Medical Advisory Board Meeting Minutes
Thursday, October 10, 2019
Palace Hotel – San Francisco, CA

I. Call to Order

Dr. Jennifer Li called the meeting to order at 1:00pm.

The following members were present:

Jennifer Li, MD	Medical Advisory Board Chair
Winston Chamberlain, MD, PhD	Medical Advisory Board Vice Chair
Woodford Van Meter, MD	EBAA Chair
Kevin Corcoran, CAE	EBAA President & CEO
Jennifer DeMatteo	EBAA Director of Regulations & Standards
Eric Meinecke, CEBT	Medical Advisory Board Secretary
Tony Aldave, MD	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	Tech Ed & Certification Board Chair
David Glasser, MD	
Sandeer Hannush, MD	
Holly Hindman, MD	
Bennie Jeng, MD	
Christopher Ketcherside, MD	Accreditation Board Co-Chair
David Korroch, CEBT	
Anup Kubal, MD	
Marian Macsai, MD	Medical Review Subcommittee
Kyle Mavin, CEBT	Accreditation Board Co-Vice Chair
Shahzad Mian, MD	
Brian Philippy, CEBT	

Jim Quirk, CEBT	
Michelle Rhee, MD	Accreditation Board Co-Vice Chair
George Rosenwasser, MD, CEBT	
Christopher Stoeger, CEBT	Accreditation Board Co-Chair
Alan Sugar, MD	
Joel Sugar, MD	
Michael Titus, CEBT	Tech 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 June 7, 2019 meeting held in Scottsdale, Arizona.

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

III. Committee Reports

A. Medical Review Subcommittee

Dr. Marian Macsai reviewed the Online Adverse Reaction Reporting System (OARRS) summary data and graphs. Dr. Macsai informed the MAB that the EBAA has reached out to the Centers for Disease Control and Prevention (CDC) to determine if the OARRS data could be validated. A Keratoplasty Infections Surveillance Survey (KISS), in cooperation with the CDC, was proposed and Dr. Macsai requested four to five surgeons to volunteer to evaluate the survey prior to the launch of the study. The following individuals offered to work on this project with Dr. Macsai: Winston Chamberlain, Sean Edelstein, Holly Hindman, Bennie Jeng, Anup Kubal, Jennifer Li, Michelle Rhee, George Rosenwasser, and Michael Straiko.

There was significant discussion about eye banks obtaining post-operative outcomes from surgeons and the associated challenges. Dr. Li asked that Dr. Macsai and the Medical Review Subcommittee discuss this and come back to the next MAB meeting with recommendations (if any) on how to improve the process of collecting data from the surgeons. Dr. Macsai invited anyone interested in this topic to email her (mmacsai@northshore.org).

B. Policy & Position Research Subcommittee

No report.

C. Accreditation Board

Chris Stoeger reported that the Accreditation Board met that morning. Before reporting on the accreditation results, Chris wanted to inform the MAB that in 2019, three separate targeted off-cycle inspection committees were mobilized to address concerns provided to the EBAA in writing. One resulted in the denial of accreditation to a bank previously accredited, one resulted in the change of accreditation status from three years to one year, and one resulted in no change to the accreditation status.

In the current cycle, seventeen banks were inspected. Five banks had no findings, fifteen banks received a three-year accreditation, one bank received a one-year accreditation, and one bank was denied accreditation.

Kevin Corcoran informed the AB that the EBAA is beginning to formulate plans for accreditation of non-member banks. Chris said the EBAA Board of Directors would be discussing this later in the day. The AB also heard a report on the use of video in accreditation inspections and a pilot group was working on this topic.

The AB did request that the Matrix II in Medical Standard L1.100 be updated to include both the date and time that cooling of ocular tissues or body refrigeration began. The current matrix only as time.

A motion was made and seconded to change L1.100 Matrix II to read, “Date and time that cooling of ocular tissues or body refrigeration began.” Motion Passed.

D. Certification Board

Josh Galloway reported that the Fall 2019 CEBT exam will take place October 12-26. Candidates from the US, Canada and Saudi Arabia have registered for the exam. The Spring CEBT Exam will take place April 11-25, 2020. Starting spring 2020, Professional Testing Corporation will be partnering with Prometric and will be using their testing center network. This change will increase the number of location options candidates have to take the exam. Application information will be sent out in November.

E. Technician Education

Josh Galloway reported that the committee planned the webinar “Ocular Research Tissue: From the Eye Bank to the Researcher” which took place in August. The speakers for this session were Kristen McCoy (Eversight), Sung Lee (Lions Gift of Sight), David Ammar (Lions Eye Institute for Transplant and Research), and Dan Stamer (ARVO). Josh said the session was available on EBAA’s eyeLEARN. The Technician Education Committee is currently planning additional webinars and will have more information soon. The 2019 Slit Lamp Microscopy Seminar will take place October 24-25 at Lions Gift of Sight in St. Paul, Minnesota. Josh reported that registration is open but would be closing on Monday. Finally, the Technician Education

Seminar (TES) will take place February 20-22, 2020 in Philadelphia at the Lions Eye Bank of Delaware Valley.

F. Technician Procedure Manual

Michael Titus reported that the Technical Procedures Manual Subcommittee had been tasked with including the tissue evaluation recommendations of the Tissue Suitability Subcommittee during the last MAB meeting in June. The subcommittee met several times via conference call and email and proposed changes to F1.200 and F1.300 of the EBAA Technical Procedures Manual. In addition, the subcommittee proposed adding the "Recommended Minimum Standards for Surgical Suitability by Surgical Type" to F1.200. Procedure F1.400 Pachymetry Measurement was also added.

During the subcommittee's work, they identified that K-Pro was omitted from F1.300 – Determination of Surgical Suitability in the Medical Standards.

Brian Philippy commented that while measurement of arcus clear zone had been appropriately added to F1.200, clear zone was not. Michael Titus said his subcommittee would look at that. Dr. Jennifer Li also asked that pleomorphism be added back into the definition of terms for F1.300.

A motion was made and seconded to make the updates (including adding definitions of clear zone and pleomorphism) to the Procedures Manual. Motion Passed.

The discussion then turned to F1.300. After a lengthy discussion, the following friendly amendments were made:

- The word "stromal" was removed from all sections (will read No infiltrates).
- Down syndrome or evidence of ectatic dystrophy was added to K-pro section.
- The DMEK section was changed to read "No Descemet's membrane tears within intended graft area.

The section on K-Pro was modified to read as follows:

Minimum suitability for Keratoprosthesis (K-Pro):

- No infiltrates
- No pterygia, neovascularization, foreign bodies, or significant corneal thinning
- No prior refractive surgery (e.g. radial keratotomy, lamellar inserts, photoablation, etc.)
- No Down syndrome or evidence of ectatic dystrophy (e.g. keratoconus, keratoglobus, etc.).

A motion was made and seconded to update F1.300 as discussed. Motion Passed.

IV. Old Business

A. Standardized Data Collection for Surgeons

Dr. Holly Hindman reported that her subcommittee discussed this topic at length and the recommendation was to request surgeons/surgery schedulers to be clearer about the indication for use when requesting tissue and for eye banks to provide a list of indications on request forms or in their on-line tissue request portals.

B. EBAA BOD's decision regarding Transplant Connect's proposal to include additional 9 fields to the stat report

Kevin Corcoran reported that the additional fields would not be added to the stat report at this time. The EBAA Board of Directors discussed the situation with not having a proposal from Transplant Connect and the decision was made to evaluate other vendors for the EBAA statistical report data collection next year. EBAA will be requesting proposals from other vendors in addition to Transplant Connect for future statistical report data collection.

V. New Business

A. Proposed change to E1.100

With the goal of reducing fungal infections, Dr. Straiko presented a change to EBAA Medical Standard E.100. That change was as follows:

"Povidone-iodine solution shall contact the surface of any ocular tissue intended for transplant at least ~~once~~ twice between the time of the donor's death and tissue preservation (e.g. corneoscleral disc in Optisol-GS or whole eye in moist chamber). Excess povidone-iodine solution should be irrigated from the ocular surface between applications and prior to preservation. The concentration, volume of solution, and the duration of ocular surface exposures to the solution shall be specified in the eye bank's operating procedures."

The proposed change was based on Georgia Eye Bank's procedural change and the data collected by a large surgery center in its service area demonstrating that the change significantly reduced positive rim cultures and infections. There was significant discussion on this topic (both for and against making a change to the medical standards). Dr. Li asked that the word "entire" be added in front of the word surface in the first sentence.

A motion was made and seconded to modify E1.100 as presented by Dr. Straiko with the friendly amendment by Dr. Li. Motion Passed. *The change to the medical standard will be effective January 1, 2020.*

More investigation into this topic was recommended by the MAB. Dr. Li suggested a subcommittee be formed to dive deeper into this topic and report back at the next meeting with potential further recommendations on donor prep procedures. Subcommittee members include: Eric Meinecke (Chair), Dr. Michael Straiko, Dr. Sadeer Hannush, Ingrid Schunder, Brian Philippy, Kyle Mavin, William Buras, Dr. Sean Edelstein, Edwin Roberts, Dr. Shahzad Mian, Michael Titus, and Darrell Fisher.

B. Recommendation to create Subcommittee/Strikeforce to address critical and time-sensitive issues impacting EBAA members

Eye banking is becoming increasingly complex and the need to respond rapidly to emerging diseases and critical issues that could potentially impact the quality and safety of corneal tissue distributed for transplant is becoming increasingly important. Brian Philippy proposed that the MAB create a standing subcommittee or strike force charged with convening and addressing issues in a rapid manner, consistent with either our inherent need to react fast to protect recipients (e.g. Zika, Ebola, etc.) or multi-eye bank "ticking clock" items (e.g. possible reporting deadlines like 24 hours for CTO or 15 days for FDA).

Dr. Li asked how this proposal is different than how the current MAB operates. Dr. Li explained that the MAB has been able to respond quickly to issues and provide guidance and support to eye banks. Dr. Tony Aldave also commented that his subcommittee (Policy & Position Research Subcommittee) plays a role in assisting the EBAA and MAB with handling emerging diseases and critical issues. The recommendation to form a standing subcommittee/strike force was not approved but the topic did generate a lot of good discussion.

C. EBAA Statistical Report Ledger CY 2019

Jennifer DeMatteo briefly reviewed 6 months of statistical data (Jan-Jun 2019).

VI. Late Additions

A. David Korroch announced Donna Drury as the next EBAA Heise Awardee recipient.

B. Jennifer DeMatteo proposed the following revisions to EBAA Medical Standards Appendix II: FDA-defined Contraindications to Transplant:

p. Persons who have been diagnosed with vCJD or any other form of CJD. Note: If the individual knowledgeable about the donor's medical and travel history is not familiar with the term "Creutzfeldt-Jakob Disease" or "variant Creutzfeldt-Jakob Disease," you may try to describe those in layman's terms. If the person being interviewed is

still not familiar with those terms, you may consider the lack of familiarity with those terms as a negative response to questions using those terms.

q. Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology. **Examples include Parkinson, amyotrophic lateral sclerosis, multiple sclerosis, Alzheimer disease, Guillain-Barre, and Chronic Inflammatory Demyelinating Polyneuropathy (CIPD).** Potential donors who have a diagnosis of delirium (e.g., delirium caused by toxic/metabolic diseases or recent head trauma) would not necessarily be considered to have a diagnosis of dementia and should be evaluated by the Medical Director. (**Ocular tissue** from donors with dementia confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident or brain tumor and who are confirmed not to have evidence of TSE on microscopic examination of the brain may be acceptable based on an evaluation by the Medical Director).

r. Persons who are at increased risk for CJD. Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD.

s. Persons who have a history of CJD in a blood relative unless the diagnosis of CJD was subsequently found to be an incorrect diagnosis, the CJD was iatrogenic, or the laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD.

t. Persons who spent three months or more cumulatively in the United Kingdom **(England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands)** from the beginning of 1980 through the end of 1996.

u. Persons who are current or former U.S. military members, civilian military employees, or dependents of a military member or civilian employee who resided at U.S. military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.

v. Persons who spent 5 years or more cumulatively in Europe **(Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, ~~Macedonia~~, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, or former ~~and~~ Yugoslavia, Republic of Macedonia, and Czechoslovakia)** from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996).

w. Persons who received any transfusion of blood or blood components in the U.K. or France between 1980 and the present.

A motion was made and seconded to revise EBAA Medical Standards Appendix II: FDA-defined Contraindications to Transplant as presented by Jennifer DeMatteo. Motion Passed.

VII. For Information and Review

A. Informational Alert: Altaire Pharmaceuticals Recalls Multiple Ophthalmic Products (July 17, 2019)
B. Informational Alert: Altaire Pharmaceuticals Recall Update (July 25, 2019)
C. The Focal Point: Advocacy & Legislative Update (September 10, 2019)
D. 2018 Povidone-Iodine Survey
E. Increasing Povidone-Iodine Exposure (Salisbury et al., 2019)
F. Increased Bactericidal Activity of Dilute Preparations of Povidone-Iodine Solutions (Berkelman et al., 1982)

VIII. Adjournment

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