



## **MEDICAL ADVISORY BOARD MEETING MINUTES**

Eye Bank Association of America

Thursday, November 9, 2017

1:00pm – 3:30pm

Astor Crowne Plaza

New Orleans, LA

### **I. Call to Order**

Dr. Michael Nordlund called the meeting to order at 1:00pm.

The following members were present:

Michael Nordlund, MD, PhD, Chair

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

Winston Chamberlain, MD

Kevin Corcoran, CAE, President/CEO

Patricia Dahl, CEBT

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

Donna Drury, CEBT, EBAA Chair, Ex-Officio

Paul Dubord, MD, FRCSC

Sander Dubovy, MD

Sean Edelstein, MD

Sadeer Hannush, MD

Holly Hindman, MD

Douglas Holsclaw, MD

Bernie Iliakis, MHA, CEBT

Bennie Jeng, MD

Stephen Kaufman, MD, PhD

Christopher Ketcherside, Accreditation Board Vice Chair

David Korroch, CEBT

William Barry Lee, MD

Marian Macsai, MD

Kristen McCoy, CEBT, Technical Education Committee Chair

Eric Meinecke, CEBT, Accreditation Board Chair  
Shahzad Mian, MD, Accreditation Board Chair  
Tom Miller, CEBT, MAB Secretary  
Brian Philippy, BSCHE, BS, CEBT, Ex-Officio  
Charles Pivoney, CEBT  
Jim Quirk, BS, CEBT  
Michelle Rhee, MD  
George Rosenwasser, MD  
Alan Sugar, MD, Ex-Officio  
Joel Sugar, MD, Honorary Member, Ex-Officio  
Elmer Tu, MD  
Woodford Van Meter, MD  
Jim Wagner, CTBS, CEBT

## II. Approval of Minutes

Dr. Nordlund 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

No formal report. Cornea Preservation Time Study (CPTS) results will be presented November 10<sup>th</sup>. PPRS to analyze results and look at potential impact of the findings on eye banking. Findings will be presented at June 2018 meeting. Volunteers to supplement PPRS for analysis of CPTS results include Sadeer Hannush, Elmer Tu, Shahzad Mian and Marian Macsai.

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

Mr. Meinecke reported that 17 banks were inspected during the Fall cycle: 16 banks received 3-year accreditation and 1 bank received 1-year accreditation; 7 banks scored 100% in all categories. The Accreditation Board (AB) discussed the creation and implementation of a Confidentiality Policy and Non-Disclosure Agreement for AB process. Language will be added to the AB policies and procedures to mandate that banks undergoing inspection provide a crosswalk between eye bank SOPs and the Policies and Procedures section of the PIQ/SIQ. AB implemented a new subcommittee regarding training of inspectors; vice-chairs will be responsible for developing the curriculum and ongoing education & training. Forms Subcommittee identified the specific eye banking functions applicable to each question in the PIQ/SIQ to guide inspectors in determining which questions are applicable to limited function eye banks. Finally, the AB agreed to provide an evaluation tool for peer-to-peer review of inspectors for ongoing improvement of the Board.

**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 81.1% pass rate.

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

Ms. McCoy shared that the Slit Lamp Seminar was held September 14-16<sup>th</sup> at Minnesota Lions Eye Bank with 20 attendees from the US and Canada. The 2018 Technician Education Seminar (TES) will be held January 31-February 3 at LEITR in Tampa, FL (Note: Early bird registration ends November 30<sup>th</sup> and online registration closes January 5<sup>th</sup>). The Technical Education Committee hosted a webinar on July 16<sup>th</sup> by Dr. Michael Bergevin of LifeNet Health on *The Changing Paradigm of Infectious Disease Determination*. An additional 1-2 webinars will be held before the end of the TEC cycle in June 2018. The 2018 Jachin Misko Memorial Scholarship recipient will be announced in the next issue of *Insight*.

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

No report.

**IV. Old Business**

**A. C3.400 Subcommittee Report – Kristin Mathes, MA**

Dr. Nordlund reported that a subcommittee chaired by Ms. Mathes (not present) met to give more consideration to a change in language of Medical Standard C3.400, which would allow for increased flexibility for eye banks to control the management of their policies and procedures. The subcommittee ultimately decided that a change would not be feasible and the language in the Medical Standard shall remain unchanged.

**V. New Business**

**A. Allocation and Distribution – Brian Philippy, BChE, BS, CEBT**

Mr. Philippy proposed the creation of a subcommittee to determine whether it would be appropriate to further divide the current definition of “distribution” into two distinct eye bank functions: allocation and distribution, where “allocation” would involve the act of coordinating the placement of tissue while “distribution” would be defined as the physical act of shipping tissue. This change in definition would allow the EBAA to seek membership from and provide oversight of those who perform the function of allocation as limited-function eye banks. *Subcommittee volunteers are Brian Philippy (chair), Jason Brosious, Joy Roussel, Paul Dubord, Patricia Dahl, Beth Binnion and Jennifer DeMatteo.*

**B. C1.400 Change in Governance – Jennifer DeMatteo, MCM, CIC**

Ms. DeMatteo addressed recent confusion surrounding Medical Standard C1.400 and seeks to provide clarification of what an “affiliation of an eye bank with another non-eye bank organization” means, i.e. merger, contractual relationship. Formed a subcommittee to review C1.400 regarding affiliation of an eye bank with another non-eye bank organization. *Subcommittee volunteers are David Korroch (chair), Eric Meinecke, Chuck Pivoney, Bernie Iliakis and Jennifer DeMatteo.*

**C. G1.000 Quality Assurance – Jennifer DeMatteo, MCM, CIC**

Ms. DeMatteo also identified the need to establish a standard timeframe for the reporting of deviations to the EBAA. The subcommittee charged with reviewing C1.400 will also address this issue.

**D. Antifungal Supplementation Research Grants**

Drs. Kaufman, Tu and Jeng reported on their research findings to date on Antifungal Supplementation to Storage Media. Additional reports will be available at the June 2018 meeting.

**E. EBAA Statistical Report Ledger Jan-Jun 2017 – Jennifer DeMatteo, MCM, CIC**

Ms. DeMatteo reported the 6-month stats and emphasized the need for eye bank data to be reported and correction of validation errors made in a timely manner. Also highlighted were the new addition of stats on countries of destination for transplant tissue.

**F. J1.000 Labeling – Kristin Mathes, MA**

Ms. Mathes was not present. Dr. Chamberlain proposed changes to Medical Standard J1.000 language to eliminate the requirement for date/time of death and date/time of initial preservation on the tissue label for short and intermediate term preserved tissues, as this information is already required on the Tissue Report Form. This change would allow room on the label for more pertinent data to be printed in a larger text size.

**ACTION: A motion was made and seconded to adopt the proposed changes to J1.000. Motion passed.**

**VI. Late Additions**

**A. D1.110 Revision – Paul Dubord, MD, FRCSC**

Dr. Dubord reviewed language in Medical Standard D1.110, in which reference to Prion disease does not appear in the June 2017 edition. Discussion ensued, and it was determined certain entries were eliminated from the EBAA standards to harmonize with FDA standards without duplication. Dr. Dubord proposed a revision to Medical Standard D1.110 language, specifically adding a distinctive entry pertaining to Prions and related diseases as Contraindications for Corneal Transplantation.

**ACTION: A motion was made and seconded to adopt the proposed revision to D1.110. Motion passed.**

**B. Povidone Iodine Solution – Eric Meinecke, CEBT**

Mr. Meinecke noted the Medical Standards do not stipulate concentration, volume of solution and the duration of ocular surface exposure to the PI solution prior to tissue preservation, as these standards shall be specified in the eye bank's operating procedures. However, during the recent inspection cycle it came to light that perhaps the standard leaves too much room for interpretation. A subcommittee was formed to review existing research on maximum efficacy of PI solution on ocular tissue prior to recovery, determine if

further research/validation is necessary, and evaluate the need for changes to the existing Medical Standard wording to provide a more specific guideline. *Subcommittee volunteers are Eric Meinecke (chair), Woody Van Meter, Steve Kaufman, Tom Miller and Jennifer DeMatteo.*

**VII. For Information and Review**

- A. JAMA Ophthalmology research article *Association Between Fungal Contamination and Eye Bank-Prepared Endothelial Keratoplasty Tissue*
- B. FDA Alert re: Zika Virus Risk
- C. FDA Final Guidance on Deviation Reporting
- D. EBAA Alert re: GeriCare eye wash contamination
- E. Formal comments will be submitted to the FDA re: unnecessary, redundant, and/or outdated regulations on December 7<sup>th</sup>. EBAA taking comments with relevant data from the membership, due by November 24<sup>th</sup>.
- F. Dr. Van Meter looking for committee volunteers for the 2018 cycle
- G. Congratulations to the 2018 Leonard Heise Award Recipient: Beth Binnion, CEBT – Cincinnati Eye Bank

**VIII. Adjournment**

**ACTION: A motion was made and seconded to adjourn the Medical Advisory Board meeting at 2:20pm. Motion passed.**