Medical Advisory Board Meeting

June 17, 2021

Agenda

I. Call to Order

II. Approval of Minutes – November 12, 2020 Meeting

III. Committee Reports

   a. Medical Review Subcommittee (Macsai)

   b. Policy & Position Research Subcommittee (Aldave)

   c. Accreditation Board (Mavin/Rhee)

   d. Certification Board (Botsay)

   e. Technician Education (Win'E)

   f. Technical Procedures Manual (Titus)

IV. Old Business

V. New Business

   a. New Brunswick Cluster of Neurological Syndrome of Unknown Cause (Alier Marrero, MD)

   b. Letter from Dr. Woodford S. Van Meter, MD

   c. C3.300 (Pereira)

   d. C3.400 and Appendix V (Bonnier)

   e. G1.200 and H1.000 (Philippy)

VI. Late Additions

VII. Announcements

VIII. Adjourn

Medical Advisory Board Meeting Minutes
November 12, 2020

I. Call to Order

Dr. Jennifer Li called the meeting to order at 8:00pm. The following

members were present:

Jennifer Li, MD	MAB Chair
Winston Chamberlain, MD, PhD	MAB Vice Chair
Anthony Aldave, MD	PPR Subcommittee Chair, Ex-Officio
Gregg Berdy, MD	Committee Member
Beth Binnion, CEBT	Committee Member
Sara Botsay, CEBT	Certification Board Chair
Lisa Brooks, CEBT, CTBS	Accreditation Board Vice Chair
Brychan Clark, MD	FDA Liaison, Ex-Officio
Kevin Corcoran, CAE	EBAA President & CEO
Jennifer DeMatteo, MCM, CIC	EBAA Director of Regulations & Standards, Ex-Officio
Donna Drury, MBA, CEBT, CTBS	Committee Member
Paul Dubord, MD	Committee Member
Sander Dubovy, MD	Committee Member
Sean Edelstein, MD	Committee Member
David Glasser, MD	Committee Member
Mark A. Greiner, MD	Ex-Officio Member
Brian Ha, MSc, CEBT	Committee Member
Sadeer Hannush, MD	Committee Member
Holly Hindman, MD	Committee Member
Roman Hitchev, MD	AATB Liaison, Ex-Officio
Edward Holland, MD	Honorary Member, Ex-Officio
Joshua Hou, MD	Committee Member
Bennie Jeng, MD	Committee Member

Christopher Ketcherside, MD	Committee Member
Anup Kubal, MD	Committee Member
W. Barry Lee, MD	Committee Member
John Lohmeier, CEBT	Committee Member
Marian Macsai, MD	Medical Review Subcommittee Chair
Mark Mannis, MD	Honorary Member, Ex-Officio
Kristin Mathes, MA, MS	Ex-Officio Member
Kyle Mavin, CEBT, CTBS	Accreditation Board Co-Chair
Eric Meinecke, CEBT	MAB Secretary
Shahzad Mian, MD	Committee Member
Noel Mick	EBAA Chair, Ex-officio
Michael Nordlund, MD, PhD	Honorary Member, Ex-Officio
Brian Philippy, CEBT	Committee Member
Jim Quirk, BS, CEBT	Committee Member
Irving M. Raber, MD	Ex-Officio Member
Michelle Rhee, MD	Accreditation Board Co-Chair
Edwin Roberts MPA, CEBT	Committee Member
Christopher S. Sales, MD, MPH	Committee Member
C. Drew Salisbury, MD	Committee Member
Chris Stoeger, MBA, CEBT, CTBS	Ex-Officio Member
Alan Sugar, MD	Ex-Officio Member
Joel Sugar, MD	Honorary Member, Ex-Officio
Michael Titus, CEBT	Technical Procedures Manual Subcommittee Chair
Michael Tramber, MBA, CEBT, CTBS	Committee Member
Woodford Van Meter, MD	Ex-Officio Member
David Verdier, MD	Ex-Officio Member
Jim Wagner, CTBS, CEBT	Committee Member
William H. Waldrop, MD	Committee Member
Troy Win'E, CEBT	Technician Ed Committee Chair

II. Approval of Minutes

Dr. Li called for a motion to accept the minutes from the June 20, 2020 meeting.

A motion was made and seconded to approve the minutes without change. **Motion Passed.**

III. Committee Reports

A. Medical Review Subcommittee

Dr. Marian Macsai gave the Medical Review Subcommittee (MRS) Report. Dr. Macsai informed the MAB that her comments would largely be focused on 2018 and 2019 data. There were 88 Primary Graft Failures (PGFs) reported in 2018 compared to 93 in 2019. There were 52 Early Regrafts in 2018 compared to 80 in 2019. Dr. Macsai commented specifically on the increase in

PGFs and Early Regrafts related to DMEK procedures. There were 9 cases of endophthalmitis reported in 2019 compared to 13 in 2018. There were 6 reported cases of infectious keratitis in 2019 compared to 14 cases in 2018. Dr. Macsai said that while cases of endophthalmitis and infectious keratitis both decreased from 2018 to 2019, the MRS believes there is likely a significant amount of under reporting by surgeons. Surgeons could also be better at monitoring and treating patients when donor tissue is culture positive. The MRS is curious if the MAB should request eye banks to inquire when they receive a request for EK prepared tissue if the patient has had a prior transplant and the tissue request is a regraft. A discussion followed which centered around how eye banks could potentially capture more "true data" and how the EBAA could help educate surgeons on the importance of adverse reaction reporting.

B. Policy & Position Research Subcommittee

Dr. Tony Aldave gave the Policy & Position Research Subcommittee (PPRS) Report. The updated guidance on COVID-19 screening recommendations which was released on October 19, 2020 was reviewed. Dr. Aldave highlighted the two changes in the Donor Eligibility table. The PPRS changed the eligibility pathway, specifically related to whether or not there was close contact for when there is a negative PCR test, yes COVID-19 signs, yes or no COVID-19 symptoms, and a plausible alternative etiology of signs/symptoms. If there is close contact, the eye bank's medical director should review. If there is no close contact, the donor should be considered eligible according to the screening recommendations. A similar change was made in the table for when there is a negative PCR test, no COVID-19 signs, yes COVID-19 symptoms, and plausible alternative etiology of signs/symptoms. If there is close contact, the eye bank's medical director should review and when there is no close contact, the PPRS recommends the donor be determined eligible. Dr. Aldave reminded the MAB that the screening recommendations will continue to be updated as we learn more about COVID-19. He also asked all MAB members to continue to share their feedback and suggestions with the PPRS on the guidance document.

The PPRS also had no further recommendations to the MAB with regard to the suitability of corneal tissue for transplantation from donors with a history of Lyme Disease. The subcommittee had been asked to consider whether a recommendation was needed for Chronic Lyme Disease or Post Treatment Lyme Disease Syndrome. The PPRS had no further recommendations beyond continuing to exclude donors with active (known or suspected) Lyme Disease. Dr. Li thanked Dr. Aldave and his subcommittee for their hard work.

C. Accreditation Board

Kyle Mavin gave the Accreditation Board (AB) Report. The AB met on Tuesday, November 10th. The previous meeting's minutes were approved. A guidance on the use of video during accreditation inspections was approved as well as a revision to AB policy and procedure G1.000 (Identification of Accreditation Status). The most recent inspection cycle was a "hybrid" one, in which the lead inspector (the eye bank member of the inspection team) went on site while the

co-inspector (the physician member of the team) stayed back and participated remotely. The AB formed a subcommittee to define the regularity of alarm testing and will bring their recommendations to the AB at its next meeting. Nine eye banks were inspected and all nine received a three-year accreditation. Of the nine banks inspected, three banks had no findings and scored 100% in all areas. Dr. Li thanked Kyle and the AB for continuing their important work during the pandemic.

D. Certification Board

Sara Botsay gave the Certification Board (CB) Report. The spring cycle of the CEBT was postponed due to the pandemic. The exam did place July 11 – July 25. Twelve of the fifteen individuals that took the exam, passed. Sara congratulated Nathan Hawley (Regional Tissue Bank) who had the highest score. The fall CEBT exam was October 10 – October 25 and eleven people took the exam. Scores for this exam should be released soon. The next CEBT exam will be April 10 – April 24, 2021.

E. Technician Education Committee

Troy Win'E gave the Technician Education Committee Report. The committee hosted a webinar in August on corneal endothelial image quality and analysis. That webinar is available on EBAA's eyeLEARN. The committee also hosted a technician community chat in October. This chat focused on technical operations and challenges eye bankers have faced during the pandemic. Troy informed the board of an upcoming webinar on November 19th entitled "Risk Above Mission: Keeping Staff Safe." The Technician Education Committee is in the process of developing a webinar focused on tissue processing for early 2021. The Technician Education Seminar (TES) will take place in 2021 as a hybrid course of on-demand content available on eyeLEARN and live interactive sessions conducted via Zoom. Details and registration will be available soon.

F. Technical Procedures Manual Subcommittee

Michael Titus gave a short Technical Procedures Manual Subcommittee Report. While the subcommittee had no proposed changes to the manual for MAB review/approval, the subcommittee will be working in advance of the next MAB meeting. Specifically, they will be developing best practices regarding donor prep and recent changes in the Medical Standards regarding the use of povidone-iodine.

IV. Old Business

A. Adverse Reaction Subcommittee

Kristin Mathes, from Lions VisionGift, gave the Adverse Reaction Subcommittee Report. The MAB created the Adverse Reaction Subcommittee at the June 2020 meeting. The committee

was charged with evaluating a proposed change to the Medical Standards to allow for distributing eye banks to perform investigations of reported graft failures. This request was based on a desire to collect consistent data points on surgical outcomes to have the best data to make decisions on processing techniques. The subcommittee met twice, and it did not support the request to change the standards as requested in June 2020. The subcommittee did agree that
the data collected in OARRS is not sufficient to be able to assess a "true" graft failure rate. The subcommittee had two recommendations for the MAB to consider: 1) The data collected or missing in OARRS should be closely evaluated to confirm we are collecting meaningful and actionable information. This effort needs to be driven by surgeons, but eye bankers should play a role in this to help with providing operational context. 2) Ask the EBAA to develop curriculum aimed at educating surgeons on the importance of participating in the postoperative outcome process. This could be a video, pamphlets, etc. that eye banks would provide to new and existing surgeons. This curriculum could also be shared at events like AAO or ASCRS. A discussion amongst the MAB members followed Kristin's report. Jennifer DeMatteo commented that it would be easy to add data points to OARRS but it is unclear how easy it would be for eye banks to collect that new data. Eye banks would also need time to revise forms and implement changes. Dr. Li indicated that another subcommittee may be formed, one in which several surgeons would participate. This subcommittee would focus on surgeon outreach and education regarding adverse reaction reporting, perhaps in partnership with the EBAA Board of Directors. Dr. Li asked MAB members to give the discussion some thought and to stay tuned as it is clear that we want the very best data that we can reasonably ask eye banks to collect and surgeons to report.

B. Changes to the Medical Standards Definitions Section

During the June 2020 EBAA Medical Advisory Board meeting, Brian Philippy had proposed changes to the Medical Standards "Definitions" section. However, during the meeting, it was pointed out that the suggested change to the Donation Identification Number (DIN) and Product Codes were errant. Additionally, the Distributing Eye Bank proposed change had implications on the definition of consignee. Since the last meeting, Brian corrected the errors and explained the two definitions needing revision and the one to create.

Distributing Eye Bank. The last EBAA-accredited entity that provides tissue to a consignee, ~~such as an eye bank intermediary, or transplantation surgeon (whether agency, institution, organization, or researcher)~~. A **process** must be in place to ensure the principles of tracking, traceability, and adverse event reporting.

Consignee. Any eye bank not accredited by EBAA, third-party distributor, ~~eye banking intermediary~~ or transplanting surgeon, surgical facility, researcher, or educational facility (whether individual, agency, institution, or organization) that receives tissue and assumes responsibility for any step in the processing, storage, distribution and/or use of such tissue.

A motion was made and seconded to approve the revisions to the definitions. Beth Binnion commented that M1.400 would need to be revised as well. **Motion Passed.**

The addition to the definitions proposed by Brian Philippy:

Product Code. An eight-character sequence starting with the letter V and followed by 7 digits. Product codes are assigned by the facility from a list of codes established by ICCBBA. The first four digits in the product code
have been defined for unique combinations of tissue type, tissue sub-type, storage solution, storage conditions, anatomic position, and processing executed. The last three digits in the product code (3-character 'division
code') describe if there are multiple packs (units) from that same tissue, with 000 set as the default for tissue not divided into parts.

A motion was made and seconded to approve the addition of a definition for Product Code. **Motion Passed.**

V. New Business

A. Statistical Report Committee

The Statistical Report Committee proposed two changes to the Statistical Ledger to enrich the EBAA data.

The proposal was to add two fields:

VIII.B.1.a. Preloaded into a device following processing by microkeratome
VIII.B.3.a. Preloaded into a device following processing by manual dissection

VIII. Tissue Processing for Transplant by My Eye Bank

A. Eye Processing (does not include in situ excision)

1. Processed for cornea preservation (corneas only)
2. Processed for sclera preservation (incl. cornea/sclera preservation, sclera preservation from poles removed after in situ excision, etc.)
3. Processed for other ocular materials (regardless of cornea or sclera preservation)

B. Cornea Processing

1. Processed by microkeratome
2. Processed by laser
3. Processed by manual dissection (e.g. DMEK, DMAEK, cornea dissection for long-term preservation)

4. Processed by transfer into long-term preservation (incl. sectioned
   tissue only once)
5. Processed by other methods

A motion was made and seconded to approve the changes to the Statistical Ledger. **Motion Passed.**

B. Additional Proposed Changes to Statistical Ledger

Brian Philippy from the Statistical Report Committee proposed four changes to the Statistical Ledger to
enrich the EBAA data.

The proposal was to add a new header and three new data fields:

Header: II. Tissue Recoveries – Add item D. "Recovery by"
Data field 1: II. Tissue Recoveries – Add item D.1. "Recovered by this reporting eye bank"
Data field 2: II. Tissue Recoveries – Add item D.2. "Recovered by an EBAA-accredited partner agency"
Data field 3: II. Tissue Recoveries – Add item D.3. "Recovered by a partner agency, not accredited by EBAA"

Brian explained that donor tissue recovery by non-accredited entities is anecdotally on the rise, but the ledger had no way to measure it. The Statistical Report Committee felt that the EBAA cannot best determine how to respond now, or in the future, to a trend of eye bank functions executed outside of the EBAA "umbrella" without measuring the data.

A motion was made and seconded to approve the four changes to the Statistical Ledger. **Motion Passed.**

C. EBAA Statistical Report 2020 and 2019 Six-Month Comparison

Jennifer DeMatteo reported that due to a large eye bank not submitting their data to EBAA, she was unable to provide her report.

VI. Late Additions

There were no late additions.

VII. Announcements

Kristin Mathes, from the Legislative and Regulatory Affairs Committee, asked that eye banks

gather and submit their data on high-risk and travel rule-outs. This data is needed to help compel the FDA to update its donor eligibility guidance.

Kevin Corcoran discussed EBAA's Accreditation Campaign (Tagline: *Safety First. Innovation Always.*) For more information about the campaign, please visit www.restoresight.org/accreditation.

Beth Binnion announced Brian Philippy as the 2021 Leonard Heise Awardee.

Dr. Woody Van Meter announced Dr. Jennifer Li as the 2021 R. Townley Paton Awardee.

VIII. Adjourn

Dr. Jennifer Li adjourned the meeting at 9:20pm Eastern.

OARRS

The Online Adverse Reaction Reporting System

EYE BANK ASSOCIATION OF AMERICA

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

Report generated 25 May 2021 12:21pm EDT

	2015	2016	2017	2018	2019	2020	2021	Mean
Primary Graft Failure	**48**	**45**	**56**	**89**	**100**	**65**	**10**	**46.06**
Recipient's Age (mean)	64.25	64.59	64.71	68.95	69.41	66.73	69.3	66.63
Donor's Age (mean)	54.48	56.89	57.02	57.25	59.56	55.67	56.4	56.17
Donor Cause of Death								
Heart disease	16 (33%)	15 (33%)	13 (23%)	28 (31%)	26 (26%)	15 (23%)	1 (10%)	13.69 (30%)
Cancer	12 (25%)	8 (18%)	18 (32%)	14 (16%)	29 (29%)	19 (29%)	0 (0%)	11.13 (24%)
Cerebrovascular accident	4 (8%)	5 (11%)	3 (5%)	10 (11%)	7 (7%)	11 (17%)	2 (20%)	4.25 (9%)
Respiratory disease	2 (4%)	2 (4%)	6 (11%)	6 (7%)	6 (6%)	4 (6%)	2 (20%)	3.38 (7%)
Trauma	1 (2%)	4 (9%)	5 (9%)	6 (7%)	7 (7%)	5 (8%)	1 (10%)	4.25 (9%)
Toxic / Accident	2 (4%)	0 (0%)	2 (4%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0.75 (2%)
Other	11 (23%)	11 (24%)	9 (16%)	25 (28%)	24 (24%)	11 (17%)	4 (40%)	8.63 (19%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Procedure Type								
Penetrating keratoplasty (includes LAK/IEK)	22 (46%)	17 (38%)	12 (21%)	10 (11%)	15 (15%)	12 (18%)	2 (20%)	14.25 (31%)
Anterior lamellar keratoplasty (includes ALK, DALK)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)	0.25 (1%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	20 (42%)	21 (47%)	34 (61%)	57 (64%)	50 (50%)	30 (46%)	3 (30%)	24.5 (53%)
Endothelial keratoplasty: DMEK or DMAEK	6 (13%)	7 (16%)	10 (18%)	22 (25%)	35 (35%)	22 (34%)	5 (50%)	7 (15%)
Scleral graft	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (0%)
Source of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	1 (1%)	13 (13%)	13 (20%)	2 (20%)	1.81 (5%)
Surgeon	2 (8%)	1 (4%)	2 (5%)	5 (6%)	13 (13%)	2 (3%)	0 (0%)	3.31 (10%)
Processing establishment - source eye bank	19 (73%)	21 (75%)	31 (70%)	45 (56%)	53 (54%)	30 (46%)	7 (70%)	21.63 (65%)
Other processing establishment	5 (19%)	6 (21%)	11 (25%)	29 (36%)	20 (20%)	20 (31%)	1 (10%)	6.75 (20%)
Type of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	1 (1%)	21 (21%)	14 (22%)	2 (20%)	2.38 (7%)
Microkeratome	23 (92%)	23 (82%)	35 (80%)	61 (76%)	49 (49%)	28 (43%)	3 (30%)	25.19 (76%)
Manual Dissection	2 (8%)	5 (18%)	9 (20%)	18 (23%)	29 (29%)	23 (35%)	5 (50%)	5.75 (17%)
Tissue Preloaded								
Yes	0 (0%)	0 (0%)	0 (0%)	6 (7%)	24 (24%)	18 (28%)	2 (20%)	3.13 (16%)
No	0 (0%)	1 (100%)	48 (100%)	83 (93%)	76 (76%)	47 (72%)	8 (80%)	16.44 (84%)
Location of Tissue Transplant								
United States	25 (52%)	28 (62%)	37 (66%)	70 (79%)	64 (64%)	44 (68%)	7 (70%)	35.69 (77%)
International	23 (48%)	17 (38%)	19 (34%)	19 (21%)	36 (36%)	21 (32%)	3 (30%)	10.38 (23%)
Preoperative Diagnosis								
A. Post-cataract surgery edema	11 (23%)	13 (29%)	7 (13%)	13 (15%)	13 (13%)	10 (15%)	2 (20%)	8.06 (18%)
B. Keratoconus	5 (10%)	5 (11%)	8 (14%)	2 (2%)	2 (2%)	3 (5%)	0 (0%)	3.75 (8%)
C. Fuchs' dystrophy	15 (31%)	14 (31%)	26 (46%)	44 (49%)	43 (43%)	22 (34%)	0 (0%)	16.69 (36%)
D. Repeat corneal transplant	0 (0%)	3 (7%)	5 (9%)	6 (7%)	9 (9%)	9 (14%)	2 (20%)	4.88 (11%)
E. Other degenerations or dystrophies	4 (8%)	1 (2%)	4 (7%)	9 (10%)	7 (7%)	5 (8%)	0 (0%)	2.56 (6%)
F. Post-refractive surgery	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (0%)
G. Microbial changes	1 (2%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0.44 (1%)

H. Mechanical or chemical trauma	2 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.31 (1%)
I. Congenital opacities	0 (0%)	1 (2%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.31 (1%)
K. Non- infectious ulcerative keratitis or perforation	1 (2%)	3 (7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.25 (1%)
L. Other causes of corneal dysfunction or distortion (non-endothelial)	3 (6%)	2 (4%)	1 (2%)	3 (3%)	2 (2%)	2 (3%)	0 (0%)	3.69 (8%)
M. Other causes of endothelial dysfunction	2 (4%)	3 (7%)	2 (4%)	9 (10%)	16 (16%)	12 (18%)	6 (60%)	3.81 (8%)
Z. Unknown, unreported, or unspecified	4 (8%)	0 (0%)	2 (4%)	3 (3%)	7 (7%)	2 (3%)	0 (0%)	1.25 (3%)
Endothelial Density (mean)	2779.3	2809.76	2859.73	2906.35	2839.89	2863.94	2834.5	2823.74
Death to Cooling (mean hrs)	4.41	4.66	4.53	4.91	4.82	3.69	3.4	4.18
Range	0–16.17	0.3–21.6	0–20.62	0–21	0–20.6	0–15	2–6	0–21.6
Death to Preservation (mean hrs)	13.94	11.86	11.16	12.14	45.56	11.11	11	15.92
Range	5.25–23.38	4–23.83	2–24	3–24	3.8–1810	3–23	4–20	1–1810
Death to Surgery (mean days)	7.19	7.04	7.32	6.4	6.39	6.68	7	6.85
Range	2–13	3–14	3–14	2–14	2–15	3–13	5–9	1–243
Preservation Method								
Optisol-GS	42 (88%)	39 (87%)	54 (96%)	77 (87%)	87 (87%)	60 (92%)	10 (100%)	43 (93%)
Life4C	5 (10%)	6 (13%)	1 (2%)	9 (10%)	13 (13%)	5 (8%)	0 (0%)	2.63 (6%)
Eusol-C	0 (0%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (0%)
Cornea Cold®	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0.06 (0%)
Other	1 (2%)	0 (0%)	0 (0%)	2 (2%)	0 (0%)	0 (0%)	0 (0%)	0.25 (1%)
Was storage solution changed after processing?								
No	0 (0%)	1 (100%)	20 (42%)	27 (30%)	33 (33%)	21 (32%)	3 (30%)	6.56 (34%)
Yes	0 (0%)	0 (0%)	28 (58%)	62 (70%)	67 (67%)	44 (68%)	7 (70%)	13 (66%)
Post-Processing Preservation Method								
Optisol-GS	0 (0%)	0 (0%)	24 (80%)	37 (59%)	61 (91%)	36 (82%)	6 (86%)	10.25 (78%)
Life4C	0 (0%)	0 (0%)	6 (20%)	7 (11%)	4 (6%)	6 (14%)	1 (14%)	1.5 (11%)
Cornea Cold®	0 (0%)	0 (0%)	0 (0%)	9 (14%)	0 (0%)	0 (0%)	0 (0%)	0.56 (4%)
Other	0 (0%)	0 (0%)	0 (0%)	10 (16%)	2 (3%)	2 (5%)	0 (0%)	0.88 (7%)
Antifungal Supplementation?								
No	0 (0%)	0 (0%)	29 (100%)	61 (97%)	79 (87%)	51 (78%)	10 (100%)	14.38 (89%)
Yes	0 (0%)	0 (0%)	0 (0%)	2 (3%)	12 (13%)	14 (22%)	0 (0%)	1.75 (11%)
Recovery Procedure								
In-situ corneal excision	48 (100%)	44 (98%)	56 (100%)	88 (99%)	97 (97%)	62 (95%)	10 (100%)	45.13 (98%)
In-laboratory corneal and/or scleral excision after enucleation	0 (0%)	1 (2%)	0 (0%)	1 (1%)	3 (3%)	3 (5%)	0 (0%)	0.94 (2%)
Donor Site Facility								
Hospital	21 (44%)	31 (69%)	35 (63%)	45 (51%)	65 (65%)	45 (69%)	4 (40%)	29.69 (64%)
Medical examiner	4 (8%)	5 (11%)	3 (5%)	7 (8%)	7 (7%)	3 (5%)	0 (0%)	4.44 (10%)
Funeral home or mortuary	12 (25%)	1 (2%)	5 (9%)	12 (13%)	11 (11%)	5 (8%)	1 (10%)	4.25 (9%)
Other	11 (23%)	8 (18%)	13 (23%)	25 (28%)	17 (17%)	12 (18%)	5 (50%)	7.69 (17%)

	2015	2016	2017	2018	2019	2020	2021	Mean
Early Regraft	**36**	**35**	**42**	**52**	**82**	**73**	**19**	**41.8**
Recipient's Age (mean)	67.53	65.09	68.33	66.63	66.98	65.78	69	66.57
Donor's Age (mean)	56.42	53.74	59.52	58.85	62.35	59.86	61.37	59.07
Donor Cause of Death								
Heart disease	11 (31%)	11 (31%)	17 (40%)	13 (25%)	21 (26%)	20 (27%)	8 (42%)	12.4 (30%)
Cancer	7 (19%)	3 (9%)	4 (10%)	8 (15%)	36 (44%)	19 (26%)	4 (21%)	10.8 (26%)
Cerebrovascular accident	8 (22%)	5 (14%)	6 (14%)	10 (19%)	5 (6%)	8 (11%)	2 (11%)	5.1 (12%)
Respiratory disease	4 (11%)	6 (17%)	3 (7%)	4 (8%)	6 (7%)	2 (3%)	3 (16%)	3.4 (8%)
Trauma	3 (8%)	4 (11%)	0 (0%)	6 (12%)	4 (5%)	4 (5%)	1 (5%)	2.9 (7%)

Toxic / Accident	1 (3%)	1 (3%)	0 (0%)	1 (2%)	0 (0%)	1 (1%)	0 (0%)	0.4 (1%)
Other	2 (6%)	5 (14%)	12 (29%)	10 (19%)	10 (12%)	19 (26%)	1 (5%)	6.8 (16%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Procedure Type								
Penetrating keratoplasty (includes LAK/IEK)	6 (17%)	6 (17%)	2 (5%)	5 (10%)	2 (2%)	12 (16%)	1 (5%)	4.7 (11%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	19 (53%)	18 (51%)	21 (50%)	25 (48%)	19 (23%)	22 (30%)	7 (37%)	18.9 (45%)
Endothelial keratoplasty: DMEK or DMAEK	11 (31%)	11 (31%)	19 (45%)	22 (42%)	61 (74%)	39 (53%)	11 (58%)	18.2 (44%)
Source of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	8 (11%)	4 (21%)	1.4 (4%)
Surgeon	1 (3%)	0 (0%)	4 (10%)	2 (4%)	4 (5%)	5 (7%)	1 (5%)	2.4 (6%)
Processing establishment - source eye bank	28 (93%)	23 (79%)	20 (50%)	28 (60%)	53 (65%)	44 (60%)	7 (37%)	25.2 (65%)
Other processing establishment	1 (3%)	6 (21%)	16 (40%)	17 (36%)	23 (28%)	16 (22%)	7 (37%)	9.6 (25%)
Type of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (4%)	12 (16%)	4 (21%)	1.9 (5%)
Microkeratome	21 (70%)	19 (68%)	21 (55%)	26 (55%)	20 (24%)	22 (30%)	6 (32%)	19.6 (51%)
Manual Dissection	9 (30%)	9 (32%)	17 (45%)	21 (45%)	59 (72%)	39 (53%)	9 (47%)	16.8 (44%)
Tissue Preloaded								
Yes	0 (0%)	0 (0%)	2 (7%)	14 (27%)	44 (54%)	27 (37%)	9 (47%)	9.6 (38%)
No	0 (0%)	1 (100%)	26 (93%)	38 (73%)	38 (46%)	46 (63%)	10 (53%)	16 (63%)
Location of Tissue Transplant								
United States	32 (89%)	34 (97%)	38 (90%)	51 (98%)	74 (90%)	59 (81%)	13 (68%)	36.6 (88%)
International	4 (11%)	1 (3%)	4 (10%)	1 (2%)	8 (10%)	14 (19%)	6 (32%)	5.2 (12%)
Preoperative Diagnosis								
A. Post-cataract surgery edema	7 (19%)	3 (9%)	4 (10%)	6 (12%)	3 (4%)	3 (4%)	0 (0%)	3.8 (9%)
B. Keratoconus	3 (8%)	2 (6%)	1 (2%)	3 (6%)	0 (0%)	3 (4%)	0 (0%)	1.9 (5%)
C. Fuchs' dystrophy	13 (36%)	18 (51%)	23 (55%)	30 (58%)	59 (72%)	36 (49%)	10 (53%)	22.9 (55%)
D. Repeat corneal transplant	3 (8%)	2 (6%)	3 (7%)	4 (8%)	3 (4%)	12 (16%)	0 (0%)	3.4 (8%)
E. Other degenerations or dystrophies	4 (11%)	4 (11%)	5 (12%)	5 (10%)	10 (12%)	8 (11%)	4 (21%)	4.4 (11%)
F. Post-refractive surgery	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.1 (0%)
G. Microbial changes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.1 (0%)
H. Mechanical or chemical trauma	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	1 (5%)	0.2 (0%)
I. Congenital opacities	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.1 (0%)
L. Other causes of corneal dysfunction or distortion (non-endothelial)	2 (6%)	1 (3%)	0 (0%)	1 (2%)	1 (1%)	2 (3%)	0 (0%)	1 (2%)
M. Other causes of endothelial dysfunction	4 (11%)	3 (9%)	6 (14%)	3 (6%)	4 (5%)	5 (7%)	1 (5%)	2.9 (7%)
Z. Unknown, unreported, or unspecified	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	3 (4%)	3 (16%)	1 (2%)
Endothelial Density (mean)	2813.31	2815.51	2925.14	2857.19	2795.9	2772.82	2762.11	2817.54
Death to Cooling (mean hrs)	3.19	3.87	4.33	3.86	3.89	3.36	2.77	3.76
Range	0–11	0.78–18	0.58–17	0–13.4	0–13.6	0–10	0–5	0–18
Death to Preservation (mean hrs)	11.81	11.43	10.98	56.91	11.65	11.43	12.56	20.45
Range	3–23.5	2.85–23.5	2.18–24	1–2356	1–23	3.2–23	6–21	1–2356
Death to Surgery (mean days)	6.61	5.51	5.79	5.79	5.83	6.16	6.53	6.06
Range	3–14	2–9	1–9	2–13	2–13	1–12	4–10	1–20
Preservation Method								
Optisol-GS	35 (97%)	33 (94%)	42 (100%)	45 (87%)	72 (88%)	63 (86%)	14 (74%)	37.8 (90%)
Life4C	1 (3%)	2 (6%)	0 (0%)	7 (13%)	10 (12%)	10 (14%)	5 (26%)	4 (10%)
Was storage solution changed after processing?								

No	0 (0%)	0 (0%)	6 (21%)	14 (27%)	13 (16%)	16 (22%)	9 (47%)	5.8 (23%)
Yes	0 (0%)	1 (100%)	22 (79%)	38 (73%)	69 (84%)	57 (78%)	10 (53%)	19.8 (77%)
Post-Processing Preservation Method								
Optisol-GS	0 (0%)	1 (100%)	17 (77%)	23 (61%)	63 (91%)	47 (82%)	7 (70%)	15.9 (80%)
Life4C	0 (0%)	0 (0%)	5 (23%)	8 (21%)	6 (9%)	8 (14%)	3 (30%)	3 (15%)
Cornea Cold®	0 (0%)	0 (0%)	0 (0%)	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0.2 (1%)
Other	0 (0%)	0 (0%)	0 (0%)	5 (13%)	0 (0%)	2 (4%)	0 (0%)	0.7 (4%)
Antifungal Supplementation?								
No	0 (0%)	1 (100%)	22 (100%)	37 (97%)	58 (74%)	53 (73%)	13 (68%)	18.5 (80%)
Yes	0 (0%)	0 (0%)	0 (0%)	1 (3%)	20 (26%)	20 (27%)	6 (32%)	4.7 (20%)
Recovery Procedure								
In-situ corneal excision	34 (94%)	35 (100%)	40 (95%)	52 (100%)	82 (100%)	73 (100%)	17 (89%)	40.7 (97%)
In-laboratory corneal and/or scleral excision after enucleation	2 (6%)	0 (0%)	2 (5%)	0 (0%)	0 (0%)	0 (0%)	2 (11%)	1.1 (3%)
Donor Site Facility								
Hospital	26 (72%)	24 (69%)	23 (55%)	33 (63%)	47 (57%)	54 (74%)	15 (79%)	27.1 (65%)
Medical examiner	3 (8%)	3 (9%)	4 (10%)	5 (10%)	7 (9%)	4 (5%)	2 (11%)	3.1 (7%)
Funeral home or mortuary	4 (11%)	2 (6%)	6 (14%)	4 (8%)	16 (20%)	4 (5%)	0 (0%)	4.8 (11%)
Other	3 (8%)	6 (17%)	9 (21%)	10 (19%)	12 (15%)	11 (15%)	2 (11%)	6.8 (16%)

	2015	2016	2017	2018	2019	2020	2021	Mean
Endophthalmitis	**20**	**20**	**21**	**13**	**9**	**11**	**2**	**12.19**
Recipient's Age (mean)	59.8	72.75	65.57	71.17	69.33	60.36	62.5	66.86
Donor's Age (mean)	56.25	54.7	58.1	58	64.78	61.55	68	57.66
Donor Cause of Death								
Heart disease	2 (10%)	11 (55%)	8 (38%)	4 (31%)	4 (44%)	3 (27%)	0 (0%)	4.13 (34%)
Cancer	5 (25%)	2 (10%)	1 (5%)	3 (23%)	2 (22%)	4 (36%)	1 (50%)	2.06 (17%)
Cerebrovascular accident	0 (0%)	1 (5%)	1 (5%)	2 (15%)	0 (0%)	0 (0%)	0 (0%)	0.31 (3%)
Respiratory disease	4 (20%)	1 (5%)	1 (5%)	1 (8%)	0 (0%)	3 (27%)	0 (0%)	1.5 (12%)
Trauma	3 (15%)	0 (0%)	3 (14%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0.81 (7%)
Toxic / Accident	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0.25 (2%)
Other	6 (30%)	5 (25%)	6 (29%)	2 (15%)	3 (33%)	0 (0%)	1 (50%)	3.13 (26%)
Mated Cases	1 (5%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.31 (3%)
Procedure Type								
Penetrating keratoplasty (includes LAK/IEK)	6 (30%)	4 (20%)	2 (10%)	4 (31%)	2 (22%)	3 (27%)	0 (0%)	3.63 (30%)
Anterior lamellar keratoplasty (includes ALK, DALK)	1 (5%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	11 (55%)	12 (60%)	15 (71%)	7 (54%)	2 (22%)	4 (36%)	0 (0%)	6.75 (55%)
Endothelial keratoplasty: DMEK or DMAEK	1 (5%)	4 (20%)	3 (14%)	2 (15%)	5 (56%)	4 (36%)	2 (100%)	1.5 (12%)
Keratoprosthesis (K-Pro)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Scleral graft	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Source of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (22%)	3 (27%)	0 (0%)	0.31 (4%)
Surgeon	2 (15%)	5 (31%)	3 (16%)	0 (0%)	0 (0%)	2 (18%)	0 (0%)	1.63 (19%)
Processing establishment - source eye bank	10 (77%)	9 (56%)	11 (58%)	5 (56%)	4 (44%)	4 (36%)	2 (100%)	5.19 (60%)
Other processing establishment	1 (8%)	2 (13%)	5 (26%)	4 (44%)	3 (33%)	2 (18%)	0 (0%)	1.56 (18%)
Type of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (22%)	3 (27%)	0 (0%)	0.31 (4%)
Microkeratome	11 (85%)	11 (69%)	15 (79%)	7 (78%)	2 (22%)	4 (36%)	0 (0%)	6.63 (77%)
Manual Dissection	2 (15%)	5 (31%)	4 (21%)	2 (22%)	5 (56%)	4 (36%)	2 (100%)	1.69 (20%)
Tissue Preloaded								
Yes	0 (0%)	0 (0%)	1 (8%)	1 (8%)	3 (33%)	3 (27%)	1 (50%)	0.56 (17%)
No	4 (100%)	1 (100%)	11 (92%)	12 (92%)	6 (67%)	8 (73%)	1 (50%)	2.69 (83%)

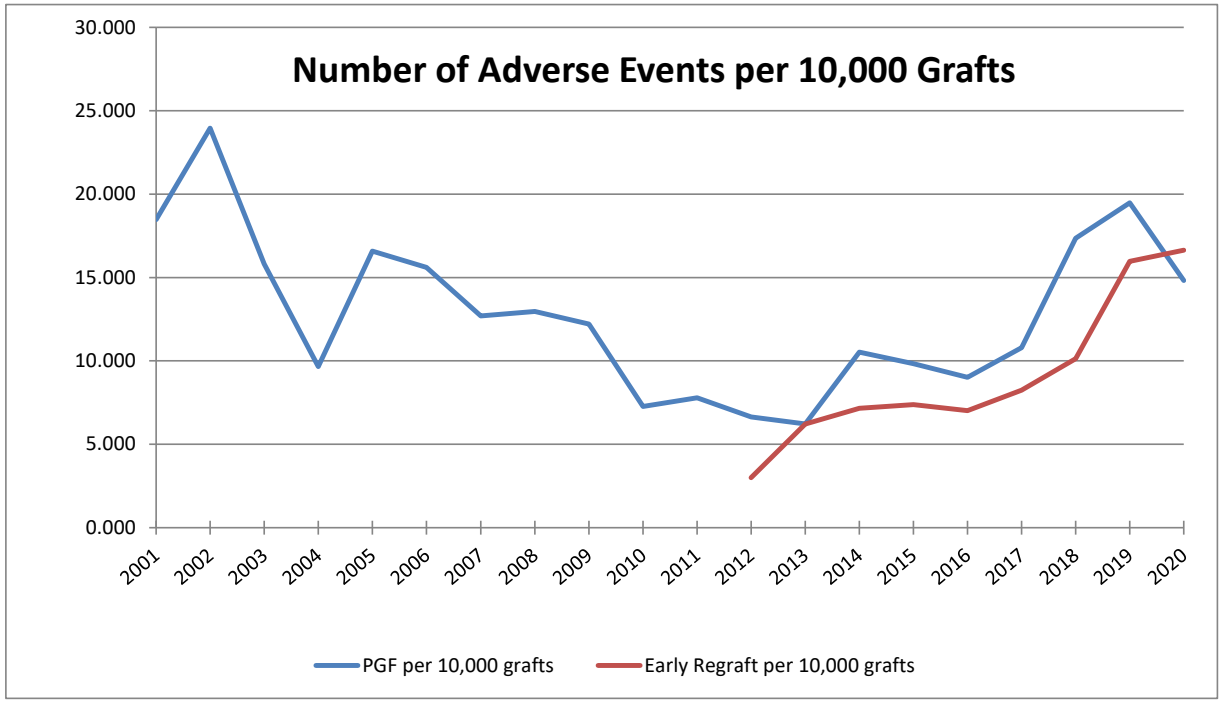
Location of Tissue Transplant								
United States	13 (65%)	13 (65%)	18 (86%)	10 (77%)	8 (89%)	10 (91%)	1 (50%)	10.13 (83%)
International	7 (35%)	7 (35%)	3 (14%)	3 (23%)	1 (11%)	1 (9%)	1 (50%)	2.06 (17%)
Concordant Positive Cultures	7 (35%)	4 (20%)	5 (24%)	5 (38%)	5 (56%)	1 (9%)	0 (0%)	4.44 (36%)
Recipient Culture Results								
Achromobacter (formerly Alcaligenes)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Candida albicans	1 (5%)	1 (5%)	1 (5%)	1 (9%)	1 (11%)	1 (9%)	0 (0%)	1.19 (10%)
Candida glabrata	1 (5%)	8 (40%)	6 (27%)	1 (9%)	4 (44%)	2 (18%)	0 (0%)	3.06 (25%)
Candida parapsilosis	0 (0%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Candida tropicalis	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.19 (2%)
Candida unspecified	2 (9%)	2 (10%)	2 (9%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0.94 (8%)
Clostridium perfringens	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (11%)	0 (0%)	0 (0%)	0.19 (2%)
Enterobacter spp.	2 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0.19 (2%)
Enterococcus faecalis	2 (9%)	0 (0%)	1 (5%)	1 (9%)	2 (22%)	1 (9%)	0 (0%)	0.69 (6%)
Enterococcus faecium	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Enterococcus spp.	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Enterococcus unspecified	1 (5%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.44 (4%)
Escherichia coli	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Haemophilus influenzae	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Penicillium spp.	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Pseudomonas aeruginosa	0 (0%)	0 (0%)	1 (5%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Staphylococcus aureus	0 (0%)	0 (0%)	2 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.25 (2%)
Staphylococcus epidermidis / coagulase negative	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Staphylococcus unspecified	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Streptococcus agalactiae (Group B Strep)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.19 (2%)
Streptococcus pneumonia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Streptococcus unspecified	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.31 (3%)
Viridans streptococci (alpha hemolytic)	0 (0%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Yeast - non- specified	0 (0%)	1 (5%)	2 (9%)	1 (9%)	0 (0%)	1 (9%)	0 (0%)	0.44 (4%)
Other Organism	1 (5%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Not done	4 (18%)	3 (15%)	5 (23%)	4 (36%)	1 (11%)	2 (18%)	1 (50%)	1.88 (15%)
No growth	5 (23%)	2 (10%)	1 (5%)	0 (0%)	0 (0%)	2 (18%)	1 (50%)	1.31 (11%)
Death to Cooling (mean hrs)	5.15	5.13	5.49	3.6	3.89	4.64	6.6	4.57
Range	1–13	2–15.7	1.5–17	1.5–10.5	1–6.15	1.5–15	2.2–11	0–19
Death to Preservation (mean hrs)	13.07	14.38	13.23	10.93	10.36	14.45	14.69	12.03
Range	5.25–23	6–23.58	5.75–24	4–23.83	6.8–17	5–20	11–18.37	2–24
Death to Surgery (mean days)	6.2	5.95	5.76	7.08	6	5.55	7	6.59
Range	2–11	2–10	3–13	2–13	3–8	4–10	5–9	2–128
Preservation Method								
Optisol-GS	19 (95%)	19 (95%)	19 (90%)	13 (100%)	6 (67%)	7 (64%)	1 (50%)	10.75 (88%)
Life4C	1 (5%)	0 (0%)	2 (10%)	0 (0%)	3 (33%)	4 (36%)	1 (50%)	1.31 (11%)
Eusol-C	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Was storage solution changed after processing?								
No	4 (100%)	0 (0%)	6 (50%)	7 (54%)	4 (44%)	3 (27%)	0 (0%)	1.5 (46%)
Yes	0 (0%)	1 (100%)	6 (50%)	6 (46%)	5 (56%)	8 (73%)	2 (100%)	1.75 (54%)
Post-Processing Preservation Method								
Optisol-GS	0 (0%)	1 (100%)	6 (86%)	5 (83%)	5 (100%)	6 (75%)	1 (50%)	1.5 (83%)
Life4C	0 (0%)	0 (0%)	1 (14%)	0 (0%)	0 (0%)	2 (25%)	1 (50%)	0.25 (14%)
Other	0 (0%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0.06 (3%)
Antifungal Supplementation?								
No	0 (0%)	1 (100%)	7 (100%)	5 (83%)	7 (100%)	11 (100%)	2 (100%)	2.06 (97%)
Yes	0 (0%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0.06 (3%)
Recovery Procedure								

In-situ corneal excision	20 (100%)	20 (100%)	21 (100%)	13 (100%)	9 (100%)	11 (100%)	2 (100%)	12.13 (99%)
In-laboratory corneal and/or scleral excision after enucleation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Donor Site Facility								
Hospital	13 (65%)	17 (85%)	10 (48%)	9 (69%)	5 (56%)	6 (55%)	1 (50%)	8.19 (67%)
Medical examiner	3 (15%)	0 (0%)	3 (14%)	0 (0%)	1 (11%)	2 (18%)	0 (0%)	1.06 (9%)
Funeral home or mortuary	4 (20%)	3 (15%)	3 (14%)	1 (8%)	0 (0%)	0 (0%)	1 (50%)	1.19 (10%)
Other	0 (0%)	0 (0%)	5 (24%)	3 (23%)	3 (33%)	3 (27%)	0 (0%)	1.75 (14%)

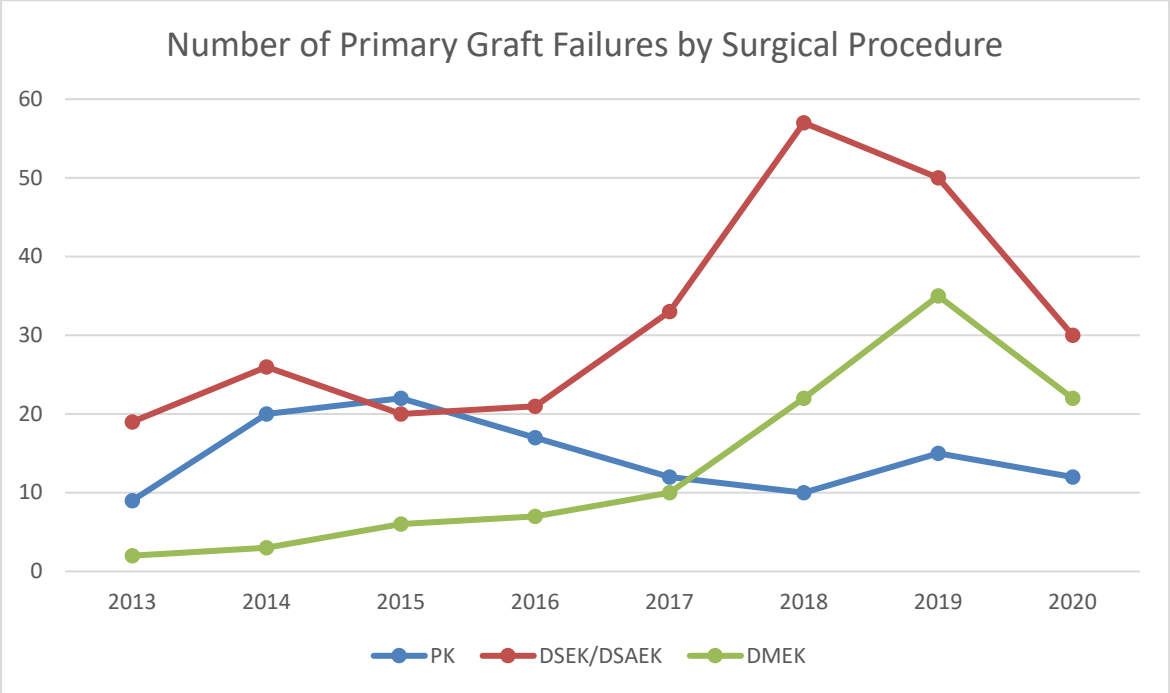
	2015	2016	2017	2018	2019	2020	2021	Mean
Infectious Keratitis	**16**	**14**	**21**	**14**	**6**	**6**	**3**	**9.19**
Recipient's Age (mean)	62.75	71.46	64.95	70.69	62.33	55.6	63.5	66.71
Donor's Age (mean)	54.07	51.14	54.29	59.14	49.83	45.6	61.33	52.41
Donor Cause of Death								
Heart disease	7 (44%)	4 (29%)	6 (29%)	7 (50%)	1 (17%)	0 (0%)	0 (0%)	3.38 (37%)
Cancer	5 (31%)	1 (7%)	2 (10%)	0 (0%)	1 (17%)	0 (0%)	1 (33%)	1.25 (14%)
Cerebrovascular accident	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.19 (2%)
Respiratory disease	0 (0%)	3 (21%)	2 (10%)	1 (7%)	1 (17%)	1 (17%)	0 (0%)	0.63 (7%)
Trauma	1 (6%)	1 (7%)	1 (5%)	0 (0%)	0 (0%)	2 (33%)	0 (0%)	0.94 (10%)
Toxic / Accident	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Other	3 (19%)	5 (36%)	10 (48%)	6 (43%)	3 (50%)	3 (50%)	2 (67%)	2.69 (29%)
Mated Cases	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Procedure Type								
Penetrating keratoplasty (includes LAK/IEK)	6 (38%)	4 (29%)	2 (10%)	3 (21%)	2 (33%)	0 (0%)	1 (33%)	2.38 (26%)
Anterior lamellar keratoplasty (includes ALK, DALK)	2 (13%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.31 (3%)
Endothelial keratoplasty: DSEK, DSAEK, DLEK	7 (44%)	8 (57%)	12 (57%)	9 (64%)	0 (0%)	6 (100%)	0 (0%)	5.31 (58%)
Endothelial keratoplasty: DMEK or DMAEK	0 (0%)	2 (14%)	6 (29%)	2 (14%)	4 (67%)	0 (0%)	2 (67%)	1.06 (12%)
Keratoprosthesis (K-Pro)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Other (e.g. experimental surgery)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Source of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (33%)	0 (0%)	1 (33%)	0.19 (3%)
Surgeon	1 (11%)	0 (0%)	4 (21%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0.94 (14%)
Processing establishment - source eye bank	7 (78%)	9 (90%)	8 (42%)	8 (73%)	2 (33%)	5 (83%)	0 (0%)	4.5 (65%)
Other processing establishment	1 (11%)	1 (10%)	7 (37%)	3 (27%)	1 (17%)	1 (17%)	2 (67%)	1.25 (18%)
Type of Lamellar Cut								
N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (33%)	0 (0%)	1 (33%)	0.19 (3%)
Microkeratome	8 (89%)	8 (80%)	12 (71%)	9 (82%)	0 (0%)	6 (100%)	0 (0%)	5.31 (79%)
Manual Dissection	1 (11%)	2 (20%)	5 (29%)	2 (18%)	4 (67%)	0 (0%)	2 (67%)	1.25 (19%)
Tissue Preloaded								
Yes	0 (0%)	0 (0%)	0 (0%)	1 (7%)	2 (33%)	0 (0%)	2 (67%)	0.31 (11%)
No	0 (0%)	3 (100%)	13 (100%)	13 (93%)	4 (67%)	6 (100%)	1 (33%)	2.5 (89%)
Location of Tissue Transplant								
United States	14 (88%)	12 (86%)	17 (81%)	10 (71%)	6 (100%)	5 (83%)	3 (100%)	8.25 (90%)
International	2 (13%)	2 (14%)	4 (19%)	4 (29%)	0 (0%)	1 (17%)	0 (0%)	0.94 (10%)
Concordant Positive Cultures	3 (19%)	1 (7%)	4 (19%)	1 (7%)	2 (33%)	1 (17%)	2 (67%)	2.06 (22%)
Recipient Culture Results								
Acanthamoeba spp.	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Achromobacter (formerly Alcaligenes)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Candida albicans	2 (13%)	2 (14%)	5 (23%)	2 (17%)	0 (0%)	2 (33%)	2 (100%)	1.69 (19%)
Candida glabrata	1 (6%)	0 (0%)	2 (9%)	2 (17%)	1 (20%)	0 (0%)	0 (0%)	1.06 (12%)
Candida other	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.19 (2%)

Candida parapsilosis	0 (0%)	1 (7%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Candida tropicalis	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Candida unspecified	1 (6%)	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0.63 (7%)
Escherichia coli	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Fusarium spp.	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Herpes simplex	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)	0.25 (3%)
Mycobacterium chelonae	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Pseudomonas aeruginosa	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Staphylococcus unspecified	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.06 (1%)
Streptococcus agalactiae (Group B Strep)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)	0.13 (1%)
Streptococcus unspecified	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0.06 (1%)
Yeast - non- specified	0 (0%)	0 (0%)	1 (5%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)	0.19 (2%)
Other Organism	0 (0%)	1 (7%)	0 (0%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0.13 (1%)
Not done	6 (38%)	9 (64%)	9 (41%)	7 (58%)	0 (0%)	1 (17%)	0 (0%)	2.94 (33%)
No growth	4 (25%)	1 (7%)	1 (5%)	0 (0%)	1 (20%)	1 (17%)	0 (0%)	1 (11%)
Death to Cooling (mean hrs)	3.31	3.77	4.99	4.53	3.25	8.58	3.33	3.89
Range	0.25–9	0.23–13	1–11	2–13	2–6	5–11.51	1.5–7	0–13
Death to Preservation (mean hrs)	10.97	14.43	11.23	11.89	13.24	15.52	12.67	11.37
Range	3–22	5.88–23.9	4.68–16.12	5–23.83	6.57–23.85	10.75–23	8–15	1.7–23.9
Death to Surgery (mean days)	6.13	5.43	5.76	6.64	4.83	5.75	4	5.51
Range	2–11	3–9	2–11	2–12	2–7	2–11	2–5	2–13
Preservation Method								
Optisol-GS	13 (81%)	13 (93%)	19 (90%)	12 (86%)	5 (83%)	6 (100%)	2 (67%)	8.19 (89%)
Life4C	3 (19%)	1 (7%)	0 (0%)	2 (14%)	1 (17%)	0 (0%)	1 (33%)	0.88 (10%)
Other	0 (0%)	0 (0%)	2 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.13 (1%)
Was storage solution changed after processing?								
No	0 (0%)	3 (100%)	4 (31%)	6 (43%)	3 (50%)	4 (67%)	2 (67%)	1.38 (49%)
Yes	0 (0%)	0 (0%)	9 (69%)	8 (57%)	3 (50%)	2 (33%)	1 (33%)	1.44 (51%)
Post-Processing Preservation Method								
Optisol-GS	0 (0%)	0 (0%)	6 (67%)	5 (63%)	3 (100%)	2 (100%)	0 (0%)	1 (70%)
Life4C	0 (0%)	0 (0%)	3 (33%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0.25 (17%)
Other	0 (0%)	0 (0%)	0 (0%)	3 (38%)	0 (0%)	0 (0%)	0 (0%)	0.19 (13%)
Antifungal Supplementation?								
No	0 (0%)	0 (0%)	9 (100%)	8 (100%)	4 (80%)	6 (100%)	3 (100%)	1.88 (97%)
Yes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)	0.06 (3%)
Recovery Procedure								
In-situ corneal excision	13 (81%)	14 (100%)	21 (100%)	14 (100%)	6 (100%)	6 (100%)	3 (100%)	9 (98%)
In-laboratory corneal and/or scleral excision after enucleation	3 (19%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.19 (2%)
Donor Site Facility								
Hospital	10 (63%)	10 (71%)	18 (86%)	9 (64%)	3 (50%)	2 (33%)	2 (67%)	6.5 (71%)
Medical examiner	2 (13%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0.5 (5%)
Funeral home or mortuary	1 (6%)	3 (21%)	0 (0%)	1 (7%)	0 (0%)	1 (17%)	0 (0%)	0.75 (8%)
Other	3 (19%)	1 (7%)	2 (10%)	4 (29%)	3 (50%)	2 (33%)	1 (33%)	1.44 (16%)
Scleral Graft Infection	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0.06**
Donor Corneal Dystrophy or Degeneration	**2**	**1**	**0**	**1**	**0**	**0**	**0**	**0.56**
Donor Corneal Refractive Surgery	**0**	**0**	**2**	**0**	**0**	**0**	**0**	**0.25**
Donor-to-host Transmission of Systemic Infection	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0.44**
Malignancy	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0.19**
Other (or Multiple)	**0**	**1**	**0**	**1**	**0**	**2**	**0**	**0.31**

YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
PGF	61	78	51	31	53	53	50	54	52	31	36	31	30	50	48	45	55	89	100	65
Early Regraft												14	30	34	36	35	42	52	82	73
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
PGF per 10,000 grafts	18.465	23.957	15.819	9.656	16.587	15.606	12.693	12.965	12.205	7.270	7.793	6.640	6.220	10.520	9.838	9.024	10.798	17.351	19.480	14.815
Early Regraft per 10,000 grafts												2.999	6.220	7.153	7.378	7.018	8.246	10.138	15.973	16.639

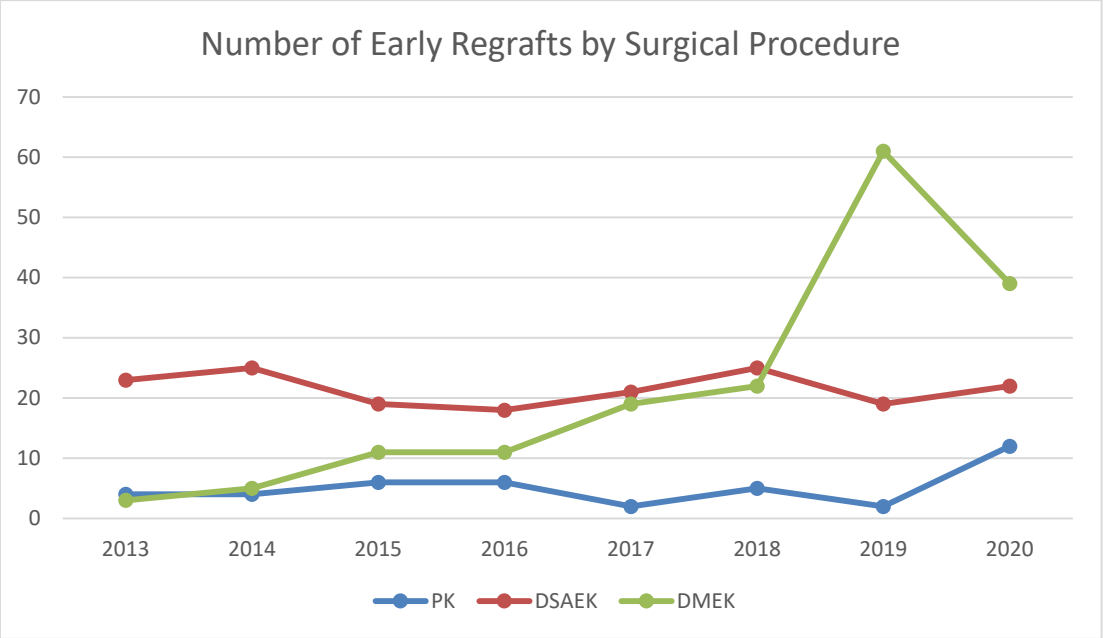


Year	2013	2014	2015	2016	2017	2018	2019	2020
PK	9	20	22	17	12	10	15	12
DSAEK	19	26	20	21	33	57	50	30
DMEK	2	3	6	7	10	22	35	22
TOTAL	**30**	**50**	**48**	**45**	**56**	**89**	**100**	**65**

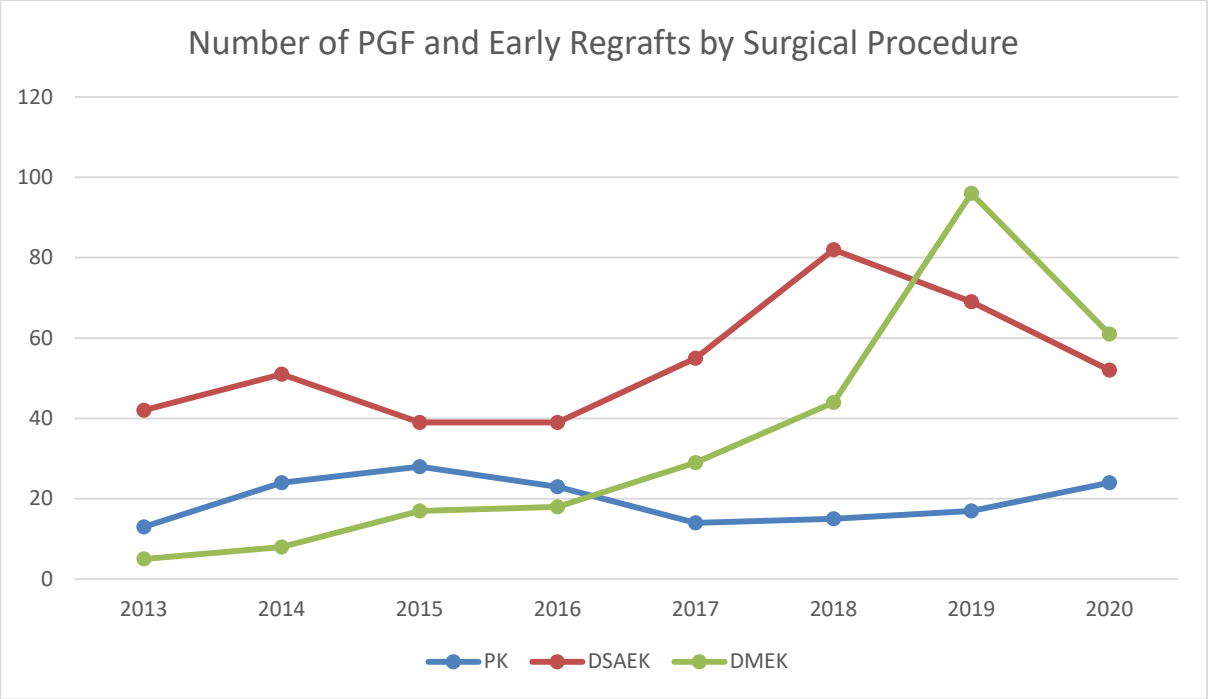


Early Regrafts

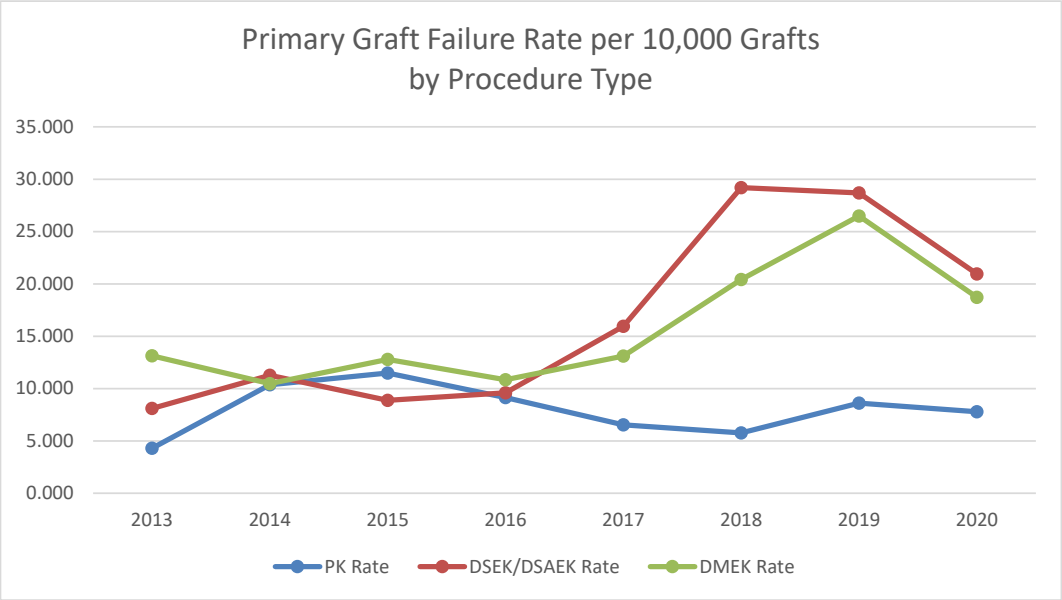
Year	2013	2014	2015	2016	2017	2018	2019	2020
PK	4	4	6	6	2	5	2	12
DSAEK	23	25	19	18	21	25	19	22
DMEK	3	5	11	11	19	22	61	39
TOTAL	**30**	**34**	**36**	**35**	**42**	**52**	**82**	**73**



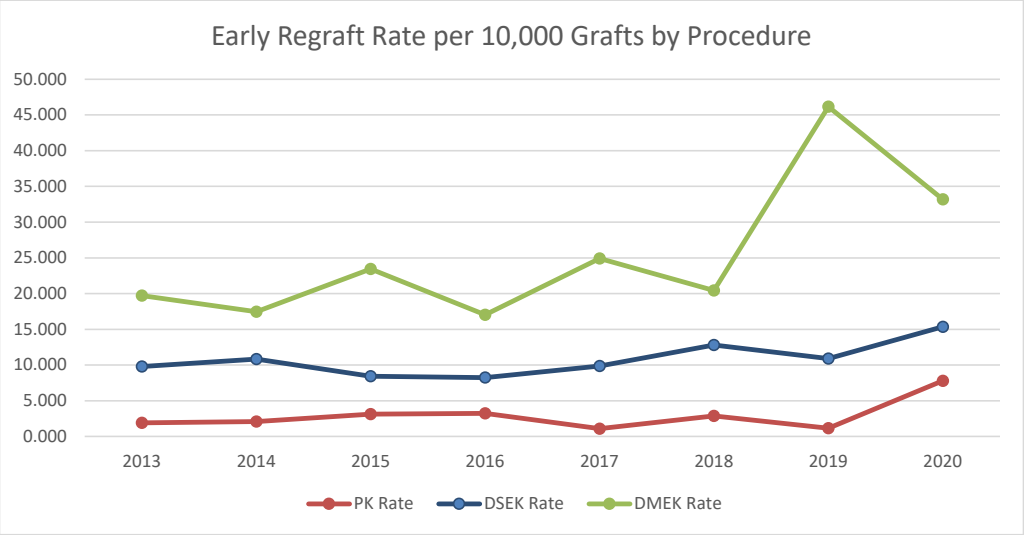
	PGF + Early Regrafts							
Year	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
PK	13	24	28	23	14	15	17	24
DSAEK	42	51	39	39	55	82	69	52
DMEK	5	8	17	18	29	44	96	61
TOTAL	**60**	**84**	**84**	**80**	**98**	**141**	**182**	**138**



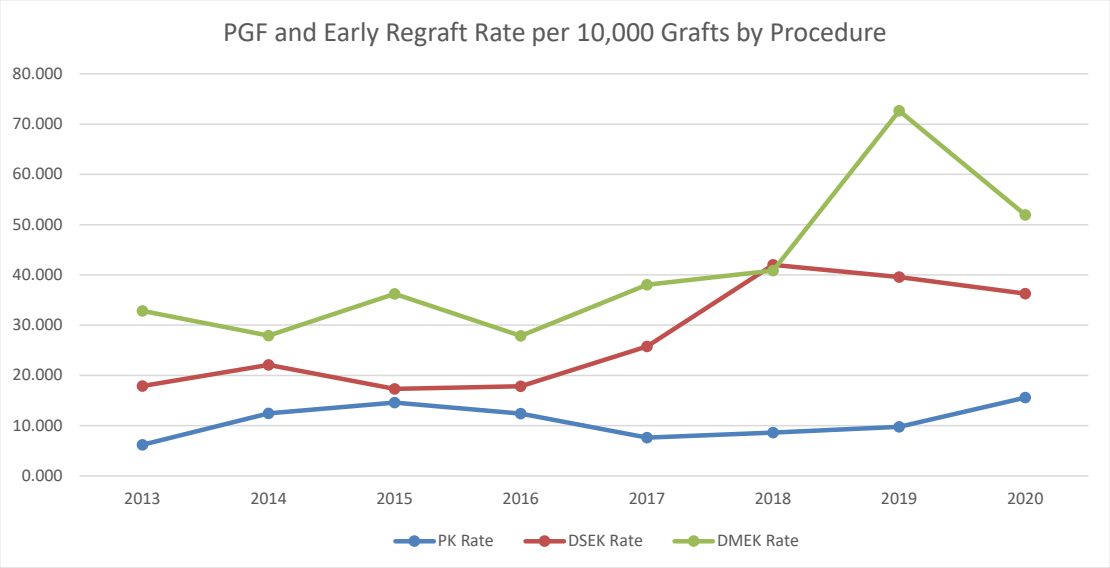
Year	2013	2014	2015	2016	2017	2018	2019	2020
PGF following PK	9	20	22	17	12	10	15	12
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402
PGF rate per 10,000 PK	**4.295**	**10.366**	**11.482**	**9.150**	**6.541**	**5.765**	**8.616**	**7.791**
PGF following DSEK	19	26	20	21	34	57	50	30
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331
PGF rate per 10,000 DSEK	**8.097**	**11.255**	**8.883**	**9.603**	**15.935**	**29.192**	**28.689**	**20.934**
PGF following DMEK	2	3	6	7	10	22	35	22
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749
PGF rate per 10,000 DMEK	**13.141**	**10.471**	**12.782**	**10.838**	**13.110**	**20.421**	**26.485**	**18.725**



Year	2013	2014	2015	2016	2017	2018	2019	2020
Early Regraft following PK	4	4	6	6	2	5	2	12
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402
Early regraft rate per 10,000 PK	**1.909**	**2.073**	**3.132**	**3.229**	**1.090**	**2.882**	**1.149**	**7.791**
Early Regraft following DSEK	23	25	19	18	21	25	19	22
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331
Early Regraft rate per 10,000 DSEK	**9.802**	**10.823**	**8.439**	**8.231**	**9.842**	**12.803**	**10.902**	**15.351**
Early regraft following DMEK	3	5	11	11	19	22	61	39
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749
Early regraft rate per 10,000 DMEK	**19.711**	**17.452**	**23.434**	**17.031**	**24.908**	**20.421**	**46.160**	**33.194**

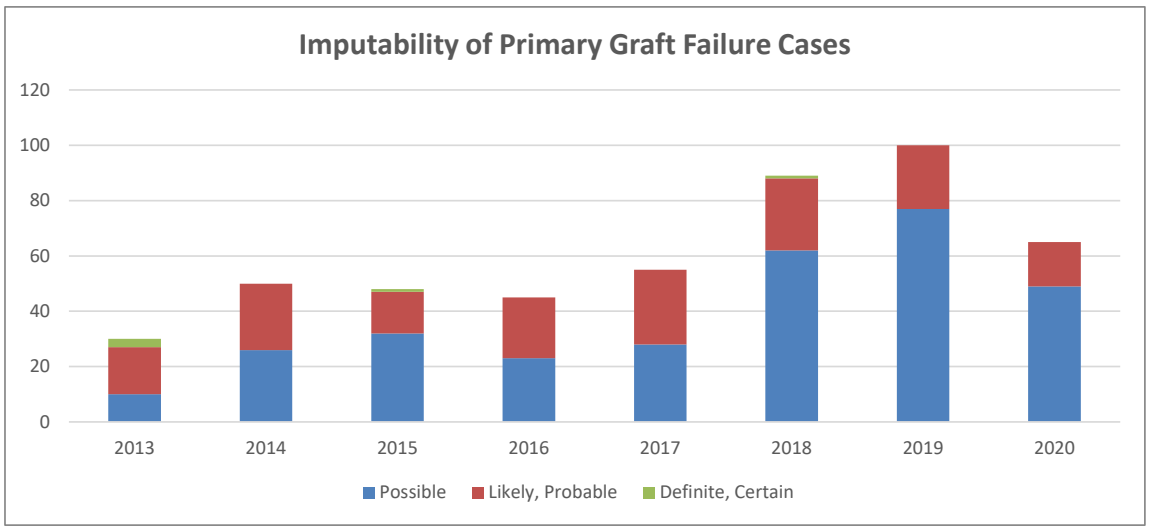


Year	2013	2014	2015	2016	2017	2018	2019	2020
PGF + Early Regaft following PK	13	24	28	23	14	15	17	24
PK Procedures	20,954	19,294	19,160	18,579	18,346	17,347	17,409	15,402
PGF + Early Regraft Rate per 10,000 PK	**6.204**	**12.439**	**14.614**	**12.380**	**7.631**	**8.647**	**9.765**	**15.582**
PGF+ Early Regraft following DSEK	42	51	39	39	55	82	69	52
DSEK Procedures	23465	23100	22514	21868	21337	19526	17,428	14,331
PGF+ Early Regraft Rate per 10,000 DSEK	**17.899**	**22.078**	**17.323**	**17.834**	**25.777**	**41.995**	**39.591**	**36.285**
PGF+ Early Regraft following DMEK	5	8	17	18	29	44	96	61
DMEK Procedures	1522	2865	4694	6459	7628	10773	13,215	11,749
PGF+ Early Regraft Rate per 10,000 DMEK	**32.852**	**27.923**	**36.216**	**27.868**	**38.018**	**40.843**	**72.645**	**51.919**



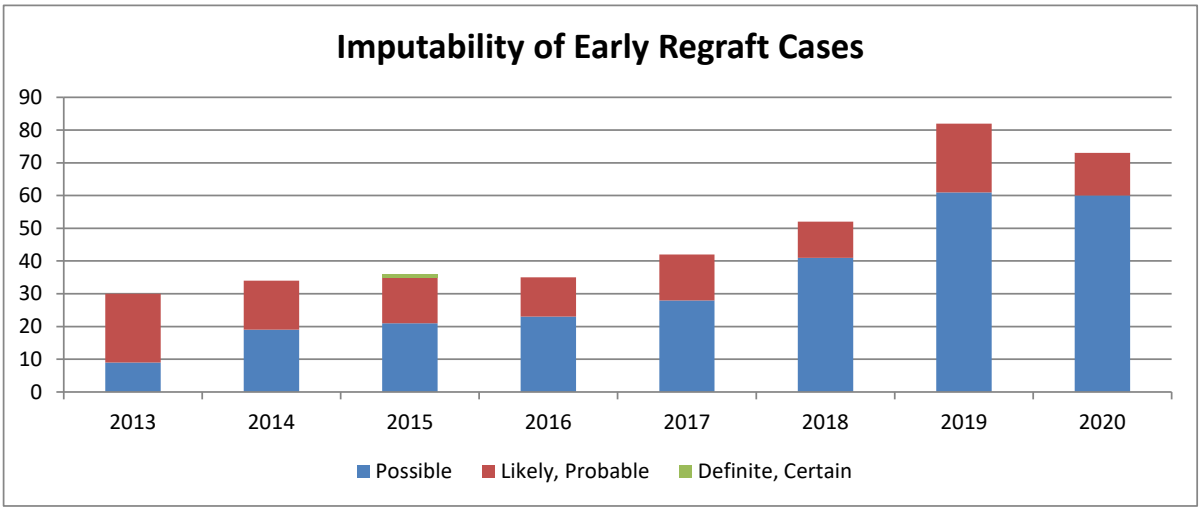
Imputability of PGF

PGF	2013	2014	2015	2016	2017	2018	2019	2020
Possible	10	26	32	23	28	62	77	49
Likely, Probable	17	24	15	22	27	26	23	16
Definite, Certain	3	0	1	0	0	1	0	0
Total Reported	**30**	**50**	**48**	**45**	**56**	**89**	**100**	**65**

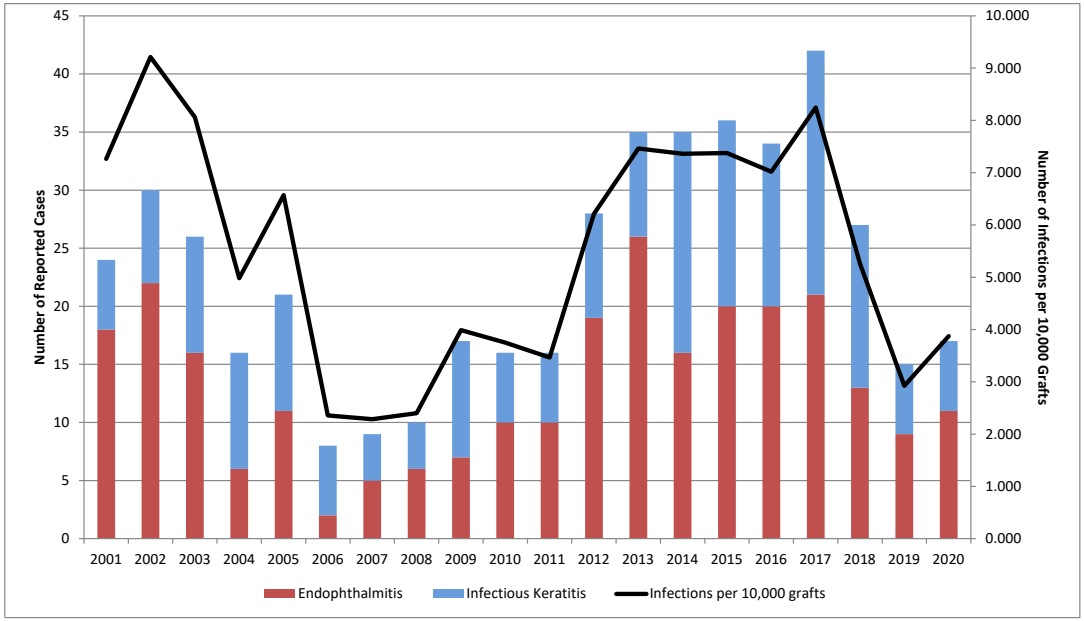


Imputability of Early Regraft

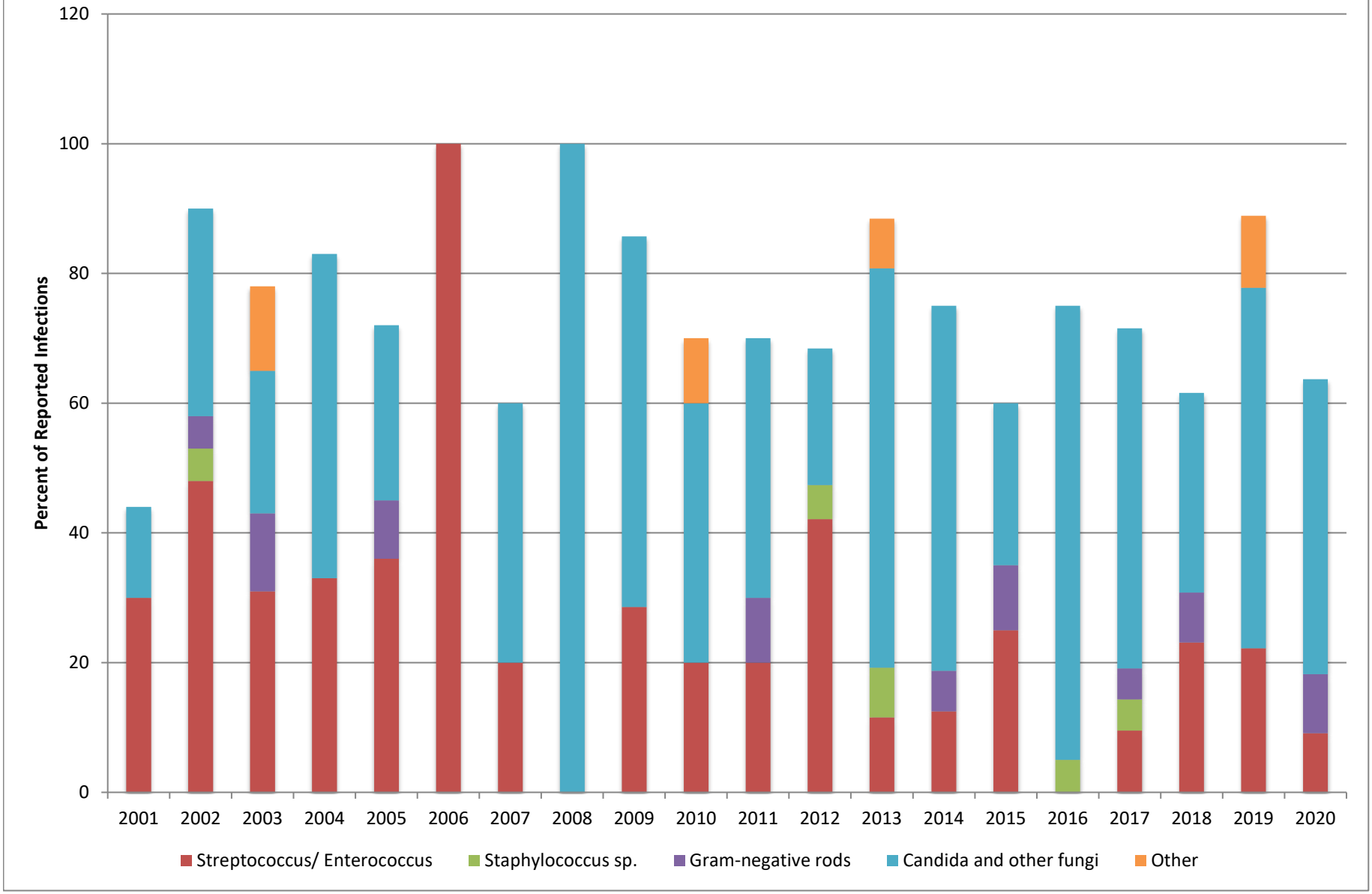
Early Regraft	2013	2014	2015	2016	2017	2018	2019	2020
Possible	9	19	21	23	28	41	61	60
Likely, Probable	21	15	14	12	14	11	21	13
Definite, Certain	0	0	1	0	0	0	0	0
Total Reported	**30**	**34**	**36**	**35**	**42**	**52**	**82**	**73**



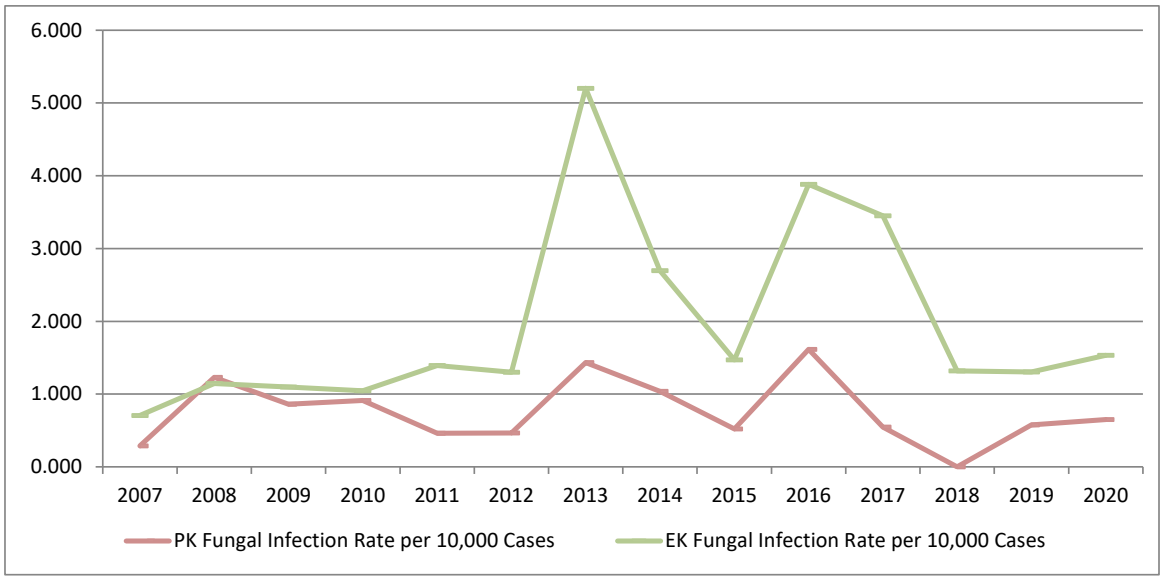
YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Endophthalmitis	18	22	16	6	11	2	5	6	7	10	10	19	26	16	20	20	21	13	9	11
Infectious Keratitis	6	8	10	10	10	6	4	4	10	6	6	9	9	19	16	14	21	14	6	6
Total Infections*	24	30	26	16	21	8	9	10	17	16	16	29	36	35	36	35	42	27	15	17
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
Infections per 10,000 grafts	7.265	9.214	8.065	4.983	6.572	2.356	2.285	2.401	3.990	3.752	3.464	6.212	7.464	7.364	7.378	7.018	8.246	5.264	2.922	3.875



Endophthalmitis Pathogens



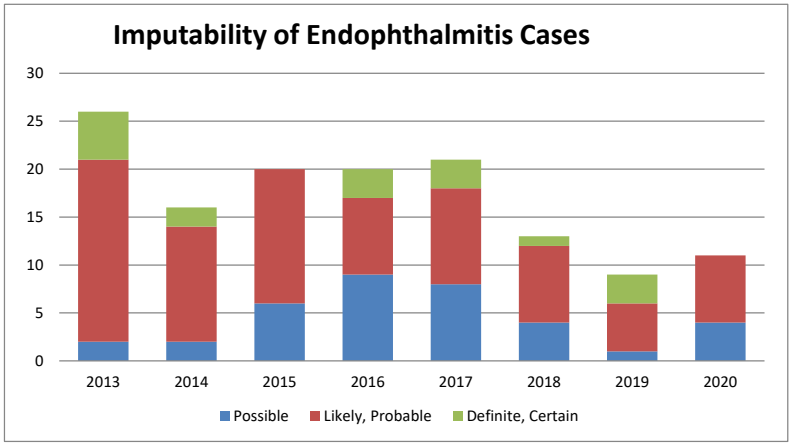
Year	Total Endophthalmitis Cases	Fungal Endophthalmitis Cases	PK Fungal Cases	EK Fungal Cases	Total Domestic PK Procedures	Total Domestic EK Procedures	PK Fungal Infection Rate per 10,000 Cases	EK Fungal Infection Rate per 10,000 Cases
2007	5	2	1	1	34806	14159	0.287	0.706
2008	6	6	4	2	32524	17468	1.230	1.145
2009	7	4	2	2	23269	18221	0.860	1.098
2010	10	4	2	2	21970	19159	0.910	1.044
2011	10	4	1	3	21620	21555	0.463	1.392
2012	19	4	1	3	21422	23049	0.467	1.302
2013	26	16	3	13	20954	24987	1.432	5.203
2014	16	9	2	7	19294	25965	1.037	2.696
2015	20	5	1	4	19160	27208	0.522	1.470
2016	20	14	3	11	18579	28327	1.615	3.883
2017	21	11	1	10	18346	28993	0.545	3.449
2018	13	4	0	4	17347	30336	0.000	1.319
2019	9	5	1	4	17409	30,650	0.574	1.305
2020	11	5	1	4	15402	26,095	0.649	1.533

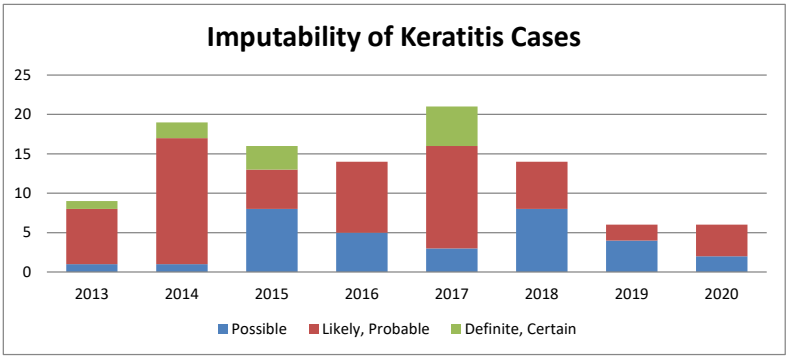


Imputability of Endophthalmitis and Infectious Keratitis

Endophthalmitis	2013	2014	2015	2016	2017	2018	2019	2020
Possible	2	2	6	9	8	4	1	4
Likely, Probable	19	12	14	8	10	8	5	7
Definite, Certain	5	2	0	3	3	1	3	0
Total Reported	**26**	**16**	**20**	**20**	**21**	**13**	**9**	**11**

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





YEAR	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Primary Graft Failure	61	78	51	31	53	53	50	54	52	31	36	31	30	50	48	45	56	89	100	65
Early Regraft												14	30	34	36	35	42	52	82	73
Endophthalmitis	18	22	16	6	11	2	5	6	7	10	10	19	26	16	20	20	21	13	9	11
Infectious Keratitis	6	8	10	10	10	6	4	4	10	6	6	9	9	19	16	14	21	14	6	6
Total Infections*	24	30	26	16	21	8	9	10	17	16	16	29	36	35	36	35	42	27	15	17
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
Percent Infections	0.073	0.092	0.081	0.050	0.066	0.024	0.023	0.024	0.040	0.038	0.035	0.062	0.075	0.074	0.074	0.070	0.082	0.053	0.029	0.039
Infections per 10,000 grafts	7.265	9.214	8.064	4.983	6.572	2.356	2.285	2.401	3.990	3.752	3.464	6.212	7.464	7.364	7.378	7.018	8.246	5.264	2.922	3.875
PGF per 10,000 grafts	18.465	23.957	15.819	9.656	16.587	15.606	12.693	12.965	12.205	7.270	7.793	6.640	6.220	10.520	9.838	9.024	10.995	17.351	19.480	14.815
Early Regraft per 10,000 grafts												2.999	6.220	7.153	7.378	7.018	8.246	10.138	15.973	16.639

Endophthalmitis Pathogens	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Streptococcus/ Enterococcus	30	48	31	33	36	100	20	0	28.57	20	20	42.11	11.54	12.5	25	0	9.52	23.1	22.2	9.1
Staphylococcus sp.	0	5	0	0	0	0	0	0	0	0	0	5.26	7.69	0	0	5	4.8	0	0	0
Gram-negative rods	0	5	12	0	9	0	0	0	0	0	10	0	0	6.25	10	0	4.8	7.7	0	9.1
Candida and other fungi	14	32	22	50	27	0	40	100	57.14	40	40	21.05	61.54	56.25	25	70	52.4	30.8	55.6	45.5
Other	0	0	13	0	0	0	0	0	0	10	0	0	7.69	0	0	0	0	0	11.1	0
No growth	28	5	22	0	9	0	0	0	0	20	10	15.79	7.69	12.50	20	10	0	0	0	18.2
Not done	28	5	0	17	18	0	40	0	0	10	20	21.05	3.85	12.50	20	15	23.8	38.5	11.1	18.2

	2001	2002	2003	2004	2005	2006	2006	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Fungal	14	32	22	50	27	0	40	100	57.14	40	40	21.05	61.54	56.25	25	70	52.4	30.8	55.6	45.5
Bacterial	30	58	56	33	45	100	20	0	28.57	30	30	47.37	26.92	18.75	35	5	23.8	30.8	33.3	18.2

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

JUNE 1, 2021 INFORMATIONAL ALERT:
UPDATED GUIDANCE AND COVID-19 SCREENING RECOMMENDATIONS

DONOR ELIGIBILITY

PCR Test Status*	COVID-19 Signs†	COVID-19 Symptoms‡	Plausible Alternative Etiology (Signs / Symptoms)	Close Contact§	Donor Fully Vaccinated¶	Eligibility
Positive within the last 28 days	Yes or No	Yes or No	Yes or No	Yes or No	Yes or No	Not Eligible
Negative (post-mortem or recent pre-mortem test)	Yes	Yes or No	Yes	Yes	Yes or No	Medical Director Review
				No	Yes or No	Eligible
			No	Yes or No	Yes or No	Not Eligible
	No	Yes	Yes	Yes	Yes or No	Medical Director Review
				No	Yes or No	Eligible
			No	Yes or No	Yes or No	Not Eligible
		No	N/A	Yes	Yes	Eligible
					No	Medical Director Review
				No	Yes or No	Eligible
Not done	Yes	Yes or No	Yes	Yes	Yes	Medical Director Review
					No	Not Eligible
				No	Yes or No	Medical Director Review
			No	Yes or No	Yes or No	Not Eligible
	No	Yes	Yes	Yes	Yes	Medical Director Review
					No	Not Eligible
				No	Yes or No	Medical Director Review
			No	Yes or No	Yes or No	Not Eligible
		No	N/A	Yes	Yes	Medical Director Review
					No	Not Eligible
				No	Yes or No	Eligible

[*]PCR Test Status	
RT-PCR SARS-CoV-2 test performed 28 days prior to or less than 24 hours after death. If performed, but result is indeterminate or inconclusive, then donor should be deferred.	
[†]COVID-19 Signs	
Development of one of the following signs consistent with possible COVID-19 infection within the 28 days prior to death: • ARDS • Pneumonia • Pulmonary computed tomography (CT) showing "ground glass opacities"	
[‡]COVID-19 Symptoms	
Development of acute symptoms consistent with COVID-19 infection within the 28 days prior to death	
One of the following: • Fever or chills • Cough • Shortness of breath or difficulty breathing • New loss of taste or smell	**OR** two of the following: • Fatigue • Muscle or body aches • Headache • Sore throat • Congestion or runny nose • Nausea or vomiting • Diarrhea
[§]Close Contact	
Close contact is defined by the CDC as: *(**IF** such contact occurs while not wearing recommended personal protective equipment)*	
a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case	**OR** b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on).
[¶]Vaccination	
Donor would be considered fully vaccinated, as defined by the CDC , at the time of death if he/she were: • 2 weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or • 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine	

GUIDANCE RATIONALE

The EBAA Policy & Position Review Subcommittee of the Medical Advisory Board continues to update guidance and screening recommendations as the COVID-19 pandemic evolves. Progression in our understanding of the utility of donor screening for the SARS-CoV-2 virus, the risk of transmission via corneal transplantation and means to minimize this risk will allow for the continued provision of safe corneal tissue to patients while minimizing the wastage of suitable donor corneal tissue. As we return to pre-pandemic levels of elective corneal transplantation procedures across the US, eye bankers and corneal surgeons should keep in mind the following with regard to the safety of corneal tissue:

1. 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.[1] If vaccination status of a donor is known, it must be communicated to end-users on Tissue Report Forms or other supporting documents.
2. Current Medical Standards of the EBAA requires use of a double povidone iodine donor prep; povidone iodine has documented in vitro viricidal activity against coronaviruses.
3. The EBAA acknowledges that other associations, hospital systems, eye banks, departments of health, or governments may require that all donors be tested for COVID-19. Eye banks must establish a protocol to ensure access to testing notification and results obtained by partner agencies. Results of such testing must be communicated to end-users on Tissue Report Forms or other supporting documents.
4. 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.

5. There have been no reported cases of transmission of SARS-CoV-2, MERS-CoV, or any other coronavirus via transplantation of ocular tissue.[2]

REFERENCES

[1]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, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments.

[2]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 Mar 29. Epub ahead of print.

Accreditation Board Report June 2021

1) Proposed Revision to Medical Standard C3.200

C3.200, paragraph 2 from "Testing of the alarm system must be performed and documented on a regular basis." to "Testing of the alarm system must be performed and documented on a regular basis in accordance with manufacturer recommendations, but at least annually."

Additionally, add a question to the SIQ stating "Does the alarm system function properly".

> *This question can be verified by having the eye bank perform a high or low alarm test during the inspection. The inspector should make sure the alarm is triggered and any call out is initiated. If the eye bank has a call tree, then it is unnecessary to have the alarm system go through the entire call tree. Having it trigger one call out will show that the alarm system is functioning.*

2) Proposal to add to the Definition of Terms

Annually. A period less than or equal to 365 calendar days.

E1.000 Recovery, Open-Container Processing and Preservation

Reference:

Croasdale, C. R., Schwartz, G. S., Malling, J. V., & Holland, E. J. (1999). Keratolimbal allograft: Recommendations for tissue procurement and preparation by eye banks, and standard surgical technique. *Cornea, 18*(1), 52-58.

Lindquist, T. D., Miller, T. D., Elsen, J. L., & Lignoski, P. J. (2009). Minimizing the Risk of Disease Transmission During Corneal Tissue Processing. *Cornea*, 28(5), 481-484.

Oiland, D. (1997). Ch. 37 tissue removal. In J. H. Krachmer, M. J. Mannis & E. J. Holland (Eds.), *Cornea, fundamentals of cornea and external disease* (pp. 493-500). St. Louis: Mosby

Rosenwasser, G. O. D., & Nicholson, W. J. (2003). Surgical processing techniques in eye banking. *Introduction to eye banking: a handbook and atlas.* (1st ed.) (pp. 17-24).

Soper, M. C., & Lisitza, M. A. (1999). Ch. 103 tissue removal. In F. S. Brightbill (Ed.), *Corneal surgery: Theory, technique & tissue* (3rd ed.) (pp. 882-887). St. Louis: Mosby.

E1.100 Recovery

E1.110 Pre-ocular Tissue Recovery and Donor Preparatory Procedures

Purpose:

To delineate standardized procedures for preparation of the donor and activities to be completed before the removal of the ocular tissue by enucleation or in situ corneal excision.

These procedures include the following:

Ensure appropriate supplies before traveling to donor site
Verify consent for ocular tissue removal
Check the donor's history and medical record Identification of the donor
Don personal protective equipment
Perform physical examination/inspection of the donor and penlight examination
Draw blood sample
Evaluate recovery site
Prepare the work site
Donor preparation: Irrigation and prep of the operative site
Set up of the sterile field
Draping of the donor
Penlight Examination

Reference:

Alp, B. N., Elibol, O., Sargon, M. F., Aslan, O. S., Yanyali, A., Karabas, L., Talu, H., & Caglar, Y. (2000). The effect of povidone iodine on the corneal endothelium. *Cornea*, 19(4), 546-550.

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AST Standards of Practice for Surgical Attire, Surgical Scrub, Hand Hygiene and Hand Washing https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Surgical_Attire_Surgical_Scrub.pdf

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Materials Needed:

1. Sterile Supplies:

Sterile ophthalmic irrigating solution; e.g. normal saline or balanced salt solution
Sterile 5% povidone-iodine ~~or antibiotic solution~~ (for in situ excision)
Sterile gloves
Sterile gown or sterile sleeves
Sterile supplies used in whole eye enucleation and in situ corneal excision. See procedure E1.100 and E1.200.
Povidone-iodine antiseptic swabs or sterile preoperative skin prep tray Alcohol swabs
Syringe needle or a vacutainer apparatus to draw blood
Moisture impermeable table drape and antiseptic solution to clean work table
Sterile scrub brush for hands (with antimicrobial hand soap)

2. Non-Sterile Supplies:

Forms (Screening form, enucleation/excision form, donor information form per your eye bank's policy)
Non-sterile gloves
Protective moisture impermeable clothing Protective eyewear (goggles or face shield) Mask
Cap to cover hair
Non-sterile supplies used in whole eye enucleation and in situ corneal excision Penlight

Procedure	**Rationale**
1. Ensure appropriate supply before traveling to donor site. Check expiration dates and integrity of sterile instrument kits and sterile equipment before leaving the eye bank laboratory. Pack necessary instruments kit(s), as well as all necessary supplies, and transport in clean bag or case to donor site. The eye bank must have a specific policy and procedure for back up instruments which may be missing from the kit or which become contaminated. This may be accomplished by taking an extra instrument kit and supplies.	1. To assure sterility of instruments and supplies.
2. Verify consent for ocular tissue removal. Obtain and review the consent/authorization form. Confirm that it has been completed fully and has signatures of consenting legal next-of-kin. Leave original in the donor's chart and take a photocopy for the eye bank's record. See procedure D1.300. If your eye bank uses a means of obtaining consent other than written consent it is	2. To verify whether consent is for whole eyes or corneas only and that consent is valid prior to removal of any ocular tissue.

	essential that the consent procedure conforms to state law and that documentation of the consent/authorization is retained.	
3.	Check the donor's history and medical record. Review the donor's medical history by means of chart review or interviews with knowledgeable medical staff.	3. To verify the accuracy of all reported information.
4.	Identify the donor. Match the name on the consent form to the name on the donor's ID tag, e.g., toe tag or bracelet. Never assume the identity of the donor in the absence of checking appropriate sources on the body.	4. To verify the accuracy of all reported information.
5.	Don personal protective equipment. Follow all eye bank procedures related to Standard Precautions. Put on protective apparel, including gloves, mask, cap to cover hair, protective eye wear such as goggles, safety glasses or face shield, and moisture impermeable protective clothing.	5. To protect the eye bank technician from potential exposure to infectious disease.
6.	Perform physical examination/inspection of the donor and penlight examination of the donor's eyes. Perform gross inspection of the donor. Examine the entire body of the donor for evidence of needle tracks, recent homemade tattoos, male-to- male sexual contact or physical signs of HIV, hepatitis, or evidence of sexually transmitted diseases. If an in-situ cornea recovery is to be performed, use a penlight to grossly examine the eyes for signs of infection, corneal damage, embedded foreign bodies, iris abnormalities, or previous surgery. Examination of the entire body may require assistance to remove clothing and turn the body. Also see procedure D1.200 (Y).	6. To provide and record further evidence that the donor is in physically acceptable condition and free of signs of high risk for HIV, hepatitis or other infection. See EBAA Medical Standard D1.000 Donor Eligibility Determination. Medico-legal restrictions to distinct areas of the body, as may occur in a medical examiner or Coroner's case, may warrant attainment of exam info pertaining to these specific areas by a third party. Additionally, a recent ante-mortem physical exam or a post-mortem physical exam performed by another agency (e.g. OPO) may be used to supplement an eye bank post- mortem physical when circumstances prevent a complete examination of the body (e.g. organ donor or morbidly obese donor). Document the use of any information obtained from sources other than eye bank personnel accordingly.
7.	Draw a blood sample.	7. To obtain the serum necessary for EBAA and FDA required serology testing.

See procedure E1.700. Be sure to verify the donor's infusion/transfusion history and whether a pre-infusion/transfusion sample is required. Always strictly adhere to ***Standard Precautions*** when drawing a blood sample. Immediately label every sample with the donor's identification number and date and time of draw. The sample may be drawn before or after the ocular tissue has been recovered, per your eye bank's policy.	
8. Evaluate the recovery site. The recovery site must be qualified prior to the recovery to prevent contamination and cross contamination during the recovery process. The site should be in a good state of repair; be of appropriate size and location to permit aseptic procedures; and have adequate ventilation, airflow, and lighting.	8. To prevent the introduction, transmission, and spread of communicable disease. See FDA sec. 1271.190.
9. Prepare the work site. Identify a suitable worktable, Mayo stand, or counter space near the donor on which to set up your sterile field. Clean this area with a disinfectant and cover the surface with a moisture impermeable barrier drape. The sterile field will be set up on this area.	9. To ensure a clean area for set up of the sterile field.
10. Prepare the donor.	
A. Elevate the donor's head if this has not already been done.	A. To prevent pooling of blood in the orbital area which could lead to excessive bleeding, swelling, and bruising post ocular tissue removal.
B. Gently open each eye-lid and thoroughly irrigate the corneal and conjunctival sac of each eye following the procedure approved by the eye bank medical director. The procedure must include 2 rinses with a 5% povidone-iodine (PI) solution that covers the entire corneal surface, conjunctiva, lids, and lashes. The contact time for each application must be between 2 and 5 minutes and the PI shall be irrigated between applications. ~~rinses of each eye with a sterile ophthalmic solution such as a normal saline or~~	B. To remove debris, microorganisms and other sources of contamination from the donor's eye. Antibiotic solution retards and prevents microbial growth. Povidone-iodine solutions must be carefully removed from ocular surfaces to prevent corneal toxicity. Per EBAA medical standards, a 5% p~~P~~ovidone-i-~~I~~odine solution shall contact ~~any~~ all ocular tissue intended for transplantation ~~at least once~~ twice between the time of the donor's death and tissue preservation. The concentration (5~~i.e. 1-10~~%), volume of

~~balanced salt solution. Additional rinses with ophthalmic povidone- iodine solutions may also be included.~~ Irrigation of the eyes with a broad-spectrum ophthalmic antibiotic such as gentamicin or polymyxin B may also be included in the irrigation procedure. Care should be given to rinse ~~povidone-iodine~~PI solutions and antibiotics from each eye with sterile ophthalmic solutions such as sterile saline within reasonable time limits.

solution, and the duration of ocular surface exposure (~~e.g. 3 mins.)~~ 2-5 minutes) to the solution shall be specified in the eye bank's operating procedures and ~~determined~~ approved by the Medical Director.

C. Clean the orbital area and surrounding skin, using alcohol or gauze moistened with water.

C. To remove gross blood, dirt, or debris from the donor's skin.

D. Perform a prep of the operative area (the operative site) using povidone-iodine solution. Do not use antiseptic products like Hibiclens or Phisohex, as this has been shown to be toxic to the cornea. The technique used to perform the prep should be a standard pre-operative skin prep. (See Berry and Kohn's or other surgical textbook for illustrations and in depth discussion.) The prep should start at the medial canthus of the upper closed eyelid and move out, around and below the lid, over the bridge of the nose, in an ever-widening circular pattern. Do not go over the same area twice. Cleanse each orbital area in this manner at least twice.

   Following this, a povidone-iodine paint may be applied, per your eye bank's protocol.
   Avoid getting any povidone-iodine solution or paint into the eye during this prep. Any povidone-iodine product applied to the eye at this point must be promptly rinsed to avoid toxicity to the cornea.

D. The use of friction mechanically removes microorganisms. This is combined with an antiseptic solution to further kill organisms and reduce the microbial population to the minimum possible.

E. Remove your prep gloves and dispose of them in a biohazard bag.

11. Prepare the sterile field

A. Prepare the sterile field by first placing the sterile instrument tray on your prepared work surface. Remove the plastic dust cover if one has been applied. Verify that the instrument tray is sterile by

A. Develop a sterile conscience to protect the sterile field from inadvertent contamination.

checking the expiration date and the integrity of the wrap. Carefully open the inner wraps. Open additional sterile supplies or equipment, such as cotton-tipped applicators, 4 x 4 gauze, and eye jars by carefully peeling the bags and flipping the items onto the sterile field. If performing an in situ excision, set up the vials or chambers containing corneal preservation medium adjacent to your sterile field, but not touching the field.

B. Open the outside package(s) of sterile gloves and sterile gown or sleeves. Scrub hands and forearms from fingertips to elbows, using an antiseptic scrub brush or solution such as Hibiclens, Avagard, povidone-iodine, or other approved preoperative surgical hand antisepsis product. Scrub for three to five minutes using standard surgical hand antisepsis technique or follow the manufacturer's instructions. Rinse thoroughly and dry with a sterile towel, drying from fingertips to elbows (if applicable).

B. See OR textbook (Berry and Kohn or MMWR October 25, 2002 / 51(RR16); 1-44) for a more detailed and illustrated guide on scrubbing. If a sterile gown is not used, sterile sleeves may be substituted.

C. Don sterile sleeves using aseptic technique. Double glove if this is your eye bank's policy. Powdered gloves should not be used.

C. Glove powder contaminants may appear reflective during slit lamp examination and as foreign bodies and may contribute to post- operative complications. See EBAA Informational Alert from March 16, 2012 regarding the *Potential Consequences of Use of Powdered Gloves.*

D. Don sterile sleeves by slipping on and over gloved hands.

D. If double gloving, the second pair of gloves is donned after the sterile gown or sleeves.

E. If using a sterile gown, aseptically don sterile gown, then don sterile gloves. If double gloving, don second pair after donning the first pair.

12. Drape the donor

Drape the donor with sterile drapes according to your eye bank's policy. Place a fenestrated sterile eye drape over each eye so that both eyes can be visualized. Once in place, do not move the drape(s) around. At this point consider only the inner area of the

12. The drape(s) provides the technician with a sterile surface around each eye on which to work.

In order to avoid contaminating the second eye, both eyes should be draped at once with a fenestrated drape to expose each eye. One drape for each eye may

drape to be sterile.

be used as long as a portion of one drape does not overlap the opposite eye.

E1.120 Enucleation

Purpose:

To provide a standardized method for the aseptic removal of human eye tissue.

This procedure describes the basic technique for performing an eye enucleation according to EBAA standards. Certain portions of the procedure are at the discretion and direction of your eye bank's medical director. Please refer to your eye bank's procedures manual as directed.

Regulatory:

21 CFR 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases

Reference:

Rosenwasser, G. O. D., & Nicholson, W. J. (2003). Enucleation technique. *Introduction to eye banking: a handbook and atlas.* (1st ed.) (pp. 31-40).

Materials needed:

1. Sterile Supplies:

   A sterile instrument tray: (The tray may either be irradiated, or steam or gas sterilized, appropriately wrapped, labeled with expiration date, and stored in plastic according to your eye bank's policy.)

   1 Small curved scissors
   1 Large curved enucleation scissors
   1 Small (mosquito) curved hemostat
   1 Small muscle hook (retractor)
   1 Small toothed forceps
   1 Eyelid speculum
   2 Fenestrated eye drapes or 1 double-fenestrated drape
   2 Plain drapes (optional, if the fenestrated drapes are moisture impermeable)
   1 Hemostat for handling ophthalmic irrigating solution
   2 x 2 gauze sponges
   Cotton balls
   Sterile cotton-tipped applicators
   Sterile eye jars, either glass or plastic. The eye jars may be sterilized within your instrument tray or separately. They should contain dental roll, gauze, or metal cage to hold the eye.
   Sterile gloves (at least 2 pair)
   Sterile gown or sleeves

2. Non-sterile Supplies:

   Styrofoam container for transporting the

eyes Personal protective equipment.

Procedure	Rationale
1 All donor preparatory and pre ocular tissue recovery procedures should be performed according to procedure E1.110.	1. Ensure all appropriate steps were taken for recovery of the ocular tissue from the correct donor and that tissue has been sufficiently prepared.
2 Set up the sterile right and left eye jars. Check instruments to be sure none are missing or damaged.	2. Ensure all necessary supplies/instruments are present prior to beginning the aseptic recovery
3 According to your eye bank's policy, begin with the left or right eye. Using 2 x 2 gauze or cotton tipped applicator, gently open the upper eyelid by pulling towards the top of the head, insert the closed lid speculum under the upper and lower eyelids near the nose. Slowly open the speculum while moving toward the middle of the eye. Be very careful not to touch the cornea with the speculum.	3. This provides access to the eye during the enucleation procedure.
4 Grasp the conjunctiva with the forceps, near the lateral edge of the cornea at the limbus. Cut the conjunctiva with the small, round tip scissors pointed away from the cornea. Continue this 360^{o} around the cornea.	4. Cutting the conjunctiva provides the enucleator access to the ocular muscles and optic nerve and removes a membrane that may be contaminated with bacteria.
5 Insert the closed scissors under the conjunctiva and perform a blunt dissection.	5. To facilitate access to the ocular muscles.
6 Using a muscle hook and small scissors elevate and sever ocular muscles. A hemostat may be applied to clamp either the lateral or medial rectus muscle prior to cutting to provide a safe “handle” for the eye.	6. This description of cutting the ocular muscles is one of several ways to remove the eye. Please refer to your local eye bank's procedure manual for any variation. All 6 ocular muscles must be isolated and severed; however, the order and technique may differ. Be careful not to puncture the globe while severing of the muscles. The sclera is thinnest underneath the insertion sites of the ocular muscles. Do not traumatize the cornea during this procedure.
7. With the globe still rotated laterally, insert the closed blades of the large enucleation scissors behind the back of the eye. Open the blades slightly and position the optic nerve between the blades. Push the scissors towards the back of the orbit and cut the optic nerve, leaving 5- 10mm stump.	7. A 5-10mm optic nerve stump will assure that it is not cut too close to the posterior so as to risk puncture and collapse of the globe. A generous stump also allows for sufficient length to anchor the eye in the cage, if used, by pulling the stump through the bottom.

8. Use the hemostat, which is clamped to the medial rectus muscle, to gently lift the globe from the socket. Carefully cut any remaining connective tissue.

8. The globe will be completely removed from the socket after this step.

9. Secure the eye in a sterile eye jar that can be sealed from the environment. Using a dental roll, gauze, cotton ball or metal cage, orient the eye to prevent trauma to the cornea. If using a metal cage, place the optic nerve through the hole and either clamp or pin the nerve in place. If using gauze or dental roll, ensure that the epithelium is not contacted by the material for the duration of the shipment.

9. Although pins have been used to secure the eye in the cage, they introduce increased risk of puncture to the ocular tissue and the eye bank technician. They may also be difficult to remove.

10. Pour a ***small amount*** or approximately 5 ml of balanced salt, antibiotic solution, or other sterile ophthalmic irrigating solution over the eye (just enough to moisten the gauze, dental roll or cotton in the bottom of the jar).

10. The addition of the solution maintains a moist chamber effect to avoid desiccation of the globe. Overfilling the moist chamber such that the cornea is submerged in hypertonic solution may cause irreversible damage to the cornea.

11. Reglove or remove outer glove. Repeat steps (1-13) above for the other eye. The second eye should already be draped.

12. Donor Reconstruction

    A. Remove drapes

    A. Gently remove drapes so as not to damage the donor's skin or accidentally remove eyebrow or eyelashes.

    B. Place a folded piece of gauze or a cotton ball in the socket and insert eye caps per your eye bank's policy. Close the eyelids and gently wipe off the povidone-iodine or other solution by patting with moist gauze.

    B. To restore the appearance of the donor. Minimal or gentle manipulation of the eyelids will help decrease post-mortem discoloration and swelling.

    C. If necessary, control excessive bleeding. Check with your local funeral directors and follow your eye bank's protocol. Trocar buttons, local cauterizing agents, gel foam, and other techniques may be used.

    D. Leave the donor's head elevated.

    E. Remove surgical gloves, don clean gloves, and place the lids on both jars, being careful NOT to touch the inside of the jar or lid.

    F. Label each eye jar (see procedure J1.000) and place both jars in transport container with frozen water beginning to melt to maintain the temperature between 2-8o C. (Label non-surgical tissue according to H1.000

    G. Record information about the enucleation in the donor's medical record according to your eye bank's policy.

C. These procedures may be developed in consultation with your local funeral directors, hospitals, and skin or tissue bank(s).

D. Promotes blood and fluid to drain away from the face to reduce bleeding and swelling.

E. Surgical gloves should be removed so that the exterior of the jars are not contaminated with eye tissue or body fluid, avoiding the creation of a potential biohazard.

F. The non-sterile labels are added to the jars after sterile handling of the exterior is completed.

G. To fulfill The Joint Commission requirements on documentation of tissue and organ removal. TS.03.02.01 requires documentation of dates, times, and staff involved when tissue is accepted, prepared, and issued.

H. Complete the eye bank's enucleation form, as required.

I. Leave a form or attach a tag to the body informing the funeral director that the eyes have been removed and to keep the head elevated. Also give the eye bank's name, location, and phone number with instructions to notify the eye bank if there are any questions or problems.

I. These procedures may be developed in consultation with your local funeral directors, hospitals, and skin or tissue bank(s).

J. Don nonsterile gloves and rewrap the donor in the body bag or shroud and return to the storage location from which it was removed.

K. Clean the work area. Discard all used disposables in a biohazard bag and all sharps in a sharps container.

K. Disposable instruments should be discarded as sharps in a sharps container.

L. Rewrap any non-disposable instruments for return to the eye bank or for cleaning and sterilization by the facility if necessary.

L. Be sure that used non-disposable instruments are marked as biohazardous during transport.

M. Transport the eyes to the eye bank as soon as possible.

E1.130 In Situ Cornea Excision

Purpose:

To provide a standardized method for the aseptic in situ removal of corneal tissue for surgical use that will minimize endothelial cell loss and contamination, and maximize the number and quality of cells that are ultimately grafted.

Reference:

Rosenwasser, G. O. D., & Nicholson, W. J. (2003). In-situ excision. *Introduction to eye banking: a handbook and atlas.* (1st ed.) (pp. 57-63).

Regulatory:

21 CFR 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases 21 CFR 1271.220 Process Controls

Materials needed:

Skin prep tray, 5% povidone-iodine solution ~~or other microbicidal solution~~ and sterile 4 x 4's or Sterile ophthalmic irrigant solution, such as sterile saline
Sterilized, appropriately wrapped instrument tray to include the following:

1	Lid speculum
2	Forceps with teeth
2	Pair of iris or tenotomy scissors
2	#11 or #15 blades
1	Corneal section scissors, Castroviejo scissors, or Aebli Scissors
1	Pair of forceps to handle lids of medium (optional)

2 sterile corneal storage containers (e.g. corneal viewing chambers) 2 vials of corneal tissue culture preservation medium
Two single fenestrated drapes or one double fenestrated drape, or sterile towels
Culturettes or other items specified by your eye bank if culturing of the corneoscleral rim at time of removal is desired.

Procedure	Rationale
1. All donor preparatory procedures prior to ocular tissue recovery should be performed according to procedure E1.110. As noted in step 10D, in situ excision is a tissue preservation procedure requiring 2 applications of povidone-iodine, followed by a normal saline or balanced salt solution rinse. The povidone- iodine solution concentration ~~should conform to your eye bank's standard operating procedure, generally between 1% and 10~~must be 5%.	1. Application of povidone-iodine to the corneal surface prior to preservation of the cornea for transplant is a required precaution to reduce the bioburden of the exterior corneal surface. Medical Standard E1.110 dictates that povidone-Iodine shall contact the surface of the ocular tissue intended for transplant ~~at least once~~ twice between the time of the donor's death and tissue preservation.

2. Some eye banks may perform a culture at the time of procurement. Please refer to section G1.200 and your eye bank's policy for specific direction about cultures.	2. Performing a procurement culture is at the discretion of the eye bank's medical director.
3. Label the corneal storage containers, loosen the caps to the top thread, and place the containers adjacent to a top corner of the sterile field. If sterile containers are dropped onto the sterile field the containers are labeled as soon as possible at the end of the procedure.	3. Take care in the positioning of the storage medium vials to avoid accidentally knocking over the vials while reaching for instruments if they are at the bottom of the field or contaminating the field by reaching over if they are at the top of the field.
4. If required by the coroner or medical examiner, label test tubes for blood and vitreous samples and position near the sterile field along with the syringe, needle, and cosmetic restoration materials.	
5. Open the eyelid using a sterile cotton tipped applicator and insert a solid blade eye speculum.	5. Take care not to touch cornea with the solid blade eye speculum when placing it under the eyelid.
6. Lift and cut the conjunctiva at the limbus 360o around the cornea using small-toothed forceps and iris or tenotomy scissors. Any adhesions between the conjunctiva and the anterior globe are separated so that the conjunctiva is not in contact with the anterior globe to within 5 mm of the limbus. Remove any remaining conjunctiva by carefully scraping from the limbus with a scalpel blade. If the tissue is being recovered for cadaveric limbal allograft, leave approximately a two-millimeter skirt of conjunctiva around the corneal limbus.	6. Removing the conjunctiva close to the limbus prevents slippage of the rim while it is mounted on an artificial anterior chamber. Slippage can cause damage to the cornea during the lamellar keratectomy pass of the microkeratome rendering the cornea unusable. Additionally, the conjunctival tissue can increase the burden of microorganisms that travel with the donor tissue, increasing the potential for contamination during transplantation. Leaving 2mm of conjunctiva will help ensure that tissue may be suitable for surgeries for patients in need of limbal stem cells. Any grossly contaminated or jaundiced conjunctiva should be removed completely without damaging the limbus to reduce the introduction of contaminants to the preservation media.
7. Isolate the instruments used to manipulate the exterior surfaces of the eye, including those instruments used in the removal of conjunctiva (if performed), from the other instruments on the sterile field. Use these only for the same purpose on the opposite eye.	7. Exterior surfaces of the eye have been exposed to environmental contaminants. Avoid mechanical introduction of microorganisms to the interior surfaces of the cornea by keeping instruments used for the different parts of the procedure appropriately separated.

8. Make an incision through the sclera 2 mm - 4 mm from the limbus and parallel to the limbus. Carefully cut all the way through the sclera without perforating the choroid.	8. Perforation of the choroid causes vitreous leakage, which may collapse the globe including the anterior chamber and compromise the corneal endothelium. Additionally, vitreous leakage would make cosmetic restoration more difficult.
9. Extend the scleral incision 360° around the cornea using corneal section scissors (Castroviejo or Aebli). Avoid perforating the choroid, breaking into the anterior chamber, or causing any deformation of the cornea's normal curvature. The scissor blades should not be visible in the anterior chamber. Keep the incision parallel to the limbus to produce an even scleral rim between 3 mm - 4 mm in width (with 2 mm of intact conjunctiva if recovery is being performed for limbal allografts).	9. Trauma to the cornea during excision due to bending, loss of the anterior chamber, or collapse of the globe through vitreous loss may compromise its suitability for surgical use. This indicates that the anterior chamber has been inadvertently entered, which may damage the corneal endothelium. Scleral rim width is important because some surgical corneal holding devices require a minimum of 3 mm rim while other such devices require a rim no wider than 4 mm. Also, cutting a rim less than 3 mm wide greatly increases the chance of entering the anterior chamber while performing the peripheral scleral dissection. Use of a scoring trephine may help to achieve consistent rim sizes.
10. Inspect the incision to ensure it is complete and that the anterior chamber is intact. If the incision has been made properly, the corneoscleral disc should be attached to the uvea (ciliary body-choroid) only at the scleral spur.	10. The risk of endothelial trauma or corneal contamination is greatest at this stage of the excision process.
11. Cultures of the incision site may be taken at this time, per your eye bank's policy.	11. Culturing is performed at the discretion of the eye bank medical director.
12. Complete the corneal removal using one pair of small forceps to hold the scleral rim stationary and a second set of small forceps, an iris spatula, or similar technique to push the ciliary body-choroid downward and away from the corneoscleral disc.	12. Aqueous fluid should escape from the anterior chamber at this point assuring that the anterior chamber was indeed intact.

13. Gently separate remaining adhesions away from the corneoscleral disc working side to side and taking great care to avoid pulling on the cornea and creating folds. The corneoscleral rim should never be allowed to drop back down while making this separation. The corneoscleral disc must never be pulled in such a way as to cause cross-corneal tension.	13. To avoid stretching or folds leading to potential loss of endothelial cells.
Care must also be taken to prevent the cornea from contacting the eyelids or other facial skin while removing it from the eye.	To avoid contamination of the ocular tissue.
14. Continue to hold the cornea by the scleral rim with the small-toothed forceps, transfer it to a labeled storage medium container. The preloosened cap is lifted off the vial using sterile forceps immediately prior to placing the cornea in the medium and replaced immediately afterward. If forceps are not used, reglove before starting on the next cornea.	14. Removing the vial cap at the time the cornea is placed in the storage medium minimizes the medium's exposure to airborne contaminants.
15. Examine the posterior chamber for a crystalline lens.	15. To inspect for signs of previous cataract surgery that would possibly contraindicate use of the ocular tissue for penetrating keratoplasty per EBAA Medical Standards section D1.110, depending on your eye bank's policy.
16. Repeat the excision on the second eye (Steps 1- 15). After the second cornea is placed in storage medium, both container caps are tightened and appropriately labeled.	
17. Completion	
A. Dispose of sharps in a sharps container.	A. Sharps are disposed as soon as possible to decrease the risk of exposure to contaminated sharps.
B. Remove drapes. Insert eye caps. Close the eyelids and remove all remaining prep solution with gauze and water or alcohol.	B. To restore the appearance of the donor. Use care when removing the drapes from the face to minimize the chance of damage to the skin or accidentally removing eyebrow or eyelid hair.
C. Leave the donor's head elevated.	C. Promotes blood and fluid to drain away from the face to reduce bleeding and swelling.
D. Record information about the excision in the donor's medical record according to your eye bank's policy.	D. To fulfill The Joint Commission requirements on documentation of tissue and organ removal.

E. Complete the eye bank's excision form, as required.

F. Leave a form or attach a tag to the body informing the funeral director that the corneas have been removed and to keep the head elevated. Also give the eye bank's name, location, and phone number with instructions to notify the eye bank if there are any questions or problems.

F. As a courtesy to the local funeral director. Also, hopefully, the funeral director will notify the eye bank before discussing problems related to the eye removal with the family.

G. Don non-sterile gloves and rewrap the donor in the body bag or shroud and return to the storage location from which it was removed.

H. Clean the work area. Discard all used disposables in a biohazard bag.

H. Disposable instruments should be discarded as sharps in a sharps container.

I. Rewrap non-disposable instruments for return to the eye bank or for cleaning and sterilization by the facility if necessary.

I. Be sure that used non-disposable instruments are marked as biohazardous during transport.

J. Transport the corneas to the eye bank as soon as possible.

E1.140 Blood Drawing

Purpose:

To describe the procedure for obtaining a blood sample from a donor for the purpose of serologic testing.

Reference:

Langer, C., Francke, A., Duncker, G. I., & Bredehorn, T. (2002). Procedures for blood-taking from cadaveric cornea donors. *Transplantation Proceedings, 34*(6), 2334.

Materials needed:

Sterile Supplies:

10cc syringe
Sterile povidone-iodine or alcohol swab to prep the skin
16 or 18 gauge needle or vacutainer needle and holder
10cc red top vacutainer tube purple tops or any other vacutainer tubes required by SOP or testing facility

Non-Sterile Supplies

Exam gloves
Moisture impermeable protective clothing
Mask
Protective eyewear Biohazard labels
Plastic bag with closure device
Blood specimen transportation box/container

Procedure	Rationale
1. Verify the IV infusion/transfusion status of the donor. Seek a pre-infusion specimen per EBAA Standard D1.200, if appropriate.	1. See EBAA Medical Standards section D1.200. Plasma dilution from blood products, colloids and crystalloids may affect test results and make detection of HIV 1/2 antibodies difficult leading to false negative results. Check with your local blood bank for specific volumes of each blood product administered.
2. Set up supplies near the donor.	
3. Select the blood draw site. The major vessels such as the subclavian vein and the femoral artery are the easiest. A blood sample may also be drawn from the heart.	3. Decision may be influenced by coroner or medical examiner preference, if this is a coroner or medical examiner case.
4. Put on gloves and other protective apparel.	4. Adherence to *Standard Precautions* is mandatory.
5. Cleanse skin with alcohol or povidone-iodine at the site from which you wish to draw.	5. To avoid contaminating the needle and therefore the blood sample with skin contaminants that may affect the results.

6. Locate the appropriate anatomic landmarks that overlay the chosen vessel. For example, to obtain a blood sample from the subclavian vein, the needle should be inserted through the skin, above the right clavicle (collar bone) at a 30^{o} angle, towards the throat and parallel to the clavicle.

7. Insert needle full length to hub of syringe and pull back plunger. Blood will enter the needle when the vessel has been entered or, if using a vacutainer system, insert needle and connect the red top vacuum tube.

8. If blood does not enter syringe, pull back slightly and angle needle differently until you enter the vessel and see a blood return.

9. Draw a sufficient amount of blood needed to complete the required infectious disease testing.

10. Carefully and slowly inject blood into red top tube, taking extreme care to avoid a needlestick.

10. Inject or transfer blood slowly and carefully into tube to prevent hemolysis.

11. Use ***Standard Precautions***. Do not recap needle. Discard into appropriate sharps container.

11. See procedure C3.600.

12. Apply pressure over puncture site and gently rub skin to close puncture and stop bleeding.

13. Label tube with date and time of draw, name of donor, a donor identification number, and initials of the technician.

14. Avoid freezing the blood sample while storing or transporting.

14. Freezing will hemolyze the cells and make it virtually impossible to obtain serum.

15. Transport specimen to laboratory

15. Ship blood and tissue according to your state and federal guidelines.

    See EBAA Medical Standards sections D1.210 – D1.230.

16. To provide a cleaner non-hemolyzed serum sample, the blood may be spun down in a centrifuge. Pipette the serum from the top and transfer to a clean tube and label. Extra serum may be archived in the eye bank laboratory freezer, if directed by your eye bank's policy and procedure manual.

    Avoid or minimize hemolysis by using a large bore needle. Also, wait until blood is fully clotted

before centrifugation.

17. Record results of serologic testing on the donor ocular tissue record prior to release of tissue for surgical use. ***Tissue must not be shipped prior to receipt and recording of non-reactive (negative) results from a hardcopy report.***

18. Attach copy of laboratory results in printed form to the donor record.

17. To avoid the possibility that tissue will be surgically implanted prior to receipt of required serology results.

E1.200 Open-Container Processing

Purpose:

To outline the different non-recovery methods of ocular tissue handling and processing.

Procedure	Rationale
1. Open container processing must be performed in: a) a laminar flow hood or biosafety 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 90mm settle plate per one hour exposure.	1. To ensure the environment to which the ocular tissue is exposed is sufficiently aseptic as to not contaminate the tissue.

E1.210 Whole Eye Storage for Surgical Use

Purpose:

To delineate the methods used for storage of whole globes for surgical use.

Definition of terms:

Moist chamber: A closed container with cotton gauze moistened with sterile saline or other sterile ophthalmic solution to provide a moist environment. The container is never completely filled with liquid so that the entire eye is immersed.

Decontamination: To reduce surface contamination by antimicrobial action.

Regulatory:

21 CFR 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases
21 CFR 1271.210 Supplies and Reagents

Materials needed:

Sterile Supplies

A sterile instrument tray:
2 Large toothed forceps
1 Hemostat
2 Sterile eye jars or medicine cups for soaking eyes
2 Sterile eye jars containing gauze
2 Cotton tipped applicators
1 Sterile ophthalmic irrigating solution, e.g., normal saline, balanced salt solution or antibiotic solution
~~1 Sterile ophthalmic broad-spectrum antibiotic solution vial or~~5% povidone-iodine irrigating solution
Sterile impermeable barrier drape (optional)

Sterile gloves
Sterile gown or sleeves

Sterile Instrument pack or tray containing the following:
Sterile scrub brush for hands
Jars containing donor eyes

Non-sterile Supplies:

Prep gloves
Moisture impermeable protective clothing
Mask
Cap to cover hair
Protective eyewear (goggles or face shield)
ISO Class 5 Hood or Biosafety Cabinet or approved processing room
Refrigerator and/or freezer and/or liquid nitrogen container
CDC recommended disinfectant
Sealing material e.g. shrink wrap

Procedure	Rationale
1. Turn on laminar airflow of the hood or biosafety cabinet and allow to run according to manufacturers' instructions prior to use. If a laminar airflow hood or biosafety cabinet is not being used, another environment documented annually to have less than 25 colony forming units per 90mm settle plate per one hour exposure may be used.	
2. Clean the laminar flow hood, biosafety cabinet or processing room according to the procedure established by your eye bank. Cleaning is required before and after each use.	
3. Place jars containing eyes and all sterile instruments and supplies on work surface of hood or biosafety cabinet or work table in the open container processing room.	
4. Don appropriate protective apparel, per procedure E1.110.	
5. Position the eye jars so that they are immediately adjacent to the edge of the sterile field formed when the sterile instrument pack is opened. The eye jar lids are removed and placed with inner side up next to their respective jars. Position eye jars to ensure that left and right specimen bottles are clearly and readily identified.	
~~6.~~ Place a 5% povidone- iodine solution container near the eye jars and medium vials, according to your eye bank's policy. ~~Uncap a 10 cc bottle of broad range sterile ophthalmic antibiotic solution or a povidone- iodine solution and place near the eye jars according to your eye bank's policy.~~	

6. Antibiotic or antiseptic application to the whole eye prior to corneal excision reduces the microbial population and potential contamination.

7. Set up the sterile field by opening wraps of the sterile instrument tray. Alternatively, a sterile moisture impermeable barrier drape may be opened and placed on the work surface of the hood, biosafety cabinet or processing room worktable followed by opening sterile instruments in peel packs and dropping them on. Avoid contaminating the sterile field created by touching or reaching over the field. Open individually wrapped sterile items, such as gauze or sterile cotton-tipped applicators and flip onto the sterile field with the surgical instruments.

8. Perform surgical hand antisepsis, and dry hands with a sterile towel. Don sterile gown/sleeves and gloves.

9. Lift the eye and the eye cage, if one is used, from the eye jar with sterile forceps (or the cage with a sterile cotton-tipped applicator.) Remove the fastener, if one is in place, from the optic nerve with a hemostat.

   Remove the eye from the cage using forceps to grasp a rectus muscle.

10. Soak or irrigate the eye using a 5% povidone-iodine ~~or antibiotic solution~~ for 2~~3~~ to 5 minutes in a sterile medicine cup according to your eye bank's procedure. Avoid contaminating the sterile field by wetting of a cloth drape, if one is used. Irrigation should be performed between povidone-iodine applications over a metal instrument pan or a moisture impermeable drape.

~~10.~~ 10. Studies have shown that whole eye immersion is superior to irrigation for removal of microbes (see reference list). Per EBAA medical standards, a 5% povidone-iodine solution shall contact all ocular tissue intended for transplantation twice between the time of the donor's death and tissue preservation.~~)~~

~~11.~~10. Transfer the whole eye with sterile forceps from antibiotic/antiseptic soaking solution to sterile e y e ~~ye~~ jars for storage.

~~12.~~11. Label all storage containers with appropriate identification as follows:

   a. Source eye bank name
   b. ISBT 128 tissue identifier (DIN, Product Code, and Fin(P).
   c. Type of ocular tissue
   d. Type of storage solution
   e. Date/Time of death
   f. Date/Time of preservation
   g. Expiration date of tissue
   h. Statement that ocular tissue is for single patient use and not considered sterile.
   i. 2-D data matrix symbol if distributed

internationally (effective 1/1/2017).

12. All ocular tissue must be labeled with a unique eye bank identification record number for proper quality control assurance. Proper labeling is required according to EBAA Medical Standards. See procedure J1.000.

13. Seal and store whole eyes for penetrating keratoplasty (PK) in a moist chamber at 2–8°C for 24-48 hours, or as instructed by your eye bank medical director.	13. This environment provides for short-term preservation of the cornea.
14. Store whole eyes for lamellar keratoplasty (LK) either in a moist chamber at 2–8°C or frozen at 0^{o} C. The temperature and length of storage are determined by the medical director and must be recorded in your eye bank's procedure manual.	14. Ocular tissue used for LK does not require an intact endothelium.
15. Record the method and date of storage on the tissue report form.	
16. Wipe down the work surface with a CDC recommended disinfectant solution immediately after use and allow it to air dry. Document these cleaning procedures according to your eye bank's Policies and Procedures.	

E1.221 Excision of the Corneoscleral Disc from Enucleated Whole Eyes

Purpose:

To provide a standardized method for the aseptic preservation of corneal tissue in the laboratory that will minimize endothelial cell loss and contamination and maximize the number and quality of cells that are ultimately grafted.

Regulatory:

21 CFR 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases
21 CFR 1271.220 Process Controls

Reference:

Rosenwasser, G. O. D., & Nicholson, W. J. (2003). Corneal excision. *Introduction to eye banking: a handbook and atlas.* (1^{st} ed.) (pp. 47-55).

Materials needed:

Sterile Supplies

Sterile gown or sleeves
Sterile gloves
Sterile scrub brush for scrubbing hands
1 sterile towel
Sterile ophthalmic irrigating solution

5% povidone-iodine irrigating solution
~~Sterile ophthalmic broad-spectrum antibiotic or antimicrobial solution~~
2 vials corneal storage medium
2 sterile corneal containers (e.g. corneal viewing chambers)
2 mini tipped culturettes (if cultures are performed by the eye bank)
Sterile cotton-tipped applicators
Sterile gauze
Jars containing whole eyes
Appropriately wrapped sterilized instrument tray containing the following:

2 Small toothed forceps
2 Scalpel handles
2 #11 or #15 blades
1 Corneal section scissors, or Castroviejo or Aebli scissors
2 Tenotomy or iris scissors
1 Hemostat
1 Forceps to handle cages and/or solution bottles
2 Medicine cups or other small 30 cc glass/steel container

Non-Sterile Supplies

ISO Class 5 Hood Biosafety Cabinet or an open container processing room (as described in Section E1.200)
Moisture impermeable protective clothing
Mask
Cap to cover hair
Protective eyewear (goggles or face shield)
Slit Lamp
Evaluation Form
CDC recommended disinfectant solution

Procedure	Rationale
1. Slit lamp globes. Perform the corneal removal (excision) in the laboratory in an ISO Class 5 Hood or Biosafety Cabinet or open container processing room following a whole eye enucleation. Wipe down and air-dry the work surface of the hood, cabinet, or work surface with a disinfectant solution immediately prior to use. Turn on laminar airflow of hood and allow to run at least fifteen minutes or according to manufacturers' instructions prior to use, if utilizing a hood or cabinet. Document cleaning of the hood according to each eye bank's policies and procedures.	1. Minimizes the risk of contamination by providing a decontaminated work surface. Allows laminar flow to be established.

2. Don appropriate protective apparel consistent with the biological safety cabinet being used. If using an open container processing room for this procedure, an operating room head cover, mask, eye protection, shoe covers, sterile gown, and at least one pair of sterile gloves shall be worn.	2. Use of a biosafety cabinet with a glass or plastic shield protects the technician and tissue. Therefore, protective eye wear and mask in particular may not be necessary. However, if tissue is opened outside of the hood, e.g., while slit lamping the whole globe, full protective apparel is still required.

3. Place sterile instrument pack, eye jars, antibiotic or antimicrobial solution, and corneal storage medium containers on the prepared surface of the laminar airflow work surface. If sterile corneal storage containers are dropped onto the sterile field, the containers are labeled as soon as possible at the end of the procedure.

4. Position the eye jars so that they are immediately adjacent to the edge of the sterile field formed when the sterile instrument pack is opened. The eye jar lids are removed and placed with inner side up next to their respective jars. The labeled storage medium vials are positioned so that they also will be adjacent to the sterile field. Remove the caps of the vials. Position eye jars and medium vials to ensure that left and right specimen bottles are clearly and readily identified.

5. ~~Uncap a 10 cc bottle of broad range sterile ophthalmic antibiotic solution or a povidone- iodine solution container and P~~place a 5% povidone-iodine solution container near the eye jars and medium vials, according to your eye bank's policy.

~~5.~~ Antibiotic or antiseptic application to the whole eye prior to corneal excision reduces the microbial population. Refer to EBAA Medical Standard E1.110~~—~~. A 5% povidone-iodine solution shall contact all ocular tissue intended for transplantation twice between the time of the donor's death and tissue preservation. ~~regarding the necessity of a povidone-iodine preparation of ocular tissue "at least once between the time of the donor's death and tissue preservation."~~

~~6.~~5. Using aseptic technique set up the sterile field by opening the wraps of the sterile instrument tray. Alternatively, a sterile moisture impermeable barrier drape may be opened and placed on the work surface of the laminar airflow hood, cabinet, or work surface followed by opening sterile instruments in peel packs and dropping them onto it. Avoid contaminating the sterile field created by touching or reaching over the field. Using aseptic technique, open individually wrapped sterile items, such as gauze or sterile cotton-tipped applicators and flip onto the sterile field with the surgical instruments.

~~7.~~6. Perform surgical hand antisepsis according to eye bank procedure. Dry hands with a sterile towel. Using aseptic technique don sterile gloves and gown or sleeves. Double glove if this is your eye bank's policy.

~~8.~~7. Fold a sterile 4 x 4 gauze sponge to form a long strip.

8. This is used to hold the eye during the corneal removal.

9. Lift the eye and the eye cage, if one is used,

from the eye jar with sterile forceps (or the cage with a sterile cotton-tipped applicator.) Remove the pin if one is in place from the optic nerve with a hemostat.

Remove the eye from the cage using forceps to grasp a rectus muscle.

10. Soak or irrigate the eye using a 5% povidone-iodine for 2 to 5 minutes in a sterile medicine cup according to your eye bank's procedure. Avoid contaminating the sterile field by wetting of a cloth drape, if one is used. Irrigation should be performed between povidone-iodine applications over a metal instrument pan or a moisture impermeable drape.

~~10. Soak or irrigate the eye using an antibiotic solution according to your eye bank's policies and procedures. Avoid contaminating the sterile field by wetting of a cloth drape, if one is used. Irrigation should be performed over a metal instrument pan or a moisture impermeable drape.~~

~~10.~~ Studies have shown that whole globe immersion is superior to irrigation for removal of microbes (see reference list). Per EBAA medical standards, a 5% povidone-iodine solution shall contact all ocular tissue intended for transplantation twice between the time of the donor's death and tissue preservation.~~.)~~

11. Wrap the eye securely with the gauze strip several times around the equator.

12. Lift and cut any remaining conjunctiva at the limbus and extending out 5 mm from the limbus using small toothed forceps and iris or tenotomy scissors. The exposed sclera may be carefully scraped from the limbus outward with a scalpel blade to remove all remaining conjunctival tissue. If recovering the tissue for limbal allograft purposes, lift and cut the conjunctiva at the limbus 360° around the cornea using small-toothed forceps and iris or tenotomy scissors, leaving about 2mm of conjunctiva evenly around the cornea.

12. Removing the conjunctiva close to the limbus prevents slippage of the rim while it is mounted on an artificial anterior chamber. Slippage can cause damage to the cornea during the lamellar keratectomy pass of the microkeratome rendering the cornea unusable. Additionally, the conjunctival tissue can increase the burden of microorganisms that travel with the donor tissue, increasing the potential for contamination during transplantation.
Leaving 2mm of conjunctiva will help ensure that tissue may be suitable for surgeries for patients in need of limbal stem cells. Any grossly contaminated or jaundiced conjunctiva should be removed completely without damaging the limbus to reduce the introduction of contaminants to the preservation media.

13. Isolate the instruments and scalpel blade (if used) used to remove the conjunctiva from the other instruments on the sterile field. Use these only for the same purpose on the opposite eye.

13. Exterior surfaces of the eye have been exposed to environmental contaminants.
Avoid mechanical introduction of microorganisms to the interior surfaces of the cornea by keeping instruments used for the different parts of the procedure appropriately separated.

14. Pick up the gauze-wrapped globe and hold with one hand.

15. Make an incision through the sclera 3 mm - 4 mm from the limbus and parallel to the limbus. Carefully cut all the way through the sclera without perforating the choroid.

16. Extend the scleral incision 360° around the cornea using corneal section scissors (Castroviejo or Aebli). Avoid perforating the choroid, breaking into the anterior chamber, or causing any deformation of the cornea's normal curvature. The

scissor blades should not be visible in the anterior chamber.	15. Perforation of the choroid causes vitreous leakage, which may collapse the globe including the anterior chamber. This would compromise the corneal endothelium. 16. Trauma to the cornea during cutting due to bending, loss of the anterior chamber, or collapse of the globe through vitreous loss would severely compromise its suitability for surgical use.
17. Keep the incision parallel to the limbus to	17. Scleral rim width is important because some

produce an even scleral rim between 3 mm and 4 mm in width. If the tissue is recovered for limbal allograft use, maintain 2mm of intact conjunctiva.	surgical corneal holding devices require a minimum 3 mm rim while other devices require a rim no wider than 4 mm. Also, cutting a rim less than 3 mm wide greatly increases the chance of entering the anterior chamber while performing the peritomy. Use of a scoring trephine may help to achieve consistent rim sizes.
18. Inspect to be certain the incision is complete and that the anterior chamber is intact. If the incision has been made properly, the corneoscleral button should be attached to the ciliary body-choroid only at the scleral spur.	18. The risk of endothelial trauma and cell damage is greatest at this stage of the excision process.
19. A culture of the incision site may be performed at this time, per your eye bank's policy.	19. Culturing is performed at the discretion of the eye bank medical director.
20. Set the wrapped eye down near the center of the sterile field that may be stabilized by attaching a sterile hemostat. Complete the corneal removal using one pair of the small forceps to hold the scleral rim stationary and a second set of small forceps, an iris spatula or similar technique to push the ciliary body-choroid downward and away from the corneoscleral button. Gently separate remaining adhesions from the corneoscleral button working side to side. The corneoscleral rim must never be pulled in such a way as to cause cross-corneal tension. The corneoscleral rim should never be allowed to drop back down onto the anterior chamber.	20. To avoid pulling on the cornea and creating folds. Aqueous fluid should escape from the anterior chamber at this point assuring that the anterior chamber was indeed intact. Never allow the cornea to drop back down once the removal has started. Doing so may cause endothelial cell damage if the cells come in contact with the iris.
21. Continue to hold the cornea by the scleral rim with the small-toothed forceps and transfer it to a labeled corneal storage container from which the caps have already been removed.	21. The vials may remain open under the laminar airflow hood, biosafety cabinet, or on an open container room work surface for a period of 1 hour, which is acceptable operating room practice.
22. Examine the posterior chamber for crystalline lens.	22. Inspect for signs of previous cataract surgery, which would possibly contraindicate use of the corneal tissue for penetrating keratoplasty, depending on your eye bank's policy (See EBAA Medical Standards (D1.110).
23. Carefully unwrap and return the remaining posterior segment to its respective eye jar. Avoid contaminating the posterior segment, instruments, or surgical gloves.	
24. Repeat the procedure on the second eye.	
25. After the second cornea is placed in storage medium, replace both container caps and tighten. Replace the lids on the eye jars. The containers with the ocular tissue are immediately labeled and sealed and the tissue refrigerated	25. See procedures I1.000 and J1.000.

according to each eye bank's policies and procedures.	
26. Dispose of sharps in a sharps container. Non-disposable instruments and eye jars are immediately cleaned according to your eye bank's policy and procedure. Discard all disposables in a biohazard receptacle.	26. Sharps are disposed as soon as possible to decrease the risk of exposure to contaminated sharps. See procedure C3.300 for care of instruments. Disposable instruments should be discarded as sharps in a sharps container.
27. Immediately after use, wipe down the work surface of the hood, cabinet, or open container room surface with a disinfectant and allow to air dry. Document these cleaning procedures according to your eye bank's policies and procedures.	27. See EBAA Medical Standards C3.300.

New Brunswick Cluster of Neurological Syndrome of Unknown Cause

The Province of New Brunswick is collaborating with local and national subject matter experts and health-care providers to investigate a group of individuals who are experiencing signs and symptoms of a neurological syndrome of unknown cause (NSUC).

At this time, the investigation is active and ongoing to determine if there are similarities among the reported cases that can identify potential causes for this syndrome, and to help identify possible strategies for prevention. The investigation team is exploring all potential causes including food, environmental and animal exposures.

Investigation overview

Since early 2020, physicians in New Brunswick have been identifying a number of individuals with an unusual combination of neurological symptoms. Despite extensive medical investigation, a diagnosis for these individuals has not yet been determined.

Local health-care providers in New Brunswick have engaged the Public Health Agency of Canada's Creutzfeldt-Jakob Disease Surveillance System (CJDSS) to actively investigate the possibility of human prion disease, but to date, all test results have been negative for known forms of human prion disease. Due to commonalities in signs and symptoms and the lack of a confirmed diagnosis among cases, a cluster of NSUC has been identified.

At the time of referral by their health-care provider, most of the individuals under investigation were living in the southeastern and northeastern regions of New Brunswick, around the Acadian Peninsula and Moncton areas. However, so far our investigation has not found any evidence suggesting that the residents of these regions are more at risk than those living elsewhere in the province.

Canadian health-care providers have been alerted to this investigation and are advised to contact New Brunswick Public Health for further information or to make referrals for individual cases.

Investigation status	**Active**
Cases under investigation	48
Deaths	6*
Illness onset date range in years	2013 – 2020**
Gender	50% female – 50% male
Age range in years	18 – 85

* In some cases, additional information is needed to determine if the cause of death was a result of this syndrome.

** Symptoms started in 2018, 2019 or 2020 for most cases. Only one case identified retrospectively in 2020 was found to experience symptoms in 2013.

Timeline

- Between January 2019 and July 2019, New Brunswick physicians identified a potential cluster of three Creutzfeldt-Jakob Disease (CJD) cases possibly related to cataract surgery.
    - **An investigation conducted by the Creutzfeldt-Jakob Disease Surveillance System (CJDSS), in collaboration with Regional Health Authorities in NB, demonstrated that there was no relation between the CJD cases and the surgery.**
- Through routine case management, the CJDSS noted common symptoms and diagnostic profiles among recent NB referrals that tested negative for CJD and with negative cerebrospinal fluid (CSF) protein panels. It became apparent that these atypical referrals represented a second cluster, distinct from the first, that was worth further investigation.
- In December 2020, the CJDSS contacted Public Health New Brunswick to actively include the department in this investigation.
- The first draft for the case definition was gathered on January 29, 2021.
- A memo was drafted regarding this case definition and sent to NB physicians on March 5, 2021 to inform them and encourage any health-care provider with patients that may meet the case definition for this neurological syndrome of unknown cause, to please contact Public Health, the CJDSS or the Mind Clinic at 1-506-857-5569 for more information.

Symptoms

Some symptoms include, but are not limited to:

- memory problems
- muscle spasms
- balance issues, difficulty walking or falls
- blurred vision or visual hallucinations
- unexplained, significant weight loss
- behaviour changes
- pain in the upper or lower limbs

What you can do

If you suspect that you, or your loved one, may be experiencing changes in personal health that may be similar to those described above, please speak with a health-care provider.

As the cause of the neurological syndrome is currently unknown, only a health-care provider can assess if the symptoms an individual is experiencing may be related to this NSUC investigation.

What the Government is doing

The Government of New Brunswick is committed to protecting the health of all citizens from new and emerging diseases in the province. The investigation is ongoing and Public Health New Brunswick will continue to investigate, working with the following partners:

- New Brunswick Department of Agriculture, Aquaculture and Fisheries
- New Brunswick Department of Natural Resources and Energy Development
- New Brunswick Department of Environment and Local Government.
- Public Health Agency of Canada
- Canadian Food Inspection Agency

As the investigation evolves, this webpage will be updated to provide new information about the ongoing investigation.

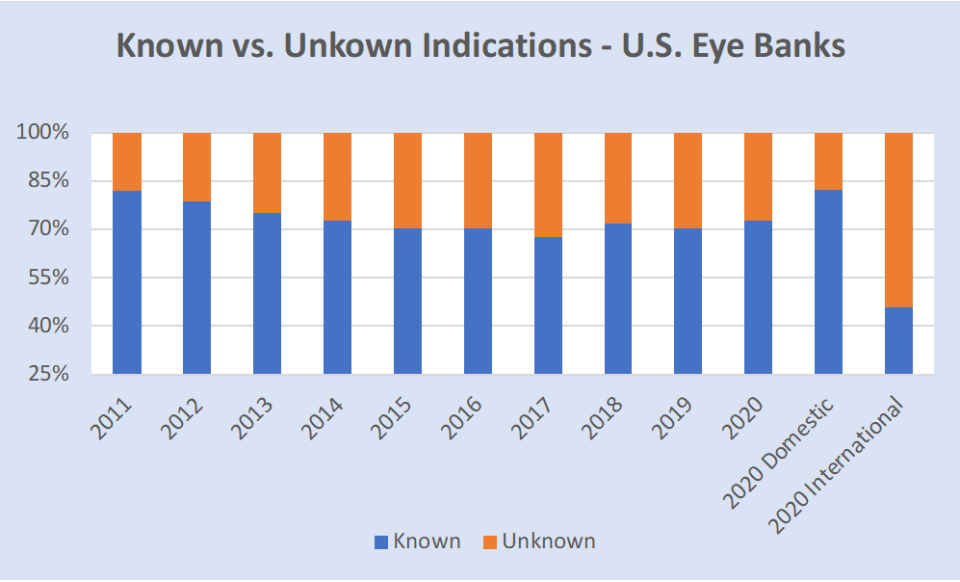
Jennifer Li, MD
Winston Chamberlain, MD
Chairs, Medical Advisory Board
Eye Bank Association of America
1101 17th Street NW, Suite 400
Washington, DC 20036

March 15, 2021

Dear Jen and Win:

The recently completed 2020 Eye Banking Statistical Report shows that recipient information that distributing eye banks get back on tissue supplied for transplant continues to be lacking and is getting worse. In 2020, the total number of unknown indications (meaning diagnosis and procedure) was 7,714, making it the second leading indication for transplant behind endothelial cell failure (and ahead of penetrating keratoplasty and lamellar grafts). The EBAA Statistical Report provides data on every single cornea recovered by US eye banks and is a complete picture of eye banking activity in the United States. Currently every eye bank operating in the US supplies data for this report. The Statistical Report, along with the Medical Standards and Accreditation, are the three most significant contributions the EBAA makes to the eye banking profession. The usefulness of the Statistical Report is only as good as the information in it. And the large gap in recipient information threatens meaningful conclusions about why patients get keratoplasty and what trends in surgical procedures are current.

The percentage of unknowns reported for domestic use of tissue by US eye banks in 2020 was 18.4 %. This percentage compares to 15.9% in 2018 and 14.8% in 2019 and is bad enough by itself. However, recipient information on tissue shipped internationally by US eye banks was missing in 69.7% of recipients in 2020, 74.6% in 2019, and 52.8% in 2018. The large number of unknown indications internationally has already led to the elimination of the international indications data from our analysis since 2017, and the rising number of domestic unknowns, now the #2 reported indication, threatens the validity – and usefulness - of the statistical report.



EBAA Medical Standard M1.500 (item 2) states that eye banks must "seek" recipient information. The MAB should investigate what is causing this erosion of data. Specifically at odds with the eroding data, is the transition of most eye banks to electronic database systems, including widely used electronic scheduling in which complete (or near-complete) recipient information is stored by an eye bank. With respect to the domestically distributed tissue, this suggests that when eye banks have to import tissue, the source eye bank is not being given the complete information (or that exporting eye banks are not seeking this data).

Regarding the historic problem of collecting these data points from internationally distributed tissue, there may be solutions that we have not yet created. Once detailed root causes have been identified, the MAB should discuss tightening the requirements for getting recipient information back from donor corneas that are distributed or find/maintain some way to keep the information in the Statistical Report about indications for transplant meaningful.

It is important for any accredited eye bank to demonstrate the ability to track tissue from donor to recipient and recipient to donor. We want to know if any patient that received tissue from an accredited eye bank has experienced a problem, what the problem was, and the outcome. Following that, for quality assurance, we want to know if there is anything we could have done about it. We are ignoring global health standards if we fail to demonstrate the ability or desire to collect this information.

A lot of time and resources go into producing this report, and anything the MAB can do to keep the validity of the report relevant would be beneficial to the eye banking community. This report on eye banking in the US is the only opus of its kind in the world that accounts for every single cornea recovered in the denominator, and, in the long term, provides invaluable information to corneal surgeons and eye bankers, as well as politicians, researchers and patients on what we are doing.

Sincerely,

Woodford S. Van Meter, MD
representing the Statistical Report Committee

Eric Meinecke

From: Jennifer DeMatteo <Jennifer@restoresight.org>
Sent: Wednesday, May 19, 2021 2:48 PM
To: Jennifer Li; Eric Meinecke
Cc: Kristen Pereira
Subject: MAB Agenda Item - MS C3.300
Attachments: Final Medical Standard proposal - C3.300 Instruments and Reagents 2.pdf

Dear Dr Li and the EBAA Medical Advisory Board,

On behalf of EBAA Quality Assurance Committee (QAC), we are requesting an amendment to the EBAA Medical Standard **C3.300 – Instruments and Reagents** for your consideration.
Please see the attached PDF document for a redlined copy of our proposed revisions.

Kristen Pereira, QA Committee Chair will be available to answer any questions from the MAB during the meeting.
If approved, the QAC would like to work with the Technical Procedures Manual Subcommittee to revise Procedure C3.300 – Instruments, Cleaning, and Maintenance.

Thank you in advance for your consideration.

EYE BANK ASSOCIATION OF AMERICA

Jennifer DeMatteo, MCM, CIC
Director of Regulations & Standards
202/775-4999 Ext 117
Jennifer@restoresight.org

C3.300 Instruments and Reagents

C3.310 Instruments

To prevent contamination or cross-contamination, all surgical instruments that come in contact with eye tissue during its 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 ~~instrumentation must~~sterile instruments shall be available ~~to provide~~ for sterile removal and processing of whole eyes and corneas. Instruments ~~must~~shall be inspected frequently enough to assure that they function properly. The eye bank shall also describe in their policy and procedures manual how the use of these instruments are documented and tracked.

An eye bank that ~~uses an autoclave to sterilize~~sterilizes its instruments, shall adhere to the use, calibration and maintenance procedures ~~for autoclaves as~~ recommended ~~in the~~by the 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 sterilizer shall be able to document sterilization parameters (e.g., time, pressure, and temperature) verifying that the instrument load was properly sterilized. The eye bank ~~must~~shall outline these steps in its procedure manual. ~~Certification to validate temperature, pressure and time shall be performed and documented according to manufacturer's recommendation or annually if not defined by manufacturer.~~ Sterilizer shall be appropriately qualified (installation, operation, and performance qualification) before use.

~~All sterilized instruments, . If instruments are sterilized outside of the eye bank, the eye bank shall provide documentation of appropriate sterilization.~~ 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 their sterilization policies and procedures follow medical standards and applicable regulatory authority. Sterilization records shall be maintained and readily available for a minimum of 3 years.

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. The calibration and preventive maintenance routine schedule shall be included in the eye bank's procedure manual.

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 are acceptable at the time of use.

C3.320 Supplies and Reagents

~~All sterilized instruments, supplies and reagents, such as corneal storage solution, must contain sterilization dates, method or appropriate expiration dates that are current at all times if applicable.~~ Each eye bank shall have a supply and reagent policy and procedure in which critical used during tissue recovery, processing, or long-term preservation, are properly identified. The critical supply/reagent receipt verification shall also be described in the eye bank's procedure manual. This policy and procedure shall be in accordance with respective regulatory authorities. The eye bank shall also request and maintain proper manufacturer's documentation of each supply/reagent lot as required by such regulatory authorities.

The reagents used during the processing and preservation of the ocular tissue must be sterile, where appropriate. Before use, the critical supplies or reagents shall be inspected to ensure that the sterile integrity and acceptable parameters are still maintained.

The critical supplies/reagents shall be stored, monitored, and maintained in accordance with manufacture's recommendations. Expired supplies and reagents shall not be used for recovery, processing, and long-term preservation of tissue intended for surgical purposes.

To add to glossary

Critical supplies and reagents – supplies or reagents that come in contact or can affect the quality of the ocular tissue during the recovery or processing of the tissue.

Eric Meinecke

From: Michelle Bonnier <Michelle.Bonnier@albertahealthservices.ca>
Sent: Friday, May 14, 2021 2:45 PM
To: jennifer.yh.li@gmail.com; Eric Meinecke
Cc: Ha, Brian [VCH]; Yan, Ivan [VCH]; Peter Huang; Holly Mackin; Kimberly Dodds; Christine Humphreys; Jefferson, Debbie (HorizonNB); Greene, Nachia
Subject: EBAA MAB Request - Agenda Item

Dear Jennifer, Eric and the EBAA Medical Advisory Board,

On behalf of EBAA Accredited Eye Banks across Canada, including the Lions Eye Bank - South Alberta, Eye Bank of BC, Tissue Bank Manitoba, the Eye Bank of Canada – Ontario Division, New Brunswick Organ and Tissue Program, and Regional Tissue Bank of Nova Scotia, we are requesting an amendment to the EBAA Medical Standards for your consideration.

We propose the removal of the annual review requirement for eye bank policies and procedures in standard C3.400 Procedures Manual.

> ***EBAA C3.400 Procedures Manual*** - Each eye bank shall maintain its own policies and procedures manual that details all aspects of its specific eye bank functions, and quality assurance practices. Each procedure must be initially approved, signed, and dated by the Director and Medical Director. A~~n annual~~ review of each eye bank's procedure with signing and dating by the Director and Medical Director is required. The frequency of the review shall be determined by each bank based upon relative risk and applicable federal, state and international standards or regulatory standard requirements. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use. Procedures must be readily available to personnel in the area where operations are performed.

In addition, we propose the following amendment to Appendix V: Accredited Eye Banks Not Located in the United States:

> **Medical Standards Specific to Canada**
> **C3.400**
> Each eye bank shall review its standard operating procedures at least every two years, and after any changes to regulatory requirements (i.e. Health Canada, EBAA).

This change will align with Health Canada Cells, Tissue, and Organ (CTO) regulations, Canadian Standards Association (CSA) standards, and upcoming changes to the American Association of Tissue Banking (AATB) standards, in effect July 31, 2021, while maintaining the important expectation of regular policy review, updating, and readership. The following are the relevant standards from Health Canada, CSA, and AATB:

> ***Health Canada CTO Regulations, Section 74 (1)*** – An establishment must review its standard operating procedures every two years and again after any amendment to these Regulations.
>
> ***Health Canada CSA General Requirements, 6.4.1*** – Every two years, procedures in the SOPs shall be reviewed by a knowledgeable person(s), revised as appropriate by a knowledgeable person(s), and approved by an authorized person.
>
> ***Health Canada CSA General Requirements, 6.4.3*** – All SOPs of a medical nature shall be reviewed every two years reviewed by the medical director and this review shall be documented.
>
> ***AATB Standards J1.600 Review of Standing Operating Procedures Manual (SOPM), effective July 31, 2021:*** A review of the SOPM and the safety manual if separate shall be performed and documented. The frequency of

review shall be determined and documented by each bank based upon relative risk and applicable federal, state and international standards or regulatory standard requirements (e.g., OSHA, ISO).

1) The Medical Director shall review relevant policies and procedures of a medical nature (e.g. donor eligibility, adverse outcomes)
2) Management with executive responsibility, or a responsible person designee, shall review policies and procedures to ensure adequacy in regard to current practice and applicable standards, laws, or regulations; and
3) Staff shall review policies and procedures for which they have been trained and are currently responsible.

Thank you in advance for your consideration.
Please feel free to contact us if you have any questions or need further clarifications.

Kind regards,

Michelle Bonnier RN MN BN BSc
Manager - Southern Alberta Organ and Tissue Donation Program (SAOTDP)
Phone: (403) 944-8206
Cell: (403) 604-2508
Pager: (403) 212-8223, Pager #00425
Michelle.Bonnier@albertahealthservices.ca

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Eric Meinecke

From: Eric Meinecke
Sent: Tuesday, June 1, 2021 4:19 PM
To: Eric Meinecke
Subject: RE: Request for MAB Agenda Item

From: Brian Philippy <brianp@lionseyebank.org>
Sent: Wednesday, April 28, 2021 2:11 PM
To: Jennifer Li <jennifer.yh.li@gmail.com>; Winston Chamberlain <chamberw@ohsu.edu>
Cc: Jennifer DeMatteo <Jennifer@restoresight.org>
Subject: Request for MAB Agenda Item

Good afternoon MAB Co-Chairs,

Following EK processing in which a graft is pre-loaded, a surgeon may request that the processing eye bank provide the tissue remnants to facilitate culturing the rim of the corneoscleral disc. This practice is common, but not universal, and with growing incidence as the popularity of pre-loaded EK tissue grows.

Problem 1 – Tissue remnants have no specific tissue ID
The problem, however, is that eye banks do not have an ISBT 128 tissue identifier for these "tissue remnants". To my knowledge, many eye banks performing this practice also do not have internal numbering or policies specific to this practice.

Problem 2 – Responsibility for seeking ISBT 128 is at eye bank level
Seeking ISBT 128 tissue numbers is not a function of EBAA, generally, but a function of eye banks. However, if eye banks approach this independently, we'll end up with a wild array of product codes (e.g. as occurred with long-term corneas), rather than a specific product code that is universal to all.

Solution – Unified response and Medical Standard inclusion

- Require a tissue ID for these non-surgical tissues.
    - By requiring a tissue ID, these tissues will be individually traceable (e.g. tissue will appear in inventory; when distributed, distribution info will be required as for any other piece of tissue
- Amend Medical Standard G1.200 part b. as follows:
    - **Surgical Culturing**

      Each eye bank shall indicate on the information sheet accompanying the tissue for transplantation whether corneoscleral disc cultures were performed prior to distribution. In the case of pre-loaded surgical tissue, in which tissue remnants from processing must accompany surgical tissue for the purpose of surgical culturing, the tissue remnants must have a unique tissue ID and be labeled clearly according to H1.000. Positive results in cases of postoperative

infection shall be reported to the eye bank that recovered the tissue as well as to the eye bank that distributed the tissue.

- Amend Medical Standard H1.000 as follows:
  - **Non-Surgical Donor Tissue**
    The use of ocular tissue from a donor determined to be ineligible is not prohibited for non-clinical uses, so as long as they bear the Bio-hazard legend and are labeled "For Non-clinical Use Only" and "Not for Transplant." Non-surgical donor tissue must have a unique tissue ID. Tissue distributed for non-clinical purposes (e.g., teaching and/or research) from a donor who has been determined to be ineligible for transplantation due to results of required testing and/or screening or from donors who have not been tested for required infectious diseases, must have a label affixed to the individual tissue container which contains the information below.
    1. "For Non-clinical Use Only"
    2. "Bio-hazardous" or bio-hazard legend
    3. "Not for Transplant"
- Either the EBAA or one eye bank request a unique ISBT 128 identifier for "corneoscleral disc remnants".
  - Once established, all eye banks providing remnants for surgical culturing may use the same product code(s).

I believe it is our responsibility to ensure that all independently-contained tissues subject to distribution are traceable and that labeling and numbering requirements prevent mix-ups, confusion, or exposure in the operating room setting.

Sincerely,

Brian Philippy, BChE, BS, CEBT
Director of Transplant and Research
Lions Medical Eye Bank & Research Center of Eastern Virginia, Inc.
(231) 584-3618 (office)
(757) 636-5563 (mobile)

LIONS MEDICAL EYE BANK
and Research Center of Eastern Virginia

The Lions Medical Eye Bank and Research Center of Eastern Virginia, Inc. is a non-profit transplant agency which provides the opportunity to donate eye tissues, health care professionals the means to end blindness and patients the ability of clearly seeing form, color, and motion.