



## Medical Advisory Board Meeting Minutes June 20, 2020

### I. Call to Order

Dr. Jennifer Li called the meeting to order at 4:00pm. The following members were present:

Jennifer Li, MD	Chair
Winston Chamberlain, MD, PhD	Vice Chair
Woodford Van Meter, MD	EBAA Chair
Kevin Corcoran, CAE	EBAA President & CEO
Jennifer DeMatteo, MCM, CIC	EBAA Director of Standards & Regulations
Eric Meinecke, CEBT	MAB Secretary
Tony Aldave, MD	Chair, Policy & Position Research Subcommittee
Tony Bavuso, CEBT	
Beth Binnion, CEBT	
Jason Brosious, CEBT	
Patricia Dahl, CEBT	
Donna Drury, CEBT	
Sander Dubovy, MD	
Sean Edelstein, MD	
Josh Galloway, CEBT	Chair, Technician Education & Certification Board
David Glasser, MD	
Brian Ha, CEBT	
Sandeer Hannush, MD	
Holly Hindman, MD	
Joshua Hou, MD	
Bennie Jeng, MD	
Christopher Ketcherside, MD	Co-Chair, Accreditation Board
David Korroch, CEBT	
Anup Kubal, MD	
W. Barry Lee, MD	
Marian Macsai, MD	Chair, Medical Review Subcommittee
Kristin Mathes	
Kyle Mavin, CEBT	Co-Vice Chair, Accreditation Board
Shahzad Mian, MD	
Michael Nordlund, MD, PhD	
Brian Philippy, CEBT	

Jim Quirk, CEBT	
Michelle Rhee, MD	Co-Vice Chair, Accreditation Board
George Rosenwasser, MD, CEBT	
Christopher Stoeger, CEBT	Co-Chair, Accreditation Board
Alan Sugar, MD	
Michael Titus, CEBT	Chair, Procedures Manual Subcommittee
David Verdier, MD	
Jim Wagner, CEBT	

## **II. Approval of Minutes**

Dr. Li called for a motion to accept the minutes from the October 10, 2019 meeting held in San Francisco, California.

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

## **III. Committee Reports**

### **A. Policy and Position Research Subcommittee**

Dr. Tony Aldave informed the MAB that their subcommittee had been asked to research, and make a recommendation to the MAB on, the suitability of corneal tissue for transplant from donors with a history of Lyme Disease (LD). After reviewing literature on LD and information regarding the possibility or likelihood that LD could be transmitted via corneal transplantation, the subcommittee recommended that D1.110 be revised to include Lyme disease (known or suspected; active or chronic; including post-treatment Lyme Disease Syndrome (PTLDS)). No changes or an addendum to the Donor Risk Assessment Interview were deemed necessary.

A motion was made and seconded to approve the changes recommended to D1.110. Dr. Li shared her concern about including “chronic” and PTLDS as there is some controversy in the infectious disease community. Dr. Aldave said that the subcommittee can continue the research and seek clarity on chronic and PTLDS. Dr. Shahzad Mian suggested that the MAB could approve including “Active Lyme Disease (known or suspected)” while the subcommittee continued their work on this topic. The motion passed.

### **B. Medical Review Subcommittee**

Dr. Marian Macsai gave the Medical Review Subcommittee report. Dr. Macsai chose to focus on a few data points, rather than the complete set of data contained in the MAB package. Of particular interest to her and the subcommittee was the incidences of Primary Graft Failure and Early Re graft in 2017, 2018 and 2019. Dr. Macsai pointed out that DMEK cases and DMEK cases done with pre-loaded tissue had significant increases in graft failure and early re grafts when compared to PK and DSAEK procedures. Dr. Macsai continued her report by pointing out there seems to be a downward trend in Endophthalmitis and Infectious Keratitis but their subcommittee could not determine if this was as a result of minimizing warming tissue, rapidly warming tissue, or changes in donor prep. Dr. Macsai called on all Medical Directors to remember their responsibility in investigating reports of adverse events. Why surgeons are choosing to do more early re grafts is of interest to Dr. Macsai and the Medical Review Subcommittee. Understanding the reason for re graft can help the eye banks and the EBAA.

One eye bank was identified as having a significant increase in Primary Graft Failure and Early Regraft. The bank investigated but was unable to determine the cause for their increases.

### **C. Accreditation Board**

Since the last MAB meeting, one targeted off-cycle inspection committee was mobilized to address concerns provided to the EBAA. There was no change in the eye bank's accreditation status.

During the spring 2020 cycle, there were 14 banks that had applied for inspection. Because of the COVID-19 pandemic, only 4 banks were inspected. All four received a 3-year accreditation status with one bank having no findings. The 10 banks that were not able to be inspected received a 6-month extension to their accreditation and will be inspected in the fall.

The Accreditation board adopted a new policy for EBAA to notify member eye banks and Paton members when an eye bank loses its accreditation and conversely, when an eye bank gains accreditation.

### **D. Certification Board**

During the fall 2019 exam cycle (October 12-26), 17 individuals from the US, Canada, and Saudi Arabia passed the exam. The Spring 2020 exam was supposed to be held in April but was postponed to July due to COVID-19 and testing centers being closed. The exams will take place July 11-25. The EBAA worked with the Professional Testing Corporation and Prometric Testing Centers to be able to offer a remote proctor option for the exam which will enable candidates to take the exam in an empty room at home or at their office. The Certification Board voted to allow remote proctoring starting with the July exam and this option will remain an option going forward. This will make it easier for candidates who do not live near a testing center.

The 2020 fall exam cycle will be October 10-24 and the application will be available soon.

### **E. Technician Education Committee**

The Technician Education Seminar was held online and in-person. It began with a fun happy hour at Lucky Strike. The in-person portion was held in Philadelphia, PA. The Lions Eye Bank of Delaware Valley was thanked for hosting. The faculty included Josh Galloway, Troy Win'E, Ingrid Schunder, Sam Ramos, and Dr. George Rosenwasser. Dr. Rosenwasser provided slit lamp microscopes and Miracles in Sight provided whole eyes to allow technicians the opportunity to perform excisions. Sierra Donor Services Eye Bank, Lions VisionGift, SightLife, CORE, and Georgia Eye Bank all provided tissue for technicians to evaluate.

There were two community chats on technical operations in May. This was an opportunity for eye bankers to come together to discuss concerns, considerations, and best practices during the COVID-19 pandemic. The sessions were very well attended.

In December, the Tech Ed and QA committees worked together on a webinar to address the significant eye wash recall that affected many eye banks.

On August 12<sup>th</sup>, Beth Ann Benetz from Case Western Reserve University will be presenting a webinar (Corneal Endothelium Image Quality and Analyses: Best Practices for Eye Banking).

## F. Technical Procedures Manual

No report was given by the Technical Procedures Manual Subcommittee.

## IV. Old Business

### Donor Prep Subcommittee

The Donor Prep Subcommittee was formed at the October 2019 MAB meeting. Dr. Jennifer Li requested that the subcommittee be created to further review data on povidone-iodine prep of donor corneal tissue and report back at the next Medical Advisory Board meeting with potential further recommendations to the medical standards. To accomplish its task, the subcommittee performed the following: 1) Reviewed published literature, 2) Surveyed several eye bank medical directors, 3) Examined specific adverse reactions related to fungal infections reported to EBAA, 4) Gathered information from eye banks that have done studies and implemented changes to their donor prep, 5) Consulted infectious disease professionals, and 6) Re-survey eye banks on donor prep procedures.

Based on the data collected, reviewed, and discussed, the subcommittee recommended that further guidance to eye banks was necessary on the use of povidone-iodine. The subcommittee accepted a couple of friendly amendments which resulted in the following recommended changes to E1.100:

A **5%** povidone-iodine (PI) solution shall contact the entire surface of any ocular tissue intended for transplantation at least twice between the time of the donor's death and tissue preservation (e.g. corneoscleral disc in corneal preservation solution or whole eye in moist chamber). **Regardless of how PI is administered (e.g. # of drops, a specific mL, soak, etc.), the amount must be sufficient to completely cover the corneal surface, conjunctiva, lids, and lashes. The contact time for each application should not be less than 2 minutes and not exceed 5 minutes.** Excess Povidone-iodine solution should be irrigated from the ocular surface with a sterile eye wash/irrigating solution between applications and prior to preservation. **This** concentration, volume of solution, and the duration of ocular surface exposure to the solution shall be specified in the eye bank's operating procedures.

A motion was made and seconded. The changes to E1.100 were approved, and eye banks were given until September 1, 2020 to implement. Eye banks were strongly encouraged to implement ASAP but no later than September 1<sup>st</sup>.

## V. New Business

### A. Recommended Changes to M1.500 and G1.000

Kristin Mathes from Lions VisionGift requested changes to two medical standards, M1.500 and G1.000. She requested that M1.500 be changed to allow the distributing eye banks to seek postoperative information sooner, specifically for endothelial keratoplasties, but no sooner than 4 weeks. The current standard requires eye banks to seek post-operative information between 3 and 6 months. There was significant discussion with several MAB members speaking for and against this change. The recommended change to M1.500 did not pass.

The discussion then turned toward Kristin's recommended changes to G1.000. Simply put, she requested that the distributing eye bank (with support from the source eye bank) should be investigating adverse events and reporting. Kristin did clarify that the source eye bank would still be responsible for investigating and reporting systemic infections (e.g. communicable disease transmission). MAB members asked many questions and Dr. Li decided that a subcommittee needed to be formed to look into this further and come back with their recommendations at the next MAB meeting. Subcommittee members: Kristin Mathes (Chair), Dr. Marian Macsai, William Buras, Dr. Win Chamberlain, Brian Philippy, Beth Binnion, Jason Brosious, Mike Tramber, Shannon Schweitzer, and Michael Titus.

## **B. QA Committee Recommendations to Technical Procedures Manual**

Over the past several years, the Quality Assurance Committee has been working on quality specific procedures for the EBAA Procedures Manual. This year, they completed two more that they submitted to the Medical Advisory Board for consideration.

The first change was a revision of G1.000 Quality Assurance. They updated the procedure to include additional information as well as add more reference information. The second change was the creation of a new procedure for managing supplies and qualifying vendors.

A motion was made and seconded to approve these changes to the Technical Procedures Manual. The motion passed.

## **C. Recommended change to M1.600**

Chris Stoeger requested the MAB to revise M1.600 as follows:

Each eye bank shall report statistics to the EBAA. ~~in accordance with a policy established by the EBAA Board.~~ Each source eye bank shall report information on surgical technique, indications for surgery, and destination country.

EBAA shall maintain an electronic reporting system through which member eye banks must submit their statistical data. Eye banks shall fully submit their operational data no later than 30 days following the end of March, June, September, and December. Data to be submitted will be defined by the EBAA Statistical Ledger and the reporting system.

A motion was made and seconded to make the changes to M1.600. A friendly amendment was made to have the standard read,

Each eye bank shall report **data for statistical reporting** to the EBAA.

EBAA shall maintain an electronic reporting system through which member eye banks must submit their **data for statistical reporting**. Eye banks shall fully submit their operational data no later than 30 days following the end of March, June, September, and December. Data to be submitted will be defined by the EBAA Statistical Ledger and the reporting system.

The motion passed.

## **D. Corrections and addition to definitions**

Brian Philippy presented some corrections and additions to the definitions section of the EBAA Medical Standards. After some discussion, Brian withdrew his request and will present again at the next MAB meeting.

## **E. COVID-19**

Dr. Li acknowledged the tremendous work of the Policy and Position Research Subcommittee (PPRS). Providing timely guidance to eye banks on how to determine donors eligible during a pandemic is challenging but the PPRS responded very well. Dr. Li acknowledged Dr. Tony Aldave and the subcommittee for their hard work. Dr. Aldave then spent a few minutes talking about the subcommittee's work and the screening recommendations they produced. MAB members shared their thoughts on donor eligibility and appreciation for the PPRS. Dr. Li informed the MAB that the PPRS would certainly continue their work and further guidance's will be released as necessary and appropriate.

## **F. E-StatIS – EBAA Statistical Information System**

Jennifer DeMatteo informed the MAB that the EBAA was going to transition to a new statistical reporting system, called E-StatIS. EBAA Connect served the association well for 10 years but the EBAA, its member eye banks, and those that use the system and data want some changes. Jennifer made it clear that there will be no changes for 2020. Data will still be submitted to EBAA Connect. The new system, E-StatIS, will go into effect 1/1/2021. Preservation Time data (time from preservation date to surgery date) for domestic surgeries will be reported beginning in 2021, as previously approved by MAB. Jennifer gave a brief demo of the system.

## **VI. Late Additions**

### **A. Safe Surgery Arkansas**

Dr. David Warner spoke briefly on Safe Surgery Arkansas which was formed in 2019 as a response to the Arkansas General Assembly passing HB1251 (now Act 579 of 2019), a new law that permits optometrists (i.e. non-medical doctors) to perform certain surgeries on your eyes, without them having to attend medical school or years of surgical residency training. Dr. Warner thanked the MAB members and those watching and listening to the MAB meeting for considering a financial contribution to Safe Surgery Arkansas (<https://www.safesurgery2020.com/>). Dr. Warner also encouraged everyone to leverage existing relationships as well as develop new ones so as much attention can be given to this important topic as possible.

## **VII. Adjournment**

A motion was made and seconded to adjourn the Medical Advisory Board meeting. Motion Passed.