Medical Advisory Board Meeting Minutes
October 17, 2024

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

Shahzad Mian, MD	MAB Chair
Christopher Ketcherside, MD	MAB Vice Chair
Kristen McCoy, CEBT, CTBS	MAB Secretary
Anthony Aldave, MD	
Patrick Becker, CEBT	Technical Procedures Manual Subcommittee Chair
Alan Blake, CEBT, CTBS	
Lisa Brooks, CEBT, CTBS	
Jason Brosious, RN, CEBT, CTBS	
Jamie Collier, MA, CEBT	
Kevin Corcoran, CAE	President & CEO
Maria Cortina, MD	
Andrea Crosson, CEBT	
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards, Ex-Officio
Marcella Dimond, CEBT, CTBS	Accreditation Board Co-Chair
Asim Farooq, MD	Policy & Position Research Subcommittee Chair, Ex-Officio
Mark Greiner, MD	
Christopher Johns, MBA, CETB, CTBS	
Stephen Kaufman, MD, PHD	
Amy Lin, MD	Accreditation Board Co-Chair
John Lohmeier, CEBT	
Rachel Peltier, CEBT, PhD	Certification Board Chair
Brian Philippy, CEBT	
Jim Quirk, CEBT	EBAA Chair
Samuel Ramos, CEBT, CTBS	
Edwin Roberts, MPA, CEBT	
Ingrid Schunder, CEBT	Technician Education Committee Chair
Shannon Schweitzer, MBA, CEBT	
Namrata Sharma, MD	
Roni Shtein, MD	
Adam Stockman, CEBT	
Michael Titus, CEBT	
Michael Tramber, MBA, CEBT, CTBS	
Concetta Triglia, CEBT	
Elmer Tu, MD	Medical Review Subcommittee Chair, Ex-Officio
Woodford Van Meter, MD	
David Verdier, MD	
Jim Wagner, CEBT, CTBS	

Minutes

MOTION: A motion was made by and seconded to approve the minutes from the June 7, 2024 meeting.

Discussion: None

All approved, no nays – Motion Passed

Medical Review Subcommittee

Dr. Elmer Tu presented the Medical Review Subcommittee Report.

Dr. Elmer Tu commented that the total adverse events have plateaued over the last few years. Over the last few years there was concern with an increase in reported Primary Graft Failures (PGF) related to PK. In 2023 we saw a significant decrease in PGFs related to PK procedures. Early regraft and imputability rates remain stable.

MRS focused on antifungal supplementation and in 2023 we see that those numbers are down however so are the total number of PGFs.

In the Spring the MRS sent a general survey to some of the larger eye banks for information on antifungal supplementation specifically focused on PK and how often this tissue was supplemented. Overall, it was relatively low at 4-5% of PK tissue was supplemented.

For tissue supplemented with antifungals the adverse events per 10,000 was 80 compared to 20 for grafts that were not supplemented.

Policy and Position Review Subcommittee

Dr. Asim Farooq presented the Policy and Position Review Subcommittee (PPRS) Report.

Last year PPRS released updated statements on COVID-19 and Mpox in August 2023 and an updated statement on TB in September 2023.

PPRS recently released a statement on Chagas disease in June 2024, in response to an increase in the number of cases reported in certain areas of the country due to migration from regions where Chagas is endemic. Studies showed that there were no reports of transmission. PPRS made the decision to NOT recommend specific screening for Chagas disease at this time. However, those donors for KLAL tissue where tests result are pending for Chagas, should be completed and if positive excluded.

Accreditation Board

Marcella Dimond presented the Accreditation Board Report. During this inspection cycle, 7 banks were inspected. All 7 banks received a 3-year accreditation. 3 of the banks have some pending corrective actions; their certificate will be held until those are completed.

Certification Board

Rachel Peltier, PhD presented the Certification Board Report.

The new committee term began in July. The Certification Board, Exam Committee, Continuing Education Committee, and Technician Education Committee have each met and have begun their respective committee work.

This past Summer, EBAA and members of the Exam Committee and Certification Board worked with the Professional Testing Corporation to update the current CEBT exam question bank for the fall exam cycle. In addition, EBAA has arranged for PTC to provide training to the Exam Committee on how to write exam questions; the recording will be a training resource moving forward.

The Fall 2024 CEBT Exam is currently taking place, and the testing period ends on October 26, 2024. There are 16 people registered to take the exam, with candidates from the US, Canada, Croatia and Saudi Arabia. We will have the results of the exam in mid-November. The Spring CEBT exam takes place April 5–19, 2025. The early bird deadline is March 3. The application will be available on the EBAA website soon.

Individuals who are up for recertification in 2024, can apply for recertification now through December 2024.

Technician Education Committee

Ingrid Schunder gave the Technician Education Committee Report.

The Technician Education Committee is excited to begin a new committee term, with a lot of new committee members. The committee has already begun planning educational sessions for the new term.

The Technician Education Seminar will be held virtually in 2025. The 2025 TES will be delivered via 25 on-demand sessions and 3 live virtual workshops. The TES takes place in January and February. The course officially begins on January 8 with the release of the first set of on-demand presentations, and the live sessions take place January 31, February 7, and February 14, 2025. Registration is currently open, and early bird rates end on November 22.

The committee plans and hosts webinars throughout the year. All webinars are free to EBAA members on eyeLEARN, and the recordings are posted once available.

- “Designing and Building a Lab: A Blueprint for Succes,” took place in August, and featured presentations from Shannon Schweitzer, from Lions Eye Bank of West Central Ohio, Nick Hicks from Eversight, Mike Tramber from Miracles In Sight, and Josh Griffin from East Tennessee Lions Eye Bank.
- UPCOMING: “Keratoconus: Overview, Current Treatments and Future Therapies,” takes place on Friday, November 8, 2024. Dr. Barry Lee will discuss the disease and treatments, and Bruce Varnum will share his experience as a bilateral cornea recipient. This session is timely as November is Eye Donation Month and World Keratoconus Day is on November 10.

New skills videos have been added to eyeLEARN:

- Corneal Tissue Processing: Endo-In DMEK – Provided by Chelsea Green from Iowa Lions Eye Bank
- Performing a Vitreous Draw – Provided by Patrick Becker and Angela Norton at Lions Gift of Sight

The Technician Education Committee is hosting the "Community Chat: Corneal Tissue Processing – Ask the Processors!" on Thursday, December 5 at 1pm Eastern. If you have questions about how to navigate difficult processing challenges, we encourage you to attend and participate in the discussion!

The committee is planning several sessions at the 2025 Annual Meeting, more information to come soon!

Dr. Mian asked about trends in attendance for these training events. Ingrid responded that the attendance has been high because the developed programs are current relevant topics with good questions.

Technician Procedures Manual Subcommittee

Patrick Becker gave the Technical Procedures Manual Subcommittee Report.

The Technical Procedures Manual subcommittee consist of 13 members representing 11 American Eye Banks. July 2024 marked the beginning of the two-year term for the committee. These first few months have been addressing old business items and prioritize projects. The focus will be to maintain a procedures manual that is accurate, current and useful.

Long term preservation has been a topic at prior meetings and the committee is preparing to present revisions at the annual meeting in June regarding the use of ethanol for long term preservation.

The committee is reviewing the procedures manual in totality to update missing and inaccurate information as well as removing outdated information. The committee welcomes comments and questions, please send those to Monica Mullins or Patrick Becker.

Old Business

Natalie Buckman presented two job aids entitled *Guidance for Coding f Cornea Transplant Recipient Diagnoses.*.

The two job aids were included in the board packet for review. This project originated in the Data Review Subcommittee. Because of competing priorities, the Statistical Committee took this project on and developed these job aids to assist surgery schedulers. The purpose is to provide eye banks with a resource that they can provide to clinicians and schedulers to assist with the selection of the appropriate indication for keratoplasty for the recipient. The intention is that eye banks may choose to provide one or both documents as needed, with the EBAA and their Eye Bank's logos.

The statistical committee would like to propose this as an EBAA resource to eye banks that they can then provide to schedulers. It would be branded with the EBAA logo and the eye bank logo.

MOTION: A motion was made and seconded to accept the Guidance for Coding Transplant Recipient Diagnosis as part of the statistics section and maintain on the of the website in a Word version.

Discussion: Surgeons should be providing this diagnosis. This form is to help guide those practices where the surgery scheduler is tasked with completing this information for the eye bank. It is a very clinical focused document, and we may see some challenges with non-clinical individuals understanding this document. This document is intended to be used as a tool to help facilitate accurate diagnoses.

All approved, no nays – Motion Passed

Jennifer DeMatteo presented the Sepsis Workgroup Update.

A sepsis working group was convened in June following the annual meeting in response to several eye banks receiving 483s and 2 eye banks receiving warning letters for failure to determine as ineligible donors with a documented diagnosis or clinical evidence of sepsis.

The Sepsis Response Workgroup met on 6/12/24 and the entire Sepsis Subcommittee met on 6/20/24 to determine what data we should request from the eye banks. The decision was to concentrate on 2023 data, since we have complete statistical data and OARRS reporting for the year. The committee looked at the total donor population with sepsis and how eye banks are handling those cases. This data will help us determine the effect on the potential donor pool we can expect from the anticipated new sepsis guidance from FDA and whether there is an actual risk to the public from accepting these donors.

Data Results:

41 eye banks responded to our sepsis data requests for 2023. This accounts for 38,653 of 50,925 (75.9%) of the domestic transplants for 2023.

Total number of referrals – 514,452
Total number of referrals with mention of sepsis – 52,963 (data missing from 8 banks)

17/41 (41.5%) eye banks use MJB as their infectious disease consultant.
10/41 (24.4%) use another consultant

Total number of referrals deferred due to sepsis concerns: - 51,843 (missing 1)
Total number of donors recovered with sepsis concerns. - 7,587 (missing 4)
Total number of donors approved for transplant via sepsis algorithm. - 5,111 (missing 5)
Total number of donors deferred due to sepsis algorithm- 3,207 (missing 3)

	Approved	Deferred	Deferral rate
Medical Director	498	233	31.9%
ID Consultant	1964	536	21.4%
Attending	807	336	29.4%

Total number of sepsis concerning donors who were determined eligible and were transplanted – 3,906 (missing 4)
Total number of infectious adverse reactions - 35
Total number of infectious adverse reactions for donors approved with sepsis concerns: - 5 but deemed not due to tissue per eye bank.

31/41 (75.6%) reviews the entire record for the most recent hospital admission.
5/41 (12.2%) reviews 5 days preceding death.
1 bank reviews 4 days; 3 banks review 3 days; 1 bank reviews only at time of death

MRS OARRS Sepsis Review

Elmer Tu presented the MRS OARRS Sepsis review.

The Subcommittee was asked to review all the infectious adverse events from 2023 to see if there was any relation between the screening and infection and whether the screenings were performed according to existing guidelines, specifically SIRS and sepsis criteria. The Subcommittee was tasked to review each of these cases and to see if there was agreement. Dr. Tu presented the findings in the attached PowerPoint.

New Business

Jennifer DeMatteo presented on behalf of the QA committee proposed revisions to G1.000 Quality Assurance.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with FDA 1271.350, adverse reactions involving a relevant communicable disease must be reported to the FDA within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention. ~~Any deviation reported to a regulatory public health authority will also be reported to EBAA.~~ *Any adverse reaction or deviation (e.g. MedWatch, HCT/P Deviation Reporting) reported to a regulatory public health authority will also be reported to EBAA concurrently."*

MOTION: A motion was made and seconded to approve the proposed revisions to G1.000 Quality assurance.

Discussion: Amendment to the language: ….public health authority SHALL also be reported.

Question: Every time we report to an entity even if it is the same report should we be reporting this to the EBAA. Answer: yes, this maintains consistency in the reporting structure.

All approved, no nays – Motion Passed

Jennifer DeMatteo reviewed the revised adult and child Uniform Donor Risk Assessment. AATB released these revised UDRAIs which include some of the questions they required for TB assessment. The revisions will be a part of the AATB standards which will be released January 2025 for implementation end of January 2025. EBAA needs to create the Eye Only DRAI. The legislative and regulatory committee went through the revised UDRAIs and highlighted proposed questions to be eliminated to create an eye only DRAI.

Uniform Donor Risk Assessment (Donor >12 Years Old)

- The following questions are approved by the MAB to be removed: Question 2, 7, 22, 29, 32, 33a, 34, 36a, 36b, 37, 38, 39, 43a, 43b.

Uniform Donor Risk Assessment (Child Donor ≤ 12 Years Old)

- The following questions are approved by the MAB to be removed: Question: 3d, 3e, 3h, 22, 29f, 31, 32, 33, 34a, 34b.

MOTION: A motion was made and seconded to approve the removal of the above listed questions to create an Eye Only Donor Risk Assessment (Donor >12 Years Old and Child Donor < 12 Years Old).

Discussion: None

All approve, no nays – Motion Passed

Kyle Mavin proposed an addition to the Medical Standards Appendix V. The proposed addition as shown in the board packet is Medical Standards Specific to Saudi Arabia.

Proposed additional sections are D2.100, D2.120, D2.200, D2.210, G1.000, L1.200 and Saudi Center for Organ Transplantation References.

MOTION: A motion was made and seconded to accept the proposed addition to the Medical Standards Appendix V entitled Medical Standards specific to Saudi Arabi and subsequent sections.

Discussion: None

All approve, no nays – Motion Passed

Jennifer DeMatteo reviewed the January – June 2024 Statistical report which was provided in the Board Packet. Donors and transplants have increased as compared to the first 6 months of 2023. We are also seeing a slight increase in donors ruled out for sepsis.

Of note: We are seeing an increase in unknowns for diagnosis - 16.5% of domestic unknowns compared to 8.4% same time last year. Collectively we need to work to decrease the number of unknowns.

This data is completed except for Lions Eye Bank of Hawaii.

Wanda Phillippy proposed a revision to J1.000 Labeling, Item 5 of the Medical Standards.

5. ~~If the Product Code and Donation Identification Number are not assigned by the same entity.~~ If tissue has undergone additional processing, then the label must include the Processing Facility Information Code, which includes the Facility Defined Product Code (FPC) and Processing Facility Identification Number (FIN(P)).

MOTION: A motion was made and seconded to approve the proposed revision to J1.000 Labeling, Item 5 of the Medical Standards as stated above.

Discussion:

Clarification: It is an ISBT128 requirement that the FIN(P) be included anytime the processing facility changes the product code for traceability. FIN(P) must be on the label and encoded on the data matrix symbol.

Proposal is for the FIN(P) to be added to all processed tissue, even if the source eye bank and the processing facility are the same. The end user will be able to see where the tissue came from and who processed it. Currently the end users cannot identify when the error has been made to notify the distributing eye bank.

Current IT platforms and workflows require a manual process to add the FIN(P) added to the label. To ensure compliance the EBAA should provide additional training to eye banks to ensure that the FIN(P) is added to the label and the data matrix.

Some Eye Banks are working with InVita to have the addition of the FIN(P) automatically included in the workflow. With this proposed change, eye banks will need time to incorporate this into their current IT platform, labeling and workload perspective. The manual process can be implemented immediately.

17 approved, 3 Nays – Motion Passed

Timeline for implementation – June 1, 2025

<u>Late Additions</u>

Noel Mick was named the 2025 Leonard Heise Award Recipient

Dr. Mian thanked the Medical Advisory Board, and a motion was made and seconded to adjourn.

MRS OARRS Sepsis Review

Elmer Tu, MD
Jennifer DeMatteo, MCM, CIC

Illinois Eye and Ear Infirmary | The University of Illinois College of Medicine — Chicago Peoria Rockford Urbana

SIRS - Systemic Inflammatory Response System

- Body temperature over 100.4 degrees Fahrenheit (38 degrees Celsius) or under 96.8 degrees F (36 degrees C).
- Heart rate greater than 90 beats per minute.
- Respiratory rate greater than 20 breaths per minute or partial pressure of CO_2 less than 32 mmHg.
- Leukocyte (white blood cell) count greater than 12,000.

SIRS - Systemic Inflammatory Response System

- Redness and swelling (edema) in the affected parts of your body.
- Intense pain.
- Loss of function of parts of your body.
- Intense fatigue.
- Fast heart rate (tachycardia).
- Abnormal breathing.
- Fever or hypothermia (low body temperature).
- Shaking or chills.
- Warm or clammy/sweaty skin.
- Skin rash.
- Confusion, agitation or other mental changes.
- Loss of consciousness.

Purpose and Scope

- To review all 2023 infectious adverse reaction reports in OARRS, as well as any MedWatch reports submitted in 2023 with regard to donor screening, specifically for sepsis.
- MRS members were asked to review the appropriateness of accepting the donor, whether the donor was septic prior to recovery, and the likelihood that sepsis was related to the recipient infection.

Methodology

- Eye banks were asked to provide additional information about each infectious OARRS case to identify donor factors of potential sepsis and were asked to provide a copy of any submitted MedWatch report.
  - OARRS Report Number
  - MedWatch Report Number
  - Donor Cause of Death
  - Did donor have any concerns for sepsis
  - If yes, were they approved for transplant via any of the following methods?
    - Sepsis algorithm
    - Medical Director consult
    - Infectious Disease consult
    - Attending physician consult
    - Other
  - Were there any positive lab cultures, imaging, or other diagnostic tests
  - If yes, list the date, culture type or test, and results including pathogen(s) isolated.
  - If easier, you may upload a copy of the donor's lab results
  - List all antibiotics the donor was on at the time of death.
  - Include any additional information you'd like the MRS to have.

Methodology

- Two reviewers were assigned to each OARRS case and were provided a copy of the OARRS submission, report of additional donor factors, and any MedWatch report for review.
- A SurveyMonkey tool was utilized for data collection for each OARRS report.
- Primary Questions
  - Do the reviewers agree with the eye bank assessment and did the bank accept a septic donor?
  - Was the sepsis related to the development of an adverse event/ infection?
  - Detect and develop criteria to help eye banks appropriately approve or decline donors.

Results

- 29 patients with reported keratoplasty- related infections in 2023
  - 16 endophthalmitis
  - 13 infectious keratitis
- The number of donors which were deemed septic by the eye bank (0) on review (1) were felt to meet FDA criteria for sepsis.
  - 25-year-old donor with cerebral palsy admitted from a skilled nursing facility at 6am with a diagnosis of sepsis, bilateral pneumonia, and acute hypoxic respiratory failure, treated with Rocephin and Azithromycin. Vital signs met SIRS criteria. Blood cultures on admission finalized as negative. Expired at 1:48pm the same day. Due to clinical evidence and a diagnosis of sepsis a few hours before death, this donor should have been determined to be ineligible.
- Two of the cases had evidence of donor infection but did not meet SIRS criteria.
- Three cases were categorized as unable to assess with the information provided (2791, 2781, and 2816) since HR and RR was generally missing from the documentation provided or the patient met SIRS criteria without site of obvious infection.

Results

- Number of cases where systemic infection was transmitted to the donor (zero)
- Regarding those corneal tissue recipients who developed an infection:
  - All but one donor was accepted consistent with existing protocol.
    - Of the donors with sufficient information to assess for sepsis, none were identified. Two donors were identified with SIRS but without a systemic source for infection not fulfilling criteria for sepsis.
    - One donor did have Pneumonia and another a UTI as a source for infection but did not fulfill the criteria for SIRS and consequently sepsis.
    - The single donor meeting sepsis criteria utilized an outside consultant.

Subcommittee Conclusions and Recommendations

1. Conclusions

- No evidence of transmission from donor to host was identified in any of the cases, including the septic donor associated with an ocular infectious adverse event.
- The deviation from existing protocols regarding sepsis were not a factor in any of the cases of reported corneal tissue transplantation - related infection in 2023.

Recommendations

1. Continuing education and emphasis on existing and updated protocols regarding sepsis and tissue donation.
   A. Should include all personnel involved in determining sepsis, e.g. medical directors, eye bank technicians and outside consultants.
2. Special attention to those donors with SIRS or systemic infection to obtain as much information as possible prior to acceptance of donation.

Thank you MRS Members

First Name	Last Name	Organization
Elmer	Tu	Eversight-Chicago
Adam	Cloud	Lions Eye Bank of West Central Ohio
Mohammad	Dastjerdi	Rutgers New Jersey Medical School
Sean	Edelstein	Mid-America Transplant
Gregory	Grossman	Advancing Sight Network
Michael	Grunewald	Lions Eye Bank of Wisconsin
Susan	Hurlbert	Eversight-Chicago
Anup	Kubal	Lions World Vision Institute
Juan	Pawirosetiko	Lions Eye Bank for Long Island
Sowmyalakshmi	Srinivasan	Lions Gift of Sight
Chris	Stoeger	VisionGift
Praneetha	Thulasi	Aniridia Foundation International
Eric	Weinlander	
Jennifer	DeMatteo	Eye Bank Association of America