



## MEDICAL ADVISORY BOARD MEETING MINUTES

Eye Bank Association of America

Friday, June 8, 2018

1:45pm – 4:00pm

Loews Philadelphia

Philadelphia, PA

### I. Call to Order

Dr. Jennifer Li called the meeting to order at 1:45pm.

The following members were present:

Jennifer Li, MD, Vice Chair

Victoria Adler, RN, BSN, CEBT

Anthony Aldave, MD, PPR Subcommittee, Ex-Officio

Tony Bavuso, CEBT

Beth Binnion, CEBT, Ex-Officio

Jason Brosious, MSN, CEBT, CTBS

Brychan Clark, MD, Ex-Officio

Kevin Corcoran, CAE, President/CEO

Patricia Dahl, CEBT

Jennifer DeMatteo, MCM, CIC, EBAA Director, Ex-Officio

Donna Drury, CEBT, EBAA Chair, Ex-Officio

Sean Edelstein, MD

Brian Ha, MSc, CEBT

Sadeer Hannush, MD

Holly Hindman, MD

Douglas Holsclaw, MD

Joshua Hou, MD

Bernie Iliakis, MHA, CEBT

Bennie Jeng, MD

Stephen Kaufman, MD, PhD

Christopher Ketcherside, MD, Accreditation Board Vice Chair

David Korroch, CEBT

William Barry Lee, MD

Marian Macsai, MD

Mark Mannis, MD, Ex-Officio

Kristen McCoy, CEBT, Technical Education Committee Chair

Eric Meinecke, CEBT, Accreditation Board Chair  
Tom Miller, CEBT, MAB Secretary  
Brian Philippy, BSCHE, BS, CEBT, Ex-Officio  
Charles Pivoney, CEBT  
Michelle Rhee, MD  
George Rosenwasser, MD  
Kevin Ross, MS, MPH, Ex-Officio  
Chris Stoeger, MBA, CEBT, Accreditation Board Vice Chair  
Woodford Van Meter, MD  
Jim Wagner, CTBS, CEBT

## II. Approval of Minutes

Dr. Li called for a motion to accept the minutes from last meeting.

**ACTION:**           **A motion was made and seconded to approve the minutes as submitted.**  
                          **Motion passed.**

## III. Committee Reports

### A. Medical Review Subcommittee – Sean Edelstein, MD

Dr. Edelstein reviewed OARRS summary data and graphs.

### B. Policy and Position Research Subcommittee – Anthony Aldave, MD

Dr. Aldave reported on the PPR Subcommittee findings regarding the impact of Cornea Preservation Time Study (CPTS) on eye banking and surgeon practices.

### C. Accreditation Board – Eric Meinecke, CEBT

Mr. Meinecke reported that several form changes were approved by the Accreditation Board (AB) including the merging of PIQ/SIQ into a single document, and Record Review Worksheets were simplified. All form changes will be communicated to the membership soon and will be in effect beginning with the Fall cycle. AB approved the Confidentiality Agreement and Inspector's Pledge created by the Modernization Subcommittee and will be presented to the Board of Director's for adoption. Mr. Meinecke also reported that 13 banks were inspected during the Spring cycle: All 13 banks received 3-year accreditation; 4 banks scored 100% in all categories. Beginning in the Fall cycle, inspection reports will be emailed to Executive Director/CEO. New Accreditation Board Vice Chairs: Chris Stoeger and Christopher Ketcherside, MD.

### D. Certification Board – Kristen McCoy, CEBT

Ms. McCoy reported that the Fall 2017 CEBT exam was held October 14-28<sup>th</sup>: 37 candidates this testing period with an 81% pass rate. Spring 2018 CEBT exam took place March 24<sup>th</sup>-April 7<sup>th</sup>: 28 candidates this testing period with a 75% pass rate. The Exam Committee has made edits to the CEBT Exam content outline, which has been approved by the Certification Board and EBAA Board of Directors. The new content outline will be in place for the Fall exam. Exam review session planned for Summer 2018.

**E. Technician Education Committee – Kristen McCoy, CEBT**

Ms. McCoy shared that the Technical Education Committee hosted a webinar on February 28<sup>th</sup> by Lt. Dustin Smith of South Carolina Law Enforcement Division & Julie Plescia of Life Banc on *The Opioid Epidemic: What Eye Banks Need to Know*. Ophthalmic Spotlight: *Descemetorhexis and Corneal Collagen Cross-Linking* took place on May 23<sup>rd</sup> by Dr. Kathryn Colby of University of Chicago Department of Ophthalmology and Dr. Parag Majmudar of Chicago Cornea Consultants, Ltd. The 2018 Technician Education Seminar (TES) was held January 31-February 3 at LEITR in Tampa, FL with 46 attendees including the 2018 Jachin Misko Memorial Scholarship recipient, Scott Van Oss of Iowa Lions Eye Bank. New Technician Education Committee Chair: Josh Galloway.

**F. Technical Procedures Manual Committee – Andrew Maxwell, CEBT**

No report.

**IV. Old Business**

**A. Use of Povidone-Iodine Subcommittee Report - Eric Meineke, CEBT**

Mr. Meineke reported that a subcommittee reviewed the existing research on maximum efficacy of Povidone-Iodine solution on ocular tissue prior to recovery to determine if further research or validation is necessary and to evaluate the need for changes to the existing Medical Standard wording to provide a more specific guideline. The subcommittee has no suggested changes to the Medical Standards at this time; the specific concentration, duration of contact and volume of Povidone-Iodine should continue to be decisions left up to the eye banks and their medical directors. The subcommittee encourages more discussion and studies on this topic to ensure eye banks are doing everything possible to provide safe tissue for transplant, and strongly recommends that medical directors review the current procedures for Povidone-Iodine use and consider whether changes may be appropriate.

**B. Antifungal Supplementation Research Grant – Anthony Aldave, MD**

- i. Stephen Kaufman, MD, PhD presented a summary of his results on “Evaluation of the Efficacy and Optimal Timing of Supplementing Cold Storage Media with Amphotericin or Nicotinamide to Prevent Fungal Infection in Cornea Transplant Recipients.”
- ii. Bennie Jeng, MD presented a summary of his results on “Randomized, Double-Blind, Placebo-Controlled Study of the Safety of Amphotericin 0.255 µg/mL in Optisol-GS.”
- iii. Bennie Jeng, MD also presented on the research of his joint study with Elmer Tu, MD on “Safety and Efficacy of the Addition of Amphotericin B 0.255ul to Optisol-GS During Hypothermic Storage.”
- iv. Benjamin Aldrich, PhD submitted a written interim report of his research on *Metabolic Health of Human Corneal Endothelial Cells in Optisol-GS Supplemented with Amphotericin B*.
- v. Trent Chiang, MS submitted a written summary of his research on *Cost Effectiveness Analysis of Universal Amphotericin Supplementation to Intermediate-Term Cold Storage*

*Media for Endothelial Keratoplasty-Prepared Cornea: Estimating Patient Benefits and Economic Impacts.* He will present his research during the EBAA Scientific Symposium.

**C. Allocation and Distribution Subcommittee Report – Brian Philippy, BScE, BS, CEBT**

Mr. Philippy reported that a subcommittee met to consider whether the definition of “distribution” should be split; allocation – the act of coordinating placement and distribution – the act of packaging and transporting. The subcommittee determined that inspection and accreditation were not feasible for allocation-only entities, given lack of Medical Standards (with exception of K1.300) specific to functions of allocation.

**D. Change in Governance Subcommittee – David Korroch, CEBT**

Mr. Korroch reported that a subcommittee met to examine Medical Standard C1.400 with the intention of clarifying its meaning and intent regarding the definition of “governance.” The subcommittee proposed that the MAB (i.) recommend the EBAA Constitution and Bylaws Committee review membership policies and bylaws to ensure notification of changes in corporate structure are properly addressed at the association level and (ii.) retain the current wording of C1.400 until a clear requirement of reporting changes in member corporate structure is adopted in the bylaws or other governing document. Upon the adoption of these two recommendations, changes to wording of Medical Standard C1.400 could then be considered.

**E. Eye Only DRAI Subcommittee – Kristin Mathes, MA**

Ms. Mathes reported that the Eye Only DRAI subcommittee would like to revise the Adult, Child and Birth Mother UDRAIs based on recent changes in eye banking, adding questions pertaining to HTLV and diabetes, and removing questions related to receipt of human derived clotting factors. No vote from the MAB is required to make these changes. Ms. Mathes also asked for additional volunteers for the Eye Only DRAI Subcommittee.

**V. New Business**

**A. Definition of Tissue Evaluation – Kristin Mathes, MA**

Ms. Mathes proposed an updated definition of “tissue evaluation” in the Medical Standards. The proposed wording defines tissue evaluation as the “microscopic or other analysis of donor eye tissue to determine if tissue is suitable for intended use(s).”

**ACTION: A motion was made and seconded to adopt the proposed changes to the Medical Standards definition of tissue evaluation. Motion passed.**

**B. C3.300 Instruments and Reagents – Josh Galloway, CEBT**

Mr. Galloway proposed changes to the wording of Medical Standard C3.300 in order to harmonize ANSI/AAMI ST79 with the current EBAA Standard to reflect current practices.

**ACTION: A motion was made and seconded to adopt the proposed changes to Medical Standard C3.300 wording. Motion passed.**

**C. Gender Reassignment Discussion – Chris Hanna**

Mr. Hanna brought up the topic of gender reassignment surgery and asked the MAB for guidance in determining donor eligibility in these cases. A comment was made about the need to address gender fluidity, as opposed to just gender reassignment. Brian Philippy addressed the question from the perspective of the UDRAI, which inherently addresses the key-issues pertaining to donor eligibility in these cases, specifically concerning male to male sexual activity. In the *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*, FDA recommends that male or female gender be taken to be self-identified and self-reported in the context of the donor history questionnaire.

**D. ISBT 128 Discussion – Victoria Adler, RN, BSN, CEBT**

Ms. Adler reported on inconsistencies in ISBT 128 codes and requested a survey of the Membership regarding how ISBT 128 is working, discuss any issues and promote further dialog. Additional comments were made on the varying inconsistencies other Eye Banks have noted. A subcommittee was proposed to look further into this issue with the possibility of revising the existing EBAA guidance document to reflect current best practice and QA standards. *Subcommittee volunteers are Patricia Dahl (chair), Victoria Adler, Brian Philippy, Holly Hindman, Kristin Mathes, Tiffany Ramirez, and Holly Hindman, MD.*

**E. Tissue/Surgical Suitability Subcommittee Request – Brian Philippy, BScE, BS, CEBT**

Mr. Philippy proposed the creation of a subcommittee to discuss standardizing tissue evaluation methods and surgical suitability standards. *Subcommittee volunteers are Brian Philippy (chair), Jason Brosious, Jim Wagner, Kristen McCoy, Bernie Iliakis, Chris Conwell, Jonathan Lass, MD, Chris Ketcherside, MD and Jameson Clover.*

**VI. Late Additions**

No Late Additions.

**VII. For Information and Review**

**A.** 2017 Eye Banking by the Numbers

**B.** FDA Statement on Antifungal Supplementation

**C.** FDA ZIKV Donor Screening Recommendations Guidance

**D.** FDA HCT/P Minimal Manipulation and Homologous Use Guidance

**E.** ECDC Technical Report: Geographic Distribution of Areas with a High Prevalence of HTLV-1 Infection.

**VIII. Adjournment**

**ACTION: A motion was made and seconded to adjourn the Medical Advisory Board meeting at 3:24pm. Motion passed.**