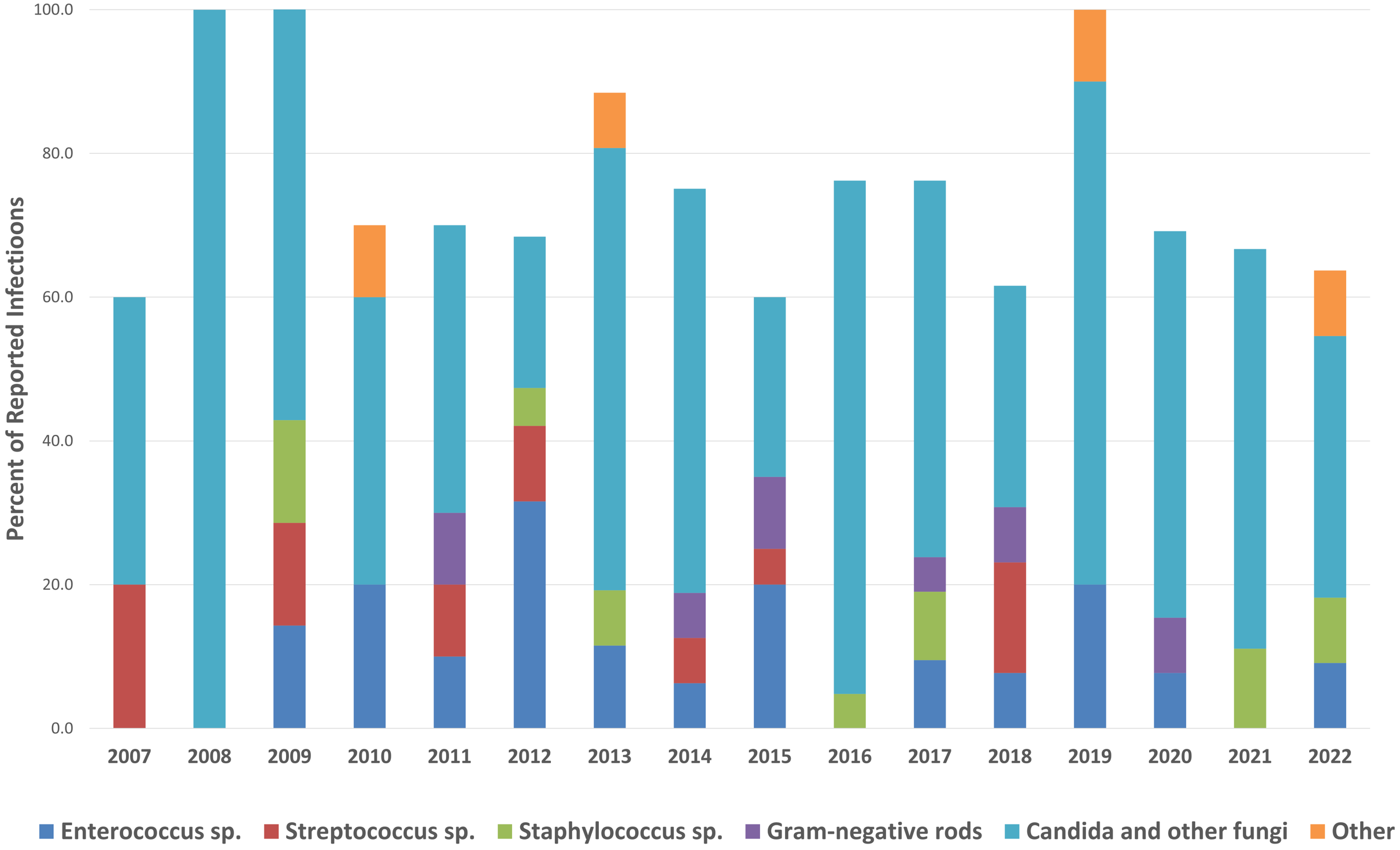




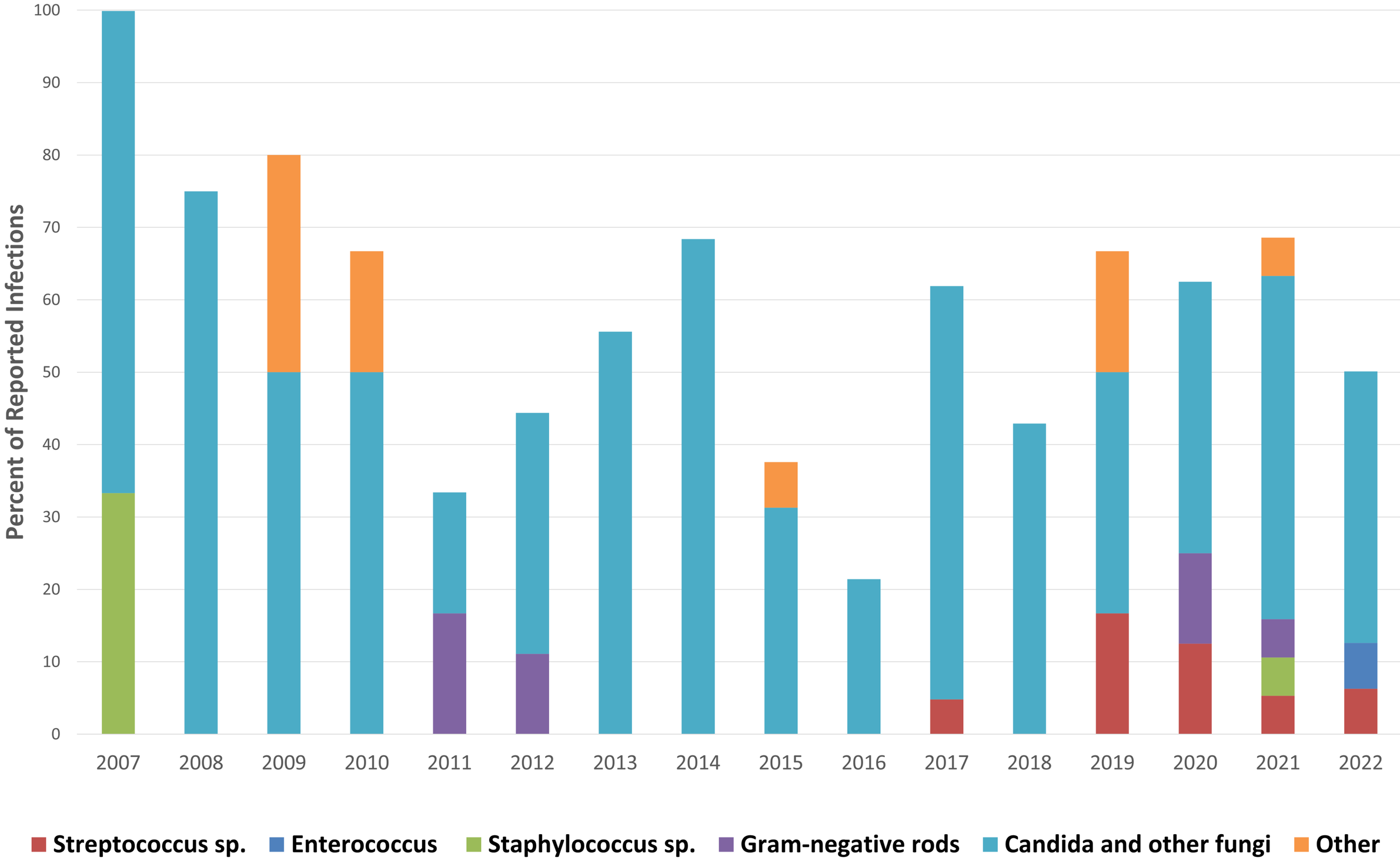
Year	Total Keratitis Cases	Fungal Keratitis Cases	PK Fungal Cases	DSEK Fungal Cases	DMEK Fungal Cases	ALK Fungal Cases	Total Domestic PK Procedures	Total Domestic DSEK Procedures	Total Domestic DMEK Procedures	Total Domestic ALK Procedures	PK Fungal Infection Rate per 10,000 Cases	DSEK Fungal Infection Rate per 10,000 Cases	DMEK Fungal Infection Rate per 10,000 Cases	ALK Fungal Infection Rate per
2011	6	1	1	0	0	0	21,620	21,555	344	932	0.46	0.00	0.00	0.00
2012	9	3	2	1	0	0	21,422	22,301	748	883	0.93	0.45	0.00	0.00
2013	9	5	0	5	0	0	20,954	23,465	1,522	951	0.00	2.13	0.00	0.00
2014	19	13	2	11	0	0	19,294	23,100	2,865	914	1.04	4.76	0.00	0.00
2015	16	5	1	4	0	0	19,160	22,514	4,694	1,115	0.52	1.78	0.00	0.00
2016	14	3	0	1	2	0	18,579	21,868	6,459	1,232	0.00	0.46	3.10	0.00
2017	21	12	1	8	2	1	18,346	21,337	7,628	1,027	0.55	3.75	2.62	9.74
2018	14	6	0	5	1	0	17,347	19,526	10,773	884	0.00	2.56	0.93	0.00
2019	6	2	1	0	1	0	17,409	17,428	13,215	745	0.57	0.00	0.76	0.00
2020	8	3	0	3	0	0	15,402	14,391	11,749	505	0.00	2.08	0.00	0.00
2021	19	9	3	2	3	1	16,269	15,935	14,128	544	1.84	1.26	2.12	18.38
2022	16	6	0	2	3	1	15,835	15,544	15,248	476	0.00	1.29	1.97	21.01



Endophthalmitis Pathogens
2007 -2022



Infectious Keratitis Pathogens
2007 - 2022



YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Primary Graft Failure	61	78	51	31	53	53	50	54	52	31	36	31	30	50	48	45	56	89	100	70	87	75
Early Regraft												14	30	34	36	35	43	52	82	78	65	89
Endophthalmitis	18	22	16	6	11	2	5	6	7	10	10	19	26	16	20	21	21	13	10	13	9	11
Infectious Keratitis	6	8	10	10	10	6	3	4	10	6	6	9	9	19	16	14	21	14	6	8	19	16
Total Infections*	24	30	26	16	21	8	8	10	17	16	16	29	36	35	36	35	42	27	16	21	28	27
No. Corneal Grafts performed in U.S.	33035	32559	32240	32106	31952	33962	39391	41652	42606	42642	46196	46,684	48,229	47,530	48,792	49,869	50,934	51,294	51,336	43,873	49,110	49,597
Percent Infections	0.07	0.09	0.08	0.05	0.07	0.02	0.02	0.02	0.04	0.04	0.03	0.06	0.07	0.07	0.07	0.07	0.08	0.05	0.03	0.05	0.06	0.05
Infections per 10,000 grafts	7.27	9.21	8.06	4.98	6.57	2.36	2.03	2.40	3.99	3.75	3.46	6.21	7.46	7.36	7.38	7.02	8.25	5.26	3.12	4.79	5.70	5.44
PGF per 10,000 grafts	18.47	23.96	15.82	9.66	16.59	15.61	12.69	12.96	12.20	7.27	7.79	6.64	6.22	10.52	9.84	9.02	10.99	17.35	19.48	15.96	17.72	15.12
Early Regraft per 10,000 grafts												3.00	6.22	7.15	7.38	7.02	8.44	10.14	15.97	17.78	13.24	17.94

Endophthalmitis Pathogens	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Enterococcus sp.							0.0	0.0	14.3	20.0	10.0	31.6	11.5	6.3	20.0	0.0	9.5	7.7	20.0	7.7	0.0	9.1
Streptococcus sp.							20.0	0.0	14.3	0.0	10.0	10.5	0.0	6.3	5.0	0.0	0.0	15.4	0.0	0.0	0.0	0.0
Staphylococcus sp.							0.0	0.0	14.3	0.0	0.0	5.3	7.7	0.0	0.0	4.8	9.5	0.0	0.0	0.0	11.1	9.1
Gram-negative rods							0.0	0.0	0.0	0.0	10.0	0.0	0.0	6.3	10.0	0.0	4.8	7.7	0.0	7.7	0.0	0.0
Candida and other fungi							40.0	100.0	57.1	40.0	40.0	21.1	61.5	56.3	25.0	71.4	52.4	30.8	70.0	53.8	55.6	36.4
Other							0.0	0.0	0.0	10.0	0.0	0.0	7.7	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	9.1
No growth							0.0	0.0	0.0	20.0	10.0	15.8	7.7	12.5	25.0	9.5	4.8	0.0	0.0	15.4	11.1	27.3
Not done							40.0	0.0	0.0	10.0	20.0	21.1	3.9	12.5	20.0	14.3	23.8	38.5	10.0	15.4	22.2	18.2

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Fungal	40.0	100.0	57.1	40.0	40.0	21.1	61.5	56.3	25.0	71.4	52.4	30.8	70.0	53.8	55.6	36.4
Bacterial	20.0	0.0	42.9	30.0	30.0	47.4	26.9	18.8	35.0	4.8	23.8	30.8	30.0	15.4	11.1	27.3

* Note - Includes 1 Iritis case in 2012; 1 scleral graft infection in 2013; and 1 anterior chamber reaction in 2016

Infectious Keratitis	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Streptococcus sp.							0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.8	0.0	16.7	12.5	5.3	6.3
Enterococcus							0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.3
Staphylococcus sp.							33.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.3	0.0
Gram-negative rods							0.0	0.0	10. 0	0.0	16.7	11.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.5	5.3	0.0
Candida and other fungi							66.6	75.0	50.0	50.0	16.7	33.3	55.6	68.4	31.3	21.4	57.1	42.9	33.3	37.5	47.4	37.5
Other							0.0	0.0	30.0	16.7	0.0	0.0	0.0	0.0	6.3	0.0	0.0	0.0	16.7	0.0	5.3	0.0
No growth							0.0	25.0	0.0	16.7	33.3	11.1	11.1	10.5	25.0	7.1	4.8	7.1	33.3	12.5	26.3	18.8
Not done							0.0	0.0	10.0	16.7	33.3	44.4	33.3	21.1	37.5	71.4	38.1	50.0	0.0	25.0	5.3	31.3

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Fungal	66.6	75.0	50.0	50.0	16.7	33.3	55.6	68.4	31.3	21.4	57.1	42.9	33.3	37.5	47.4	37.5
Bacterial	33.3	0.0	20.0	0.0	16.7	11.1	0.0	0.0	0.0	0.0	4.8	0.0	16.7	25.0	21.1	12.5

POLICY & POSITION REVIEW SUBCOMMITTEE

INFORMATIONAL ALERT:

UPDATED GUIDANCE AND COVID-19 SCREENING RECOMMENDATIONS

August 28, 2023

The Policy & Position Review Subcommittee (PPRS) of the EBAA Medical Advisory Board continues to review its guidance and screening recommendations regarding COVID-19. As COVID-19 is no longer a public health emergency, and there have been no reported cases of transmission of SARS-CoV-2, MERS-CoV, or any other coronavirus via transplantation of ocular tissue, the following set of updated, simplified guidelines have been developed. Notably, we have eliminated consideration of close contacts and vaccination status and have eliminated the specific scenarios requiring medical director review, with the understanding that there will remain scenarios in which medical director review may be advisable. Donors who are not excluded by the criteria listed below should be considered eligible if all other eligibility criteria are met.

Donors should be determined ineligible who in the 10 days prior to death:

- Were diagnosed with acute COVID-19; or
- Tested positive for COVID-19 by direct viral testing methods (e.g., NAAT and/or antigen); or
- Developed signs and symptoms of COVID-19, in the absence of a plausible alternative etiology.

NOTES

The value of donor screening for SARS-CoV-2 is subject to ongoing assessment. This guidance provides the means to minimize COVID-19 transmission risk and will allow for the continued provision of safe corneal tissue to patients while minimizing the wastage of suitable donor corneal tissue. Eye bankers and corneal surgeons should continue to keep in mind the following with regard to the safety of corneal tissue and ocular tissue recovery:

- Individuals who have received non-replicating, inactivated, or RNA-based COVID-19 vaccines are not precluded from donating cells, tissues, or cellular or tissue-based products.
- Current EBAA Medical Standards require use of a double povidone iodine donor prep.
- Povidone iodine has documented in vitro virucidal activity against coronaviruses.
- The EBAA acknowledges that other associations, hospital systems, eye banks, departments of health, or governments may have different COVID-19 testing requirements. Eye banks must establish a protocol to ensure access to testing notification and results obtained by partner agencies to prevent discordant resulting and/or discovery of results after release of tissue for transplant use. Results of such testing must be communicated to end-users on Tissue Report Forms or other supporting documents.

- Cadaveric PCR or antigen testing for SARS-CoV-2 may be an additional tool to assist in determining donor eligibility. However, currently available tests for detecting the SARS-CoV-2 virus have not been validated for postmortem use.
- Medical Director review for final determination of donor eligibility in certain cases allows for further assessment of the full clinical picture and/or case specific scenarios.

RESOURCES

Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the Coronavirus Disease 2019 Pandemic. *US Food & Drug Administration*, US Department of Health & Human Services, January 4, 2021.

Aldave AJ, DeMatteo J, Chamberlain WD, Philippy B, Farooq AV, Buckman N, Crosson A, Li J, Meinecke E, Kaufman AH. "COVID and the Cornea: From Controversies to Consensus: Report of the Eye Bank Association of America Medical Advisory Board Policy and Position Review Subcommittee." Cornea. 2021;40:809-816.

Centers for Disease Control and Prevention: COVID-19

INFORMATIONAL ALERT:

Mpox and Eye Tissue Donation

August 28, 2023

EBAA continues to closely monitor the outbreak of mpox (formerly known as monkeypox) in the United States. Although mpox is no longer considered a public health emergency (PHE), the possibility of a resurgence remains. The Policy & Position Review Subcommittee (PPRS) of the EBAA Medical Advisory Board has reviewed the potential impact of mpox on ocular tissue safety. Specifically, this update restates the previous screening recommendations, and removes the additional, specific mpox screening questions.

Key Points about Mpox

1. The risk to recipients of donated ocular tissues in the United States is considered low at present, given the low domestic prevalence of mpox.
2. Mpox virus causes a rash characterized by deep and well-circumscribed lesions, typically with central umbilication, with progression through sequential stages. The rash can resemble that caused by more commonly encountered conditions including syphilis, herpes simplex, and herpes zoster.
3. Close contact* or contact with contaminated fomites (such as shared linens) are risk factors for human-to-human transmission.
4. According to the World Health Organization, the incubation period of mpox virus ranges from 5 to 21 days.
5. There is no evidence at present that mpox can be transmitted by blood transfusion or tissue/cell transplantation and therefore the following screening recommendations are precautionary.

Mpox Screening Recommendations for EBAA Member Eye Banks

The EBAA recommends that eye banks exclude/defer (rule out) potential ocular tissue donors who in the 21 days before death met one or more of the following criteria:

- Were diagnosed with or were suspected of having a mpox infection.
- Had close contact* with a person or an animal diagnosed with or suspected of having mpox infection regardless of the donor's vaccination status.
- Developed a rash or other symptoms suggestive of mpox infection.

Disclaimer: the selection of risk mitigation criteria pertaining to mpox, which includes symptomatology, exposure, close contact, infection status and testing for mpox, is at the sole discretion of the medical director and eye bank responsible for donor eligibility determination as long as the intent of relevant standards (e.g. D.1.110, D1.120 and Appendix II) is met.

These recommendations will be in effect until further notice or additional criteria are added.

*Close contact/exposure in the context of human-to-human spread of mpox virus includes direct contact with skin lesions, prolonged face-to-face exposure to respiratory secretions, contact with contaminated fomites (i.e., objects/fabrics/surfaces), and/or intimate physical contact. The virus also may be transmitted in utero or as a result of direct contact during or after childbirth. More information about mpox can be found below:

How It Spreads | Mpox | Poxvirus | CDC

Important Information for Human Cell, Tissue, and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Monkeypox Virus and HCT/P Donation | FDA

INFORMATIONAL ALERT:

TB and Ocular Tissue Transplantation

September 5, 2023

Background

The CDC recently informed health care providers about two fatal cases of *Mycobacterium tuberculosis* (Mtb) disease (TB) linked to a single product lot of viable bone matrix material from Aziyo Biologics, Inc., distributed in 2023. This follows a 2021 TB outbreak linked to FiberCel Fiber Viable Bone Matrix, which resulted in spinal and disseminated TB in 87 of the 113 product recipients. Schwartz, et al published the details of the investigation and findings in *Lancet Infectious Diseases.*

Standard screening practices during tissue donation were unsuccessful at identifying donor infection and additional measures are needed to enhance recipient safety. These outbreaks have garnered national attention and the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) is working on a biovigilance gap analysis to prevent transmission of disease to tissue recipients.

AATB issued Bulletin 23-6: Requirements and Recommendations for Reducing Risk of *Mycobacterium tuberculosis* Transmission on August 7, 2023. AATB-accredited establishments and their Medical Directors must comply with these requirements by September 4, 2023.

The Policy & Position Review Subcommittee (PPRS) of the EBAA Medical Advisory Board has developed the following statement for EBAA-accredited eye banks regarding screening potential ocular donors for TB.

Key points regarding TB and ocular tissue transplantation:

1) Ocular TB can manifest in a variety of ways, including scleritis, keratitis, anterior uveitis, posterior uveitis (e.g., choroidal tubercles, serpiginous-like lesions, retinal vasculitis), and optic perineuritis.
2) Ocular TB occurs in approximately 1-2% of TB cases, although higher rates have been reported in some areas of the world. It is diagnosed based on the presence of characteristic ocular signs; ancillary evidence of systemic TB (e.g., immunologic or radiologic tests); and the exclusion of alternative etiologies. Microbiologic detection of Mtb is not required for the diagnosis of ocular TB.
3) Immunologic TB testing (e.g., TB skin testing, interferon gamma release assay blood testing) cannot be performed post-mortem.

4) Attempts at microbiological detection of Mtb in ocular tissue via PCR and/or culture have shown variable results, with an inability to detect Mtb being common. This may be due, in part, to cases in which there is ocular inflammation without the presence of viable Mtb in ocular tissue.
5) There have been no reports to date of Mtb transmission via ocular tissue transplantation.

The PPRS recommends the following donors be excluded from ocular tissue donation:

1) Individuals with a history (ever) of TB disease (sometimes referred to as "active" or "clinically active" TB)
2) Individuals with a history of latent TB infection initially diagnosed within the prior two (2) years (i.e., the individual has had a positive test for TB)

Notes:

1) Although the AATB guidance excludes donors over the age of 65, we are not recommending the exclusion of these donors for ocular tissue at the present time. We feel that by excluding individuals with either a history (ever) of active TB or latent TB within the 2 years prior to death, along with the difficulties with detecting Mtb in ocular tissue, and the lack of reports of Mtb transmission via ocular tissue transplantation, the risk to recipients of including donors over the age of 65 is minimal. Furthermore, given the large percentage of ocular tissue donors in this age group, such a restriction would place an undue strain on the donor supply.
2) This guidance applies to EBAA-accredited eye banks. Non-accredited international EBAA member eye banks may follow these recommendations; however, given local differences in the incidence/prevalence of TB, they may choose to develop their own protocols for ensuring ocular tissue safety.

References:

Bates B, Crowell EL. Ophthalmic manifestations of tuberculosis. Curr Opin Ophthalmol 2023 (online ahead of print).

Donahue HC. Ophthalmologic experience in a tuberculosis sanatorium. Am J Ophthalmol 1967;64(4):742-8

Basu S. Absence of evidence as the evidence of absence: the curious case of latent infection causing ocular tuberculosis. Front Ophthalmol 2022;2:874400

Biswas J, Badrinath SS. Ocular morbidity in patients with active systemic tuberculosis. Int Ophthalmol 1995;19(5):293-8.

Gonzalez-Garcia A, Fortun J, Navas EE, et al. The changing epidemiology of tuberculosis in a Spanish tertiary hospital (1995-2013). Medicine (Baltimore) 2017;96(26):e7219.

Alvarez GG, Roth VR, Hodge W. Ocular tuberculosis: diagnostic and treatment challenges. Int J Infect Dis. 2009;13(4):432-435.

Gupta V, Gupta A, Rao NA. Intraocular tuberculosis—an update. Surv Ophthalmol 2007;52(6):561-87.

Additional Resources:

https://www.cdc.gov/hai/outbreaks/TB-bone-allograft.html

https://www.cdc.gov/mmwr/volumes/70/wr/mm7036a4.htm?s_cid=mm7036a4

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9605268/

https://www.aatb.org/bulletin-23-6

ACCREDITATION BOARD

CERTIFICATION BOARD

Subject: FW: [External] Cert Board Report to MAB
Date: Friday, September 29, 2023 at 12:09:28 PM Eastern Daylight Time
From: Stockman, Adam M
To: chamberw@ohsu.edu, Eric Meinecke
CC: Jennifer DeMatteo
Attachments: image001.png

Please see Certification Board update below:

Certification Board Update

The Fall 2023 Certified Eye Bank Technician Exam takes place October 7-21, 2023, in the US, Canada, and Hong Kong. A total of 30 individuals are taking the exam and we expect to receive the results in early November. The Spring CEBT Exam takes place April 6 - 20, 2024, and the application will be available on the EBAA website in December. The Exam Committee recently held the webinar, The CEBT Exam: What You Need to Know!, which provides information about the exam and how to prepare. The recording is available on eyeLEARN.

The Certification Board has voted to change the Eligibility Criteria for taking the CEBT Exam. Previously, there were two different experience requirements based on the education level of a candidate. The updated criteria includes one requirement for everyone.

The current eligibility criteria required the following:

1. *Possess at least a minimum of one of the following:*
    - Baccalaureate Degree AND a minimum of six (6) months of experience within the past two (2) years in a transplant organization with active involvement in the procurement and processing of eyes, tissues and/or organs, and be recommended by the Executive Director and a physician who meets the requirement of an "Eye Bank Medical Director," as defined in C1.200 of the Medical Standards.

      Or
    - High school degree or GED, AND a minimum of twelve (12) months of experience within the past two (2) years in a transplant organization with active involvement in the procurement and processing of eyes, tissues and/ or organs, and be recommended by the Executive Director, and a physician who meets the requirement of an "Eye Bank Medical Director," as defined in C1.200 of the Medical Standards.
2. Submit a completed "Practical Performance Competency Verification" form, signed by the eye bank's Medical Director, Technical Trainer, and Executive Director. Applicants must demonstrate proficiency in the recovery of corneoscleral discs by performing an in situ or laboratory excision witnessed by a Technician Trainer and Medical Director.

The Certification Board has voted to change the eligibility criteria to the following:

> *1) Possess a high school degree or GED, AND a minimum of six (6) months of experience within the past two (2) years in a transplant organization with active involvement in the procurement and processing eyes, tissues and/ or organs, and be recommended by the Executive Director, and a physician who meets the requirement of an "Eye Bank Medical Director," as defined in C1.200 of the Medical Standards.*

2) Submit a completed "Practical Performance Competency Verification" form, signed by the eye bank's Medical Director, Technical Trainer, and Executive Director. Applicants must demonstrate proficiency in the recovery of corneoscleral discs by performing an in situ or laboratory excision witnessed by a Technician Trainer and Medical Director.

The new criteria will take effect for the Spring 2024 Certified Eye Bank Technician Exam.

-Adam Stockman, MBA, CEBT
Director of Operations
Iowa Lions Eye Bank

TECHNICIAN EDUCATION COMMITTEE

TECHNICAL PROCEDURES MANUAL SUBCOMMITTEE

Subject: MAB Agenda Item November 2023 EBAA Fall Leadership Meeting
Date: Thursday, September 28, 2023 at 9:40:38 AM Eastern Daylight Time
From: Vicki Adler
To: 'chamberw@ohsu.edu', smian@med.umich.edu, Jennifer DeMatteo, Eric Meinecke
CC: Patrick Becker
Attachments: image003.jpg, image004.png

Hello Everyone -

The Procedure Manual Committee met on Friday, September 8th and respectfully submit the following change to the Procedures Manual and Medical Standards

Procedures Manual = E1.400 Long Term Preservation

Add item 5 Ethanol

Procedure : Donor corneas may be stored in ethanol for a period of time validated by the eye bank, and not to exceed the expiration date of the medium or container.

Rationale: If an eye bank elects to use ethanol methods, a detailed policy and procedure shall be included in the eye bank's written policies and procedures manual.

Medical Standard Change -

E1.400 Long Term Preservation

Some eye banks employ preservation techniques such as long-term preservation of corneal tissue.. An eye bank that uses long term preservation shall carefully document the procedure(s) in their procedures manual, and adhere to rigid aseptic technique

Change Table of Contents Medical Standards

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Thank you,

Vicki Adler (Chair, Procedures Manual Committee)
Patrick Becker (Co-Chair, Procedures Manual Committee)

Victoria Adler, RN, BSN; CEBT

Executive Director/Tissue Bank Director
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OLD BUSINESS

Subject: Data Integrity Subcommittee Report for MAB
Date: Tuesday, October 3, 2023 at 12:23:50 PM Eastern Daylight Time
From: Brian Philippy
To: Eric Meinecke, Winston Chamberlain, Jennifer DeMatteo

Dear MAB Co-Chairs,

Using the 6-month data from 2023, the Data Integrity Subcommittee was able to produce a current report on the status of EBAA membership's attention to data integrity. The report given is similar to the report card provided to eye banks last year.

Rates of Unknown Domestic Indications	Number of Eye Banks
0 - 10%	42
11 - 20%	6
21 - 30%	3
31 - 40%	3
41 - 50%	0
51% +	1
Null	1
Total Count (incl. null)	56
Total ≤ 15%	47
Overall Average 8.4%	

We still have work to do. One mid-sized eye bank has unknown surgical indication data for 66.2% of domestic PK/EK/ALK cases. The next worst offenders have 40.1%, 37.1%, 27.9%, 22.3%, and 21.6%. Most eye banks have shown great improvement, however! If all eye banks were to put forth the effort to stay under the 15% goal, as the lowest standard, combined with the stellar efforts of the bulk of membership, our overall average would likely be below 5% unknown.

Item 1 for Consideration:
The Medical Advisory Board should decide if M1.600 requires language stipulating a minimum goal to meet Standards. Up to this point, we've operated with multiple academic appeals to membership, but remain short of the goal.

Item 2 for Consideration:
The Data Integrity Subcommittee has significant conceptual overlap with the Statistical Report Committee. Consider folding the Data Integrity Subcommittee into the Statistical Report Committee.

Sincerely,

Brian Philippy
Lions Gift of Sight

Subject: Re: Re: Old Business - Indications for Keratoplasty
Date: Monday, October 9, 2023 at 8:01:01 PM Eastern Daylight Time
From: Brian Philippy
To: Eric Meinecke, Winston Chamberlain, Jennifer DeMatteo
Attachments: image001.png, image001.png, EBAA Indications List Change 11-2022.docx, Indications for Keratoplasty (Final).docx, Indications for Keratoplasty - Detailed Changes (Final).xlsx

A change made to the "Indications for Keratoplasty" previously approved by the Medical Advisory Board is due to be implemented by January 1, 2024. Since the changes to the Indications for Keratoplasty impact eye banks' data systems, it is relevant to remind the membership of the upcoming change and again provide resources to ensure the membership is prepared to implement changes on their end.

Following are three documents for the record and for membership reference.

- Indications for Keratoplasty (Word file; Official Document) - This is the new document for EBAA and membership use. This document is commonly provided by EBAA members to surgeons with tissue accompanying Recipient Information Forms.
- EBAA Indications List Change (PDF file; supplemental document useful in transition) - This document provides a summary of changes to category titles - a quick reference to category changes.
- Indications for Keratoplasty - Detailed Changes (Excel file; supplemental document useful for reference in perpetuity) - This extensive document provides details on what was revised, including which diagnosis belongs to which category. Additionally, this document provides comparison of ICD-10 codes against EBAA codes, which may be an additional tool to save eye banks time in collecting data, as some indications are reported as ICD-10 codes errantly.

Thank you for allotting time for this important reminder.

Sincerely,
Brian Philippy
Chair of Statistical Reporting Committee

EYE BANK ASSOCIATION OF AMERICA

Indications for Keratoplasty

A. Endothelial Dysfunction or Corneal Edema due to Prior Surgery (excluding prior transplants; see *D.*)

- ☐ After cataract removal (with or without IOL insertion)
- ☐ After IOL reposition/exchange/secondary IOL
- ☐ After penetrating glaucoma surgery with a bleb (trabeculectomy/tube shunt/full-thickness stent)
- ☐ After non-penetrating glaucoma surgery (MIGS/goniotomy/canaloplasty/ab interno angle surgery)
- ☐ After iris or cyclodialysis repair
- ☐ After vitrectromy
- ☐ Due to epithelial downgrowth or stromal ingrowth
- ☐ After strabismus surgery
- ☐ After ophthalmic surgery not listed above (or in *D.*)

B. Ectasias/Thinnings (primary)

- ☐ Keratoconus or keratoglobus
- ☐ Pellucid or Terrien marginal degeneration

C. Heritable Endothelial Dystrophies

- ☐ Fuchs' dystrophy
- ☐ Posterior polymorphous dystrophy
- ☐ Congenital hereditary endothelial dystrophy

D. Repeat Corneal Transplant

- ☐ Regraft following PK, EK, or ALK
- ☐ Regraft following K-Pro, KLA, other keratoplasty or limbal stem cell procedure

E. Anterior and Stromal Non-Ectatic Degenerations or Dystrophies

- ☐ Stromal and anterior corneal dystrophies (e.g. granular, lattice, macular, Reis-Bucklers)
- ☐ Non-ectatic corneal degenerations (e.g. calcific band keratopathy, amyloid degeneration)

F. Complications of Prior Refractive Surgery

- ☐ Post-refractive surgery without ectasia (automated lamellar keratoplasty, RK, HK, PRK, LASIK, LASEK, etc.)
- ☐ Post-refractive surgery with ectasia (automated lamellar keratoplasty, RK, HK, PRK, LASIK, LASEK, etc.)

Common Acronyms:

IOL –	Intraocular Lens
PK –	Penetrating Keratoplasty
ALK –	Anterior Lamellar Keratoplasty
EK –	Endothelial Keratoplasty (including Descemet's stripping automated endothelial keratoplasty, DSAEK, and Descemet's membrane endothelial keratoplasty, DMEK)
HK, RK –	Hexagonal or radial keratectomy
PRK –	Photorefractive keratectomy
LASIK –	Laser-Assisted In-Situ Keratomileusis

G. Microbial Keratitis

- ☐ Bacterial, viral, or fungal
- ☐ Spirochete (syphilitic interstitial keratitis)
- ☐ Chlamydial (trachoma)
- ☐ Parasitic (acanthamoeba, onchocerciasis, trypanosomiasis, "river blindness", etc.)
- ☐ Iridocorneal endothelial syndromes (e.g. Chandler, iris-nevus, essential iris atrophy)
- ☐ Include cases with and without perforation, if microbial

H. Mechanical (non-surgical) or Chemical Trauma

- ☐ Traumatic scarring, perforation, or corneal edema
- ☐ Thermal injury
- ☐ Chemical injuries (alkali, acid, petroleum, etc.)
- ☐ Limbal stem cell deficiency due to chronic medication (drug), toxin exposure, contact lens wear, or other medical device interaction
- ☐ Corneal edema or other damage due to medication

I. Congenital Opacities

- ☐ Peters' anomaly, sclerocornea, aniridia
- ☐ Glaucoma (congenital), buphthalmos

J. Post-Surgical Non-Edematous Corneal Opacification or Distortion (not due to prior refractive surgery or keratoplasty)

- ☐ Post-Pterygium Surgery
- ☐ Post-Keratectomy (other than pterygium)
- ☐ Post-surgical limbal stem cell deficiency
- ☐ Non-edematous corneal opacification or distortion after ophthalmic surgery not listed above

K. Noninfectious Ulcerative Keratitis, Thinning, or Perforation

- ☐ Dry eye, keratoconjunctivitis sicca, Sjogren syndrome, pemphigoid
- ☐ Immune/collagen-vascular disease, systemic vasculitides (e.g. rheumatoid, Mooren ulcer, polyarteritis nodosa)
- ☐ Neurotrophic or exposure keratopathy
- ☐ Stevens-Johnson Syndrome, toxic epidermal necrolysis
- ☐ If microbial, use Category G.

L. Secondary Endothelial Dysfunction (other than dystrophy or surgical/nonsurgical trauma)

- ☐ Due to uveitis (not microbial)
- ☐ Due to glaucoma (not congenital)
- ☐ Due to contact lens wear

Z. Unknown, Unreported, or Unspecified

Old "Indications for Keratoplasty" List (Jan. 1, 2011 through Dec. 31, 2023)	New "Indications for Keratoplasty" List (starting Jan. 1, 2024)
A. Post Cataract Surgery Edema	A. Endothelial Dysfunction, Corneal Edema Due to Prior Ophthalmic Surgery
B. Ectasias, Thinnings	B. Ectasias, Thinnings (primary)
C. Endothelial Dystrophies	C. Heritable Endothelial Dystrophies
D. Repeat Corneal Transplant	D. Repeat Corneal Transplant
E. Other Degenerations or Dystrophies	E. Anterior and Stromal Non-Ectatic Degenerations and Dystrophies
F. Refractive	F. Complications of Prior Refractive Surgery
G. Microbial Keratitis	G. Microbial Keratitis
H. Mechanical (non-surgical) or Chemical Trauma	H. Mechanical (non-surgical) or Chemical Trauma
I. Congenital Opacities	I. Congenital Opacities
J. Pterygium	J. Post-Surgical Non-Edematous Corneal Opacification or Distortion (other than due to prior refractive surgery or keratoplasty)
K. Noninfectious Ulcerative Keratitis, Thinning, or Perforation	K. Noninfectious Ulcerative Keratitis, Thinning, or Perforation
L. Other Causes of Corneal Opacification or Distortion	L. Secondary Endothelial Dysfunction (other than dystrophy or surgical/nonsurgical trauma)
M. Other Causes of Endothelial Dysfunction	
Z. Unknown, Unreported, or Unspecified	Z. Unknown, Unreported, or Unspecified

Subject: Medical Standard E1.200 Subcommittee Report
Date: Friday, October 6, 2023 at 10:26:46 AM Eastern Daylight Time
From: Stockman, Adam M
To: Eric Meinecke

Mr. Meinecke –

A Medical Advisory Board subcommittee was developed at the 2023 EBAA Annual Meeting to review Medical Standard E1.200 Processing and Preservation and recommend new verbiage, if appropriate. The subcommittee was comprised of myself, Dr. Winston Chamberlain, Dr. Soledad Cortina, Dr. Drew Salisbury, Eric Meinecke, Kristin Mathes, John Lohmeier, Jason Brosious, and Edwin Roberts, with EBAA representation from Jennifer DeMatteo. The subcommittee concluded that revised verbiage was appropriate to bring the Medical Standards in line with current standards of practice.

The current Medical Standard reads:

E1.200 Processing and Preservation

Processing must be performed in a) a laminar air flow hood or cabinet which meets ISO Class 5 standards, b) in an accredited operating room, or c) in another environment documented annually to have less than 25 colony forming units per 90 mm settle plate per one hour exposure.

Tissue must be processed in such a way as to prevent cross-contamination and labeling mix-ups (e.g., tissue from different donors may not be processed simultaneously).

Our proposal is to entirely replace the above verbiage with the following:

E1.200 Processing and Preservation

Aseptic processing shall be performed in a certified and qualified bacteriologically and climate-controlled environment, such as an ISO 5/Class 100 laminar airflow hood or clean room. The processing shall be performed by qualified, trained, and competent staff using validated methods to prevent contamination and cross-contamination and to maintain tissue quality for its intended use.

Eye banks shall establish and maintain policies, processes, and procedures designed to minimize contamination of the tissue. The following shall be addressed:

1. Environmental controls and monitoring
2. Process controls
3. Staff training in aseptic technique
4. Attire, gowning, and use of personal protective equipment
5. Workflow movement and movement of personnel through workspaces
6. Prevention of cross-contamination and labeling mix-ups (e.g., tissue from different donors may not be processed simultaneously)

I look forward to presenting the subcommittee's recommended changes during the Fall 2023 Medical Advisory Board meeting.

Adam Stockman, MBA, CEBT

NEW BUSINESS

Subject: F1.300
Date: Wednesday, October 4, 2023 at 8:39:56 PM Eastern Daylight Time
From: Jennifer DeMatteo
To: chamberw@ohsu.edu, Shahzad Mian, Eric Meinecke
Attachments: image001.png

Dear Medical Advisory Board,

The Exam Committee met on September 21, 2023, and found a discrepancy in the Medical Standards.

Matrix I: Tissue Evaluation Requirements lists DMEK/PDEK but F1.300 Determination of Surgical Suitability does not mention PDEK.

We respectfully propose the following revision to F1.300 and the Glossary:

F1.300 Determination of Surgical Suitability

The eye bank responsible for evaluation of ocular tissue shall specify whether the tissue meets the criteria for penetrating keratoplasty (PK), anterior lamellar keratoplasty (ALK/DALK), Descemet's stripping endothelial keratoplasty (DSEK/DSAEK), Descemet's membrane endothelial keratoplasty (DMEK), Pre-Descemet's endothelial keratoplasty (PDEK), keratolimbal allograft, and "other" surgical use (e.g., keratoprosthesis, long-term preservation for later shunt patch/ALK/tectonic use, experimental surgical use, etc.).

Corneoscleral Disc Minimum Suitability Standards

Minimum suitability for penetrating keratoplasty (PK):
- No infiltrates
- No pterygia, neovascularization, foreign bodies, or visually significant stromal scars within intended graft area
- No Descemet's membrane detachment or tears within intended graft area
- No evidence of endothelial dystrophy
- Minimum endothelial cell density (as defined in eye bank's policy)
- No Down syndrome or evidence of ectatic dystrophy (e.g., keratoconus, keratoglobus, etc.,
- No prior laser or incisional refractive surgery (e.g., radial keratotomy, lamellar inserts, photoablation, etc.)

Minimum suitability for anterior lamellar keratoplasty (ALK/DALK):
- No infiltrates
- No pterygia, neovascularization, foreign bodies, or visually significant stromal scars within intended graft area

- No Down syndrome or evidence of ectatic dystrophy (e.g., keratoconus, keratoglobus, etc.)
- No prior laser or incisional refractive surgery (e.g., radial keratotomy, lamellar inserts, photoablation, etc.)

Minimum suitability for Descemet's stripping endothelial keratoplasty (DSEK/DSAEK):
- No infiltrates
- No foreign bodies or visually significant scars affecting posterior stroma within intended graft area
- No Descemet's membrane detachment or tears within intended graft area
- Minimum endothelial cell density as defined in eye bank's policy
- Sufficient rim size and corneoscleral disc size to facilitate mounting on artificial anterior chamber

Minimum suitability for Descemet's membrane endothelial keratoplasty, Pre-Descemet's endothelial keratoplasty and Descemet's membrane automated endothelial keratoplasty. (DMEK/PDEK/DMAEK)
- No infiltrates
- No foreign bodies
- No Descemet's membrane tears within intended graft area
- Minimum endothelial cell density as defined in eye bank's policy)

Minimum suitability for keratolimbal allograft (KLA):
- No infiltrates
- Sufficient scleral rim (minimum must be defined in eye bank's policy)
- Conjunctiva must be intact over sufficient portion of rim to facilitate allograft (rim portions may be considered from mated pairs)
- No history of melanoma or metastatic cancer of a solid organ

Minimum suitability for Keratoprosthesis (K-Pro):
- No infiltrates
- No pterygia, neovascularization, foreign bodies, or significant corneal thinning
- No prior refractive surgery (e.g., radial keratotomy, lamellar inserts, photoablation, etc.)
- No Down syndrome or evidence of ectatic dystrophy (e.g., keratoconus, keratoglobus, etc.)

Minimum suitability for Long-Term Cornea Preservation/Other:
- No infiltrates
- No pterygia on graft segments

Sclera Minimum Suitability Standards

Minimum suitability for sclera for any surgical use:
- No infiltrates on cornea from the eye that produced scleral grafts

- No history of melanoma or metastatic cancer of a solid organ

Glossary

Anterior Lamellar Keratoplasty (ALK). Transplantation of the anterior stroma of the cornea.

Endothelial Keratoplasty. Transplantation of the corneal endothelium ~~attached to a carrier.~~ in various forms:

Pre-Descemet's layer Endothelial Keratoplasty (PDEK): Transplantation of corneal endothelium, Descemet membrane, and pre-Descemet membrane.

Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK), Transplantation of corneal endothelium, Descemet membrane, and posterior stromal layers of varying thickness.

Descemet's Membrane Endothelial Keratoplasty (DMEK). Transplantation of endothelium and Descemet membrane only.

Descemet's Membrane Automated Endothelial Keratoplasty (DMAEK). Transplantation of a peripheral ring of stroma along with a central area of Descemet's membrane and endothelium.

Penetrating Keratoplasty (PK). Full thickness cornea transplantation.

EYE BANK ASSOCIATION OF AMERICA

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EBAA Statistical Report Ledger for Calendar Year 2023

		Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
I.	**Death Referrals**			
	A. Total death referrals received by eye bank or entity on behalf of eye bank	412,561	456,753	455,542
	B. Death referrals determined eligible to donate for transplant intent	96,800	95,932	91,738
II.	**Tissue Recoveries**			
	A. Total donors	34,078	30,200	32,183
	1. Donors recovered not found on a donor registry, nor known to have first-person consent documentation	12,489	11,384	12,396
	2. Donors recovered found on a donor registry or known to have first-person consent documentation	21,589	18,816	19,787
	B. Eyes and/or corneas recovered with intent for surgical use	62,275	55,124	59,066
	C. Eyes and/or corneas recovered for other uses	5,268	4,847	4,613
	CALCULATION A: Total eyes and/or corneas recovered	67,543	59,971	63,679
	Validation A: This cell should be less than or equal to 2.	1.98	1.99	1.98
	D. Recovery by			
	1. Eyes and/or corneas recovered by this reporting eye bank	61,419	54,540	58,574
	2. Eyes and/or corneas recovered by an EBAA-accredited partner agency	2,265	2,084	2,049
	3. Eyes and/or corneas recovered by a partner agency, not accredited by EBAA	3,859	3,347	3,056
	Validation A2: This value should be equal to zero.	0	0	0
III.	**Donor Profiles**			
	A. Age Profile			
	1. Donors aged under one year	3	1	1
	2. Donors aged 1 to 10	105	110	132
	3. Donors aged 11 to 20	601	532	732
	4. Donors aged 21 to 30	1,263	1,169	1,366
	5. Donors aged 31 to 40	2,104	1,963	2,134
	6. Donors aged 41 to 50	3,569	3,270	3,619
	7. Donors aged 51 to 60	7,289	6,811	7,216
	8. Donors aged 61 to 70	12,167	10,752	11,186
	9. Donors aged 71 to 80	6,312	4,987	5,207
	10. Donors aged over 80	665	605	590
	CALCULATION B: Total donors by age	34,078	30,200	32,183
	Validation B: This value should equal zero.	0	0	0
	B. Sex Profile			
	1. Male	20,689	18,600	19,783
	2. Female	13,389	11,600	12,400
	CALCULATION C: Total donors by sex	34,078	30,200	32,183
	Validation C: This number should be zero.	0	0	0
	C. Cause of Death Profile			
	1. Heart Disease	11,258	9,967	10,817
	2. Cancer	5,621	4,648	4,846
	3. Cerebral Vascular Accident	3,196	2,794	3,000
	4. Respiratory Disease	3,498	3,226	2,706
	5. Trauma	3,051	2,749	3,247
	6. Other	7,454	6,816	7,567
	CALCULATION D: Total donors by primary cause of death	34,078	30,200	32,183
	Validation D: This value should be zero.	0	0	0
IV.	**Eligibility and suitability for tissues recovered with intent for surgical use**			
	A. Reasons tissues were not released (more than one reason per tissue may apply):			
	1. Donor eligibility:			
	a. Positive or reactive test for communicable disease agent or disease (Tests run by donation agency)	5,704	5,083	5,757
	i. HIV Antibody (HIV I/II Ab)	258	224	140
	ii. HIV Nucleic Acid Test (HIV NAT)	86	41	38
	iii. Hepatitis B Surface Antigen (HBsAg)	1,498	1,085	1,249
	iv. Hepatitis B Core Antibody (HBcAb)	2,010	1,889	2,006
	v. Hepatitis B Nucleic Acid Test (HBV NAT)	281	323	267
	vi. Hepatitis C Antibody (HCV Ab)	915	759	799
	vii. Hepatitis C Nucleic Acid Test (HCV NAT)	358	297	337
	viii. Syphilis (RPR, VDRL, FTA, etc.)	121	151	137
	ix. HTLV Antibody (HTLV I/II Ab)	36	68	34
	x. West Nile Virus Nucleic Acid Test (WNV NAT)	0	2	4
	xi. Other positive or reactive test for communicable disease	141	244	746
	b. Other communicable disease testing issue	330	277	294
	c. Medical record or autopsy findings	3,583	3,167	3,598
	i. Dementia/Neurological Issues	386	265	365
	ii. Sepsis (determined by positive blood cultures)	792	689	680
	iii. Sepsis (determined by other indicators)	934	779	841
	iv. Plasma dilution	105	99	103
	v. Unknown cause of death	29	41	68

EBAA Statistical Report Ledger for Calendar Year 2023	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
vi. Other	1,337	1,294	1,541
d. Medical/social history interview:	1,122	879	1,054
i. Travel	185	138	193
ii. Dementia/Neurological Issues	84	68	68
iii. Other	853	673	793
e. Body Exam	105	106	111
2. Tissue suitability	6,157	5,475	6,836
a. Epithelium	48	70	65
b. Stroma	4,053	3,373	3,620
i. Prior refractive surgery	139	131	293
ii. Scar	605	434	480
iii. Infiltrate	1,943	1,669	1,714
iv. Foreign body	66	46	59
v. Other	1,300	1,093	1,074
c. Descemet's membrane	58	63	155
d. Endothelium	1,998	1,969	2,996
3. Quality issue	434	385	218
a. Storage	243	136	76
b. Labeling	16	8	8
c. Processing	121	165	72
d. Supply or reagent	25	36	29
e. Environmental control	29	40	33
4. Other reason prior to tissue release	713	620	663
B. Total eyes and/or corneas intended for transplant but not released for transplant	14,768	13,284	15,679
CALCULATION E: Total eyes and/or corneas released for transplant	47,507	41,840	43,387
Validation E1: This cell should read, "Valid." The value is valid when the number of reasons for not releasing tissue is greater than or equal to the number of corneas not released for transplant.	Too few reasons	Too few reasons	Too few reasons
C. Reasons released tissues were not transplanted (more than one reason per tissue may apply):			
1. Transportation issue	98	131	228
2. Surgeon issue	37	42	45
3. Recipient issue	17	19	22
4. Returned and unable to place again	281	213	317
5. Donor information not available at time of tissue release	7	8	45
6. Expired or unable to place tissue	2,065	1,532	1,810
7. Tissue damaged during processing (tissue was released for transplant prior to cut)	1,015	760	790
8. Other reason after release of tissue	2,221	1,456	532
D. Total eyes and/or corneas released for transplant but not used for transplant	4,133	3,087	3,293
Validation E2: This cell should read, "Valid." The value is valid when the number of reasons for released tissue is not transplanted is greater than or equal to the number of corneas released but not transplanted.			
V. Intermediate-Term Tissue Distribution of Source Eye Bank Corneas			
A. Intermediate-term preserved corneas processed into corneal segments (into separate containers for use in multiple recipients)	105	107	89
B. Number of corneal segments produced from whole, intermediate-term preserved corneas processed into segments (into separate containers for use in multiple recipients)	210	213	173
C. Intermediate-term preserved corneas, cornea segments or whole eyes, transplanted domestically for:	25,465	24,010	24,708
1. PK	7,378	7,891	8,258
2. EK	16,412	14,827	14,984
a. DSEK, DSAEK, DLEK	7,863	7,575	8,097
b. DMEK or DMAEK	8,334	7,233	6,863
c. PDEK	3	0	0
d. Other EK	212	19	24
3. ALK	266	232	314
a. DALK (Deep Anterior Lamellar Keratoplasty)	148	161	232
b. SALK (Superficial Anterior Lamellar Keratoplasty)	6	7	11
c. Other ALK (e.g. peripheral, eccentric, etc.)	112	64	71
4. KLA	48	39	66
5. Keratoprosthesis (K-Pro)	84	52	83
6. Glaucoma shunt patch or other non-keratoplasty use	534	424	431
7. Other Keratoplasty (e.g. experimental surgery type)	6	7	3
8. Unknown or Unspecified	737	538	569
D. Intermediate-term preserved corneas, cornea segments or whole eyes, transplanted internationally for:	13,235	10,985	11,444
1. PK	8,198	6,525	6,873
2. EK	3,111	2,551	2,624
a. DSEK, DSAEK, DLEK	1,798	1,695	1,710

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b. DMEK or DMAEK	1,307	833	895
c. PDEK	0	1	1
d. Other EK	6	22	18
3. ALK	412	401	379
a. DALK (Deep Anterior Lamellar Keratoplasty)	315	374	342
b. SALK (Superficial Anterior Lamellar Keratoplasty)	9	4	16
c. Other ALK (e.g. peripheral, eccentric, etc.)	88	23	21
4. KLA	15	7	7
5. Keratoprosthesis (K-Pro)	2	8	5
6. Glaucoma shunt patch or other non-keratoplasty use	26	22	13
7. Other Keratoplasty (e.g. experimental surgery type)	5	10	1
8. Unknown or Unspecified	1,466	1,461	1,542
CALCULATION K: Total intermediate-term preserved corneas, cornea segments, and whole eyes used for KERATOPLASTY	38,140	34,549	35,708
CALCULATION L: Total intermediate-term preserved eyes and/or corneas used for TRANSPLANT	38,595	34,889	36,068
VI. Long-Term Preserved Tissue Preservation and Distribution of Source Eye Bank Tissue			
A. Long-term preserved corneas or whole eyes PRESERVED for transplant	4,779	3,864	4,026
B. Long-term preserved corneas, cornea segments, or whole eyes DISTRIBUTED for:	2,684	2,133	7,049
1. Keratoplasty	110	84	55
2. Glaucoma shunt patching	2,570	2,047	4,749
3. Other surgical uses	4	2	2,245
C. Long-term preserved corneas, cornea segments, or whole eyes FORWARDED to another entity for final distribution	154	289	191
D. Sclera or sclera segments PRESERVED for transplantation	3,973	3,118	3,655
E. Sclera or sclera segments DISTRIBUTED for:	1,076	1,190	2,629
1. Prosthesis following enucleation	127	116	141
2. Glaucoma shunt patching	753	800	2,089
3. Other surgical uses	196	274	399
F. Sclera or sclera segments FORWARDED to another entity for final distribution	99	104	87
CALCULATION M: Total eyes and/or corneas transplanted and long-term preserved for transplant	43,374	38,753	40,094
Validation M: This cell should be zero.	0	0	0
VII. Tissue Provided for Non-Surgical Uses			
A. Tissues provided for research (all tissue types)	7,321	6,932	7,097
B. Tissues provided for physician or technician training (all tissue types)	3,984	3,077	3,601
VIII. Tissue Processing for Transplant by My Eye Bank			
A. Eye Processing (does not include in situ excision)	1,472	2,417	4,556
1. Processed for cornea preservation (corneas only)	202	1,335	461
2. Processed for sclera preservation (incl. cornea/sclera preservation, sclera preservation from poles removed after in situ excision, etc.)	1,251	1,018	1,181
3. Processed for other ocular materials (regardless of cornea or sclera preservation)	19	64	2,914
B. Cornea Processing		19,391	25,360
1. Processed by microkeratome	9,608	9,017	10,845
a. Preloaded into a device following processing by microkeratome	799	446	251
2. Processed by laser	20	20	72
3. Processed by manual dissection (e.g. DMEK, DMAEK, cornea dissection)	8,686	7,176	8,975
a. Preloaded into a device following processing by manual dissection	7,070	6,006	5,052
4. Processed by transfer into long-term preservation (incl. sectioned tissue only once)	3,937	2,927	5,390
5. Processing included Use of Antifungal in storage media	2,577		
6. Processed by other methods	290	251	78
IX. Countries of Destination			
Country: United States	25,465	24,010	24,708
Country: Afghanistan	10	2	
Country: Aland Islands			
Country: Albania	3	7	1
Country: Algeria	179	47	9
Country: Andorra			
Country: Angola			
Country: Antigua and Barbuda	2		
Country: Argentina	271	251	176
Country: Armenia	51	36	9
Country: Aruba			
Country: Australia	1		
Country: Austria			
Country: Azerbaijan	57	25	14
Country: Bahamas	1	1	
Country: Bahrain	9	28	8

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	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
Country: Bangladesh	228	124	103
Country: Barbados	12	14	4
Country: Belarus			
Country: Belgium			
Country: Belize			
Country: Benin			
Country: Bhutan			
Country: Bolivia	37	40	30
Country: Bosnia and Herzegovina			
Country: Botswana			
Country: Brazil	14	15	51
Country: Brunei			
Country: Bulgaria	14	8	2
Country: Burkina Faso			
Country: Burundi			
Country: Cabo Verde			
Country: Cambodia			
Country: Cameroon			
Country: Canada	323	230	199
Country: Cayman Islands		2	
Country: Central African Republic			
Country: Chad			
Country: Chile	284	297	248
Country: China	42	62	95
Country: Christmas Island		1	
Country: Colombia	3	2	
Country: Comoros			
Country: Congo			
Country: Costa Rica	72	33	38
Country: Cote d'Ivoire		15	2
Country: Croatia			
Country: Cuba			2
Country: Curacao			
Country: Cyprus	52	37	26
Country: Czechia			
Country: Denmark			
Country: Djibouti	737	622	682
Country: Dominica			
Country: Dominican Republic	202	226	226
Country: Ecuador	154	108	108
Country: Egypt	1,791	1,921	2,581
Country: El Salvador	48	56	74
Country: Equitorial Guinea			
Country: Eritrea			
Country: Estonia			
Country: Eswatini			
Country: Ethiopia	12		
Country: Fiji			
Country: Finland			
Country: France	1		
Country: French Guiana			
Country: Gabon			
Country: Gambia			
Country: Georgia	21	19	19
Country: Germany	433	416	537
Country: Ghana	25	32	21
Country: Greece	114	123	115
Country: Greenland			
Country: Guam			
Country: Guatemala	2	10	13
Country: Guinea	19		
Country: Guinea-Bissau			1
Country: Guyana		4	3
Country: Haiti			
Country: Honduras	107	60	47
Country: Hong Kong	29	16	14
Country: Hungary			

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	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
Country: Iceland	1	1	6
Country: India			
Country: Indonesia	52	31	27
Country: Iran			
Country: Iraq	281	341	189
Country: Ireland	58		
Country: Israel	204	186	166
Country: Italy		25	4
Country: Jamaica	17	8	5
Country: Japan	1,159	1,070	1,114
Country: Jordan	32	70	103
Country: Kazakhstan			
Country: Kenya	18	120	93
Country: Kiribati	140		
Country: Korea, North			
Country: Korea, South	466	397	429
Country: Kosovo			
Country: Kuwait	62	54	57
Country: Kyrgyzstan	3		6
Country: Laos			
Country: Latvia	4	1	3
Country: Lebanon	37	64	155
Country: Lesotho			
Country: Liberia			
Country: Libya	48	13	
Country: Lichtenstein			
Country: Lithuania			
Country: Luxembourg			
Country: Macedonia			12
Country: Madagascar			
Country: Malawi			
Country: Malaysia	98	62	50
Country: Maldives			
Country: Mali	3		
Country: Malta			
Country: Marshall Islands			
Country: Mauritania			
Country: Mauritius		8	
Country: Mexico	539	482	512
Country: Micronesia	1		
Country: Moldova			
Country: Monaco			
Country: Mongolia	8	6	
Country: Montenegro			
Country: Morocco	131	123	156
Country: Mozambique	6		5
Country: Myanmar			
Country: Namibia	13	13	11
Country: Nauru			
Country: Nepal			
Country: Netherlands			
Country: New Zealand	28	2	9
Country: Nicaragua	2		
Country: Niger			
Country: Nigeria	18	39	37
Country: Norway	22	93	31
Country: Oman	10	6	7
Country: Pakistan	1,069	448	468
Country: Palau			
Country: Palestine	17	5	17
Country: Panama	9	6	1
Country: Papau New Guinea			
Country: Paraguay	12	3	1
Country: Peru	137	103	71
Country: Philippines			
Country: Poland			
Country: Portugal			

EBAA Statistical Report Ledger for Calendar Year 2023	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
Country: Qatar	17	19	10
Country: Republic of Congo			
Country: Romania	20	6	
Country: Russia			
Country: Rwanda	116	3	30
Country: Saint Kitts and Nevis			
Country: Saint Lucia			
Country: Saint Vincent	9	4	
Country: Samao			
Country: San Marino			
Country: Sao Tome and Principe			
Country: Saudi Arabia	672	591	558
Country: Senegal			
Country: Serbia	40	20	6
Country: Seychelles			
Country: Sierra Leone	9	20	
Country: Singapore	269	210	170
Country: Slovakia			
Country: Slovenia			
Country: Solomon Islands			
Country: Somalia			1
Country: South Africa	484	360	411
Country: South Sudan			
Country: Spain			1
Country: Sri Lanka			
Country: Sudan	33		1
Country: Suriname	4	2	10
Country: Swaziland	11	3	
Country: Sweden			
Country: Switzerland	38	36	33
Country: Syrian Arab Republic	147	105	122
Country: Taiwan	101	62	76
Country: Tajikistan	8		
Country: Tanzania	7	3	43
Country: Thailand	118	56	47
Country: Timor-Leste			
Country: Togo			
Country: Tonga			
Country: Trinidad and Tobago	28	16	15
Country: Tunisia	388	261	150
Country: Turkey	213	253	251
Country: Turkmenistan			
Country: Tuvalu			
Country: Uganda	38		11
Country: Ukraine			
Country: United Arab Emirates	124	132	143
Country: United Kingdom	113	39	18
Country: Uruguay	14	7	1
Country: Uzbekistan	60	39	27
Country: Vanuatu			3
Country: Vatican City			
Country: Venezuela	56	54	56
Country: Viet Nam	23	12	28
Country: Western Sahara			
Country: Yemen	1		
Country: Zambia	9		18
Country: Zimbabwe		2	1
Country: International			
Validation X (Domestic count): This cell should be zero.	0	0	0
Validation Y (International count): This cell should be zero.	0	0	0
X. Indications for Penetrating Keratoplasty			
A. Post-cataract surgery edema	744	592	601
1. Domestic - Post-cataract surgery edema	447	382	403
2. International - Post-cataract surgery edema	297	210	198
B. Ectasias/Thinnings	1,765	1,448	1,682
1. Domestic - Ectasias/Thinnings	1,008	1,001	1,128

EBAA Statistical Report Ledger for Calendar Year 2023	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
2. International - Ectasias/Thinnings	757	447	554
C. Endothelial Dystrophies	732	749	631
1. Domestic - Endothelial Dystrophies	400	471	439
2. International - Endothelial Dystrophies	332	278	192
D. Repeat corneal transplant	2,041	1,802	1,951
1. Domestic - Repeat corneal transplant	1,672	1,492	1,646
2. International - Repeat corneal transplant	369	310	305
E. Other degenerations or dystrophies	505	536	508
1. Domestic - Other degenerations or dystrophies	359	386	406
2. International - Other degenerations or dystrophies	146	150	102
F. Refractive	39	35	47
1. Domestic - Refractive	23	23	41
2. International - Refractive	16	12	6
G. Microbial keratitis	288	232	259
1. Domestic - Microbial keratitis	204	161	177
2. International - Microbial keratitis	84	71	82
H. Mechanical (non-surgical) or chemical trauma	368	268	264
1. Domestic - Mechanical (non-surgical) or chemical trauma	247	223	210
2. International - Mechanical (non-surgical) or chemical trauma	121	45	54
I. Congenital opacities	273	254	260
1. Domestic - Congenital opacities	132	150	123
2. International - Congenital opacities	141	104	137
J. Pterygium	16	8	2
1. Domestic - Pterygium	14	5	2
2. International - Pterygium	2	3	0
K. Non-infectious ulcerative keratitis, thinning, or perforation	688	685	670
1. Domestic - Non-infectious ulcerative keratitis, thinning, or perforation	594	627	577
2. International - Non-infectious ulcerative keratitis, thinning, or perforation	94	58	93
L. Other causes of corneal opacification or distortion	1,109	879	1,126
1. Domestic - Other causes of corneal opacification or distortion	802	675	881
2. International - Other causes of corneal opacification or distortion	307	204	245
M. Other causes of endothelial dysfunction	881	648	622
1. Domestic - Other causes of endothelial dysfunction	608	522	509
2. International - Other causes of endothelial dysfunction	273	126	113
Z. Unknown, unreported, or unspecified	6,127	6,280	6,508
1. Domestic - Unknown, unreported, or unspecified	868	1,773	1,716
2. International - Unknown, unreported, or unspecified	5,259	4,507	4,792
CALCULATION N: Total indications for penetrating keratoplasty	15,576	14,416	15,131
Validation N1 (Domestic indications): This value should be zero.	0	0	0
Validation N2 (International indications): This value should be zero.	0	0	0
XI. Indications for Anterior Lamellar Keratoplasty			
B. Ectasias/Thinnings	252	129	149
1. Domestic - Ectasias/Thinnings	113	83	114
2. International - Ectasias/Thinnings	139	46	35
D. Repeat corneal transplant	21	17	15
1. Domestic - Repeat corneal transplant	12	12	14
2. International - Repeat corneal transplant	9	5	1
E. Other degenerations or dystrophies	51	33	46
1. Domestic - Other degenerations or dystrophies	30	19	22
2. International - Other degenerations or dystrophies	21	14	24
F. Refractive	0	0	0
1. Domestic - Refractive	0	0	0
2. International - Refractive	0	0	0
G. Microbial keratitis	12	12	20
1. Domestic - Microbial keratitis	8	8	14
2. International - Microbial keratitis	4	4	6
H. Mechanical (non-surgical) or chemical trauma	10	3	7
1. Domestic - Mechanical (non-surgical) or chemical trauma	6	2	6
2. International - Mechanical (non-surgical) or chemical trauma	4	1	1
I. Congenital opacities	10	15	11
1. Domestic - Congenital opacities	5	8	5
2. International - Congenital opacities	5	7	6
J. Pterygium	1	0	0
1. Domestic - Pterygium	1	0	0
2. International - Pterygium	0	0	0
K. Non-infectious ulcerative keratitis, thinning, or perforation	25	24	27

EBAA Statistical Report Ledger for Calendar Year 2023	Jan - Jun 2023	Jan - Jun 2022	Jan - Jun 2021
1. Domestic - Non-infectious ulcerative keratitis, thinning, or perforation	23	19	23
2. International - Non-infectious ulcerative keratitis, thinning, or perforation	2	5	4
L. Other causes of corneal opacification or distortion	108	58	67
1. Domestic - Other causes of corneal opacification or distortion	48	40	54
2. International - Other causes of corneal opacification or distortion	60	18	13
Z. Unknown, unreported, or unspecified	188	342	351
1. Domestic - Unknown, unreported, or unspecified	20	41	62
2. International - Unknown, unreported, or unspecified	168	301	289
CALCULATION O: Total indications for anterior lamellar keratoplasty	678	633	693
Validation O (Domestic Indications): This value should be zero.	0	0	0
Validation O (International Indications): This value should be zero.	0	0	0
XII. Indications for Endothelial Keratoplasty			
A. Post-cataract surgery edema	2,321	2,021	2,046
1. Domestic - Post-cataract surgery edema	1,839	1,590	1,650
2. International - Post-cataract surgery edema	482	431	396
C. Endothelial Dystrophies	9,715	8,476	8,304
1. Domestic - Endothelial Dystrophies	9,251	8,168	7,943
2. International - Endothelial Dystrophies	464	308	361
D. Repeat corneal transplant	2,122	1,752	1,831
1. Domestic - Repeat corneal transplant	1,903	1,590	1,678
2. International - Repeat corneal transplant	219	162	153
M. Other causes of endothelial dysfunction	2,982	2,610	2,799
1. Domestic - Other causes of endothelial dysfunction	2,297	2,106	2,279
2. International - Other causes of endothelial dysfunction	685	504	520
Z. Unknown, unreported, or unspecified	2,383	2,519	2,628
1. Domestic - Unknown, unreported, or unspecified	1,122	1,373	1,434
2. International - Unknown, unreported, or unspecified	1,261	1,146	1,194
CALCULATION P: Total indications for endothelial keratoplasty	19,523	17,378	17,608
Validation P (Domestic Indications): This value should be zero.	0	0	0
Validation P (International Indications): This value should be zero.	0	0	0
XIII. Preservation Time			
A. Preservation Time for domestic PK Surgeries			
1. 1-7 days	6,145	6,800	7,289
2. 8-11 days	1,162	1,017	913
3. 12-14 days	71	74	56
CALCULATION Q: Total Domestic PK Surgeries	7,378	7,891	8,258
Validation Q: This value should be zero.	0	0	0
B. Preservation Time for Domestic DSEK, DSAEK, DLEK Surgeries			
1. 1-7 days	6,782	6,791	7,278
2. 8-11 days	1,056	753	792
3. 12-14 days	25	31	27
CALCULATION R: Total Domestic DSEK, DSAEK, DLEK Surgeries	7,863	7,575	8,097
Validation R: This value should be zero.	0	0	0
C. Preservation Time for Domestic DMEK or DMAEK Surgeries			
1. 1-7 days	7,177	6,312	6,227
2. 8-11 days	1,126	912	617
3. 12-14 days	31	9	19
CALCULATION S: Total Domestic DMEK, DMAEK Surgeries	8,334	7,233	6,863
Validation S: This value should be zero.	0	0	0

Transplant Rate	**69.6%**	**70.3%**	**67.9%**
Conversion Rate	**32.5%**	**28.9%**	**32.5%**

LATE ADDITIONS

FOR INFORMATION & REVIEW

Important Information for Human Cell, Tissue and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Tuberculosis Outbreaks Linked to a Bone Matrix Product

September 6, 2023

FDA is working closely with the Centers for Disease Control and Prevention (CDC) to investigate recent reports of a tuberculosis (TB) outbreak caused by *Mycobacterium tuberculosis* (Mtb) that appears to be linked to a bone matrix product. We are issuing this communication to increase your awareness regarding the risk of transmission of Mtb through use of HCT/Ps in the United States.

Decades ago, Mtb transmission from transplantation of human bone, heart valves, and a dura mater allograft were reported in other countries. In 2021, a multi-state outbreak of Mtb in the United States was linked to transplantation of a bone allograft product and resulted in significant morbidity and mortality. A new, similar outbreak is currently under investigation.

Latent tuberculosis infection (LTBI) is estimated to affect one quarter of the world's population and approximately 4% of the U.S. population. Because Mtb transmission can occur from HCT/P donors with unrecognized and undiagnosed TB infection, these circumstances demand heightened awareness when screening donors of HCT/Ps.

Routine screening measures are in place for evaluating clinical evidence of infection in HCT/P donors. FDA has provided recommendations in guidance to reduce the risk of transmission of infections, including due to sepsis (which may be caused by Mtb); however, the following risk mitigation strategies concerning Mtb are important for public health safety.

Risk Mitigation Strategies

Responsible person

The HCT/P establishment's responsible person (21 CFR 1271.3(t)) must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). The responsible person(s) who is(are) authorized to perform designated functions related to the donor eligibility determination, should have appropriate medical training and be qualified to review clinical evidence consistent with risks for sepsis and TB infection. In addition, a responsible person must verify and document that, on the basis of record review, release criteria have been met and they have determined that an HCT/P is available for distribution (21 CFR 1271.265(c)(1)).

Maintaining knowledge and awareness of these outbreaks and seeking additional training and/or re-training will help enable responsible persons to identify risk factors, conditions, clinical evidence, and physical evidence that can be associated with an increased risk for TB (including active TB and LTBI) and/or an increased risk of sepsis.

Donor screening

TB may be underdiagnosed due to the lack of clinical suspicion, inherent diagnostic difficulty, and/or attribution of a group of symptoms to alternate causes. Although a donor with LTBI may be asymptomatic, a person with TB disease may have a number of symptoms or signs that can mimic or overlap with other medical conditions.

Clinical evidence of TB may include one or more of the following: a prolonged cough lasting 3 weeks or longer, coughing up blood (hemoptysis) or sputum, weakness or fatigue, unexplained weight loss, fever, night sweats, back pain, meningoencephalitis, headache or confusion, local or generalized lymphadenopathy or lymphadenitis, and/or radiographic findings suggestive of TB disease.

Based on our emerging awareness of Mtb transmission risks, establishments may wish to consider whether an HCT/P donor has:

- ever had a diagnosis of TB, treatment for suspected TB, or a positive test for TB (i.e., a skin test, blood test, or sputum test).
- an increased risk for TB infection due to any of the following:
    - was born in, has lived in, or ever traveled to areas of the world where TB is endemic (refer to https://worldhealthorg.shinyapps.io/tb_profiles/ (https://worldhealthorg.shinyapps.io/tb_profiles/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer))
    - ever lived with another person who has TB or is currently or has been a close contact of a person with TB
    - ever worked or resided in congregate settings (e.g., correctional facility, long-term care facility, homeless shelter)
    - has certain medical conditions, or is on medication, that can impair immune function.

Refer to CDC's website for more information: https://www.cdc.gov/tb/default.htm (https://www.cdc.gov/tb/default.htm)

Donor testing

Although there are currently no FDA-licensed, cleared, or approved donor screening tests available with an indication to screen HCT/P donors for evidence of active TB or LTBI, FDA is evaluating the risks and appropriate mitigation strategies including testing.

The FDA is committed to protecting public health, and patient safety is a top priority. The agency is committed to continuing to work with the CDC to assess the most recent outbreak and to look for ways to prevent transmission of Mtb from HCT/Ps going forward. We will communicate as additional information becomes available.

Additional Resources:

1. CDC: Tuberculosis (TB) Disease Associated with Suspected Contaminated Viable Bone Matrix Material Used in Surgical and Dental Procedures | HAI | CDC (https://www.cdc.gov/hai/outbreaks/TB-bone-allograft.html)
2. CDC Tuberculosis Data and Statistics. (https://www.cdc.gov/tb/statistics/default.htm#:~:text=Data%20and%20Statistics&text=In%202022%2C%208%2C300%20TB%20cases,2.5%20c
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14. World Health Organization. Global Tuberculosis Report 2022. https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022 (https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). (Accessed August 23, 2023)

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