MEDICAL ADVISORY BOARD MEETING MINUTES
Eye Bank Association of America
Friday June 5, 2015
1:00pm – 4:00pm PDT
Loews Atlanta Hotel

I. Call to Order

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

The following members were present:

Michael Nordlund, MD, PhD, Chair
Jennifer Li, MD, Vice Chair
Anthony Aldave, MD
Tony Bavuso, Secretary
Beth Binnion, Ex-Officio
Jason Brosious
Scott Brubaker, AATB Liaison, Ex-Officio
Kevin Corcoran, EBAA President/CEO, Ex-Officio
Patricia Dahl
Jennifer DeMatteo, EBAA Director, Ex-Officio
Donald Doughman, MD, Honorary Member, Ex-Officio
Donna Drury
Paul Dubord, MD
Sean Edelstein, MD
John Fisher
W. Craig Fowler, MD
Mary Gatien
David Glasser, MD, EBAA Chair, Ex-Officio
Brenda Horn
Bernie Iliakis
Bennie Jeng, MD
David Korroch
Ellen Lazarus, MD, FDA Liaison, Ex-Officio
William Barry Lee, MD, Accreditation Board Chair
Thomas Lindquist, MD, PhD
Jay Lugo, Certification Board Chair
Jackie Malling

Andrew Maxwell, Technical Procedures Manual Subcommittee Chair, Ex-Officio
Kristen McCoy, Technical Education Committee Chair
Eric Meinecke, Accreditation Board Vice Chair, Ex-Officio
Shahzad Mian, MD, Accreditation Board Vice Chair, Ex-Officio
Tom Miller, Ex-Officio
Brian Philippy, Ex-Officio
Jim Quirk, Accreditation Board Chair
Kevin Ross
Chris Stoeger

II. Approval of Minutes

Dr. Nordlund called for a motion to accept the minutes from the 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 the OARRS summary data and graphs. Dr. Nordlund requested that data reported on the graphs reflect infections per 10,000 grafts to be consistent with the total infections graph and also plotted by procedure type. MAB members were in agreement and Ms. DeMatteo indicated that future reports can be prepared accordingly.

B. Policy and Position Research Subcommittee – Sadeer Hannush, MD

No report.

C. Accreditation Board – Jim Quirk

Mr. Quirk reported that 15 banks were inspected. Thirteen of the banks received a 3 year accreditation, one bank received a 2 year accreditation, one bank was denied and three banks deferred. Of the 13 banks that received a 3 year accreditation, 4 banks received a 100% score on their inspections.

Mr. Quirk reported that the Accreditation Board voted to pilot the 3-tier site inspection scoring system developed by the subcommittee for the fall cycle.

D. Certification Board – Jay Lugo

Mr. Lugo reported that 48 people sat for the Spring CEBT exam cycle. Thirty-nine people passed and 9 failed for a passing rate of 81.2%. The Fall CEBT Exam took place October 11-25, 2014. Out of the 19 candidates who took the

exam, 12 people passed. The exam was held in the US, Canada, and Korea. The highest score was 229 (91.6%) and the lowest score was 168 (67%). Another review of the exam will be conducted in the Spring of 2016.

E. Technician Education Committee – Kristen McCoy

Ms. McCoy reported that the committee held 2 EEI's last year, with one coming up in August. They have a goal to hold 3 to 4 EEI's next year. The committee held the first slit-lamp course in November 2014 hosted by the Minnesota Lions Eye Bank. There were 21 attendees. The committee plans to schedule another slit-lamp course for the latter half of this year to be held again at the Minnesota Lions Eye Bank. The TES was held in February in Tampa with 54 attendees from the U.S., Mexico, and Canada. There will be another TES in late January or February of next year in Tampa.

F. Technical Procedures Manual – Drew Maxwell

Mr. Maxwell reported that there three types of revisions made to the procedures manual: 1) housekeeping items, 2) terminology changes due to ICCBBA, and 3) record retention timeframes. The MAB considered these changes by category.

For the housekeeping items, the following changes were recommended:

Page 5, Procedure, Accreditation, 1. *Currently states that accreditation or re-accreditation must be applied for at least every 3 years. Suggest to remove "at least (every three years" due to some eye banks being granted fewer than 3 years. Perhaps replace with, "As indicated by terms of accreditation."*

Page 5, Procedure, Membership, 3. "*..Committee and response sent to.." should be changed to "..Committee and a response will be sent to.."*

Page 6, Procedure, 3. *Add space above so there is a separation between 2 and 3*

Page 6, Rationale, 6. *"..approval of.." should be changed to "..approval by.."*

Page 11, H. *"..quarantine, surgical, and research ocular tissue." should be changed to "..quarantined tissue, surgical tissue awaiting distribution, and research tissue." to keep consistent wording with medical standards*

Page 52, Before 11. *Remove the underline of the "s" for "procedures"*
Page 98, I*. Remove "A statement that the ocular tissue was tested and was non-reactive for required tests."*

Page 107, Procedure, 2., B. *Perhaps remove writing mistaken entry or error. If approved, also adjust C to reflect the change.*

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

For the terminology changes due to ICCBBA, the following changes were recommended:

Page 5, Procedure, Membership, *Insert as 2.* "*Register with ICCBBA for a Facility Identification Number (FIN)."*

Page 14, Procedure, *Insert as 2. "Eye banks shall utilize ICCBBA nomenclature to describe ocular tissue classes and attributes."*

Page 48, 11. *Insert as I. "Utilize ISBT 128 identifiers to label ocular tissue products. These identifiers include the Donation Identification Number (DIN), product code and all dates."*

Page 70, 11. *Insert after H. Include Donation Identification Number and product code as one of the label requirements*

Page 98, *Insert as J and K. Discuss need to utilize ISBT 128 identifiers to label ocular tissue – Donation Identification Number, product code and all dates. Discuss ISBT 128 data structures shall be used within two-dimensional symbols to label ocular tissue products distributed internationally.*

The committee will go back and add effective dates to these changes to coincide with the ICCBBA phased implementation dates.

ACTION: A motion was made and seconded to approve the ICCBBA terminology revisions as submitted. Motion passed.

For the record retention timeframes, the following changes were recommended:

Page 9, 4. *Add # of years for record retention – 3 years*

Page 10, Before 2., *Certification for 10 years*

Page 10, 2., *States cleaning records for 10 years*

Page 10, 3., B *States cleaning records for 3 years*

Page 11, F. *States cleaning records for 10 years*

Page 11, 5., A. *States cleaning records for 3 years*

Page 12, 7. *States cleaning records for 3 years*

Page 12, 8. *States cleaning records for 3 years*

Two above highlighted instances should switch to 3 years

ACTION: A motion was made and seconded to approve the record retention revisions as submitted. Motion passed.

The committee will review the references section at the next meeting.

IV. Old Business

A. Distribution Compliance Subcommittee – Paul Dubord, MD

Dr. Dubord presented revisions to the Medical Standards as follows:

K1.200 Distribution Compliance

Compliance with EBAA medical standards shall be maintained in eye bank functions performed through distribution. A~~n~~ **distribution** eye bank ~~performing distribution~~ shall inform the consignee, in writing, of requirements for tracking and traceability, outcomes and adverse reaction reporting. **A distributing eye bank shall establish, maintain, and document an agreement with each consignee to ensure that the principles of tracking, traceability, and adverse reaction reporting are maintained throughout the process of distribution.** Compliance with applicable laws, regulations and standards in eye bank functions performed after distribution is the responsibility of the consignee.

GLOSSARY

Consignee. Any eye bank, eye banking intermediary or transplanting surgeon (whether individual, agency, institution, or organization) that receives tissue and assumes responsibility for any step in the processing, storage, distribution and/or use of such tissue.

Distributing Eye Bank. **Is the entity that provides tissue to a consignee, such as an eye banking intermediary, transplanting surgeon (whether individual, agency, institution, organization, or researcher). An agreement must be in place and maintained between all parties to ensure the principles of tracking, traceability and adverse event reporting.** ~~An entity that is reimbursed for or invoices for providing tissue to the end user. Shall be responsible for tracking recipient or consignee information, post op follow up and reporting any adverse reaction to the source establishment.~~

Distribution. A process of allocation of tissue for transplant, research or educational use. This process includes receipt of request, selection,

inspection and release of tissue, to a consignee such as a surgeon, surgical center or educational research center. The principles of tracking, traceability and adverse reaction reporting will be maintained throughout the process of distribution.

After considerable discussion regarding the implications of the language “an agreement must be in place…”, it was recommended that the subcommittee revisit the definitions and refocus the recommended standards change from K1.200 to C3.510 and bring it back to the MAB for consideration at the Fall meeting.

B. Pre-operative Culture Survey Study Results – Anthony Aldave, MD

Dr. Aldave shared the results of the study of donor corneal rim cultures and fungal infections with the MAB and solicited feedback. The MAB considered limitations of the data set used for the study, and recommended that the EBAA Statistical Committee meet with the study authors to review the data set and explore how it may be improved upon for follow up studies. No other action was requested at this time.

V. New Business

A. L1.100 Tissue Report Form – Brian Philippy

Mr. Philippy recommended that the MAB form a subcommittee to review medical standards L1.100 and F1.000 and recommend changes to clarify the information which must be on the tissue report form and the tissue evaluation requirements for processed and non-processed tissue.

A subcommittee comprised of the following people was formed to evaluate L1.100 along with the evaluation matrices to ensure a tissue report form be sent with each tissue and to clarify the information that must be on the tissue report form:

Tom Miller (Chair), David Glasser, Brian Philippy, Pat Dahl and Chris Stoeger.

B. Statistical Committee Survey – Brian Philippy

Mr. Philippy shared the survey results. This was informational in nature and no MAB action was required.

C. Global Medical Standards Revisions – Brian Philippy

Mr. Philippy recommended that MAB consider revising the medical standards to eliminate references to specific external regulatory bodies. Dr. Nordlund did an informal poll to gauge support for the removal of references to FDA and/or other external regulatory bodies, and there was majority support for doing so.

A subcommittee comprised of the following people was formed to review the applicable medical standards and recommend changes:

Brian Philippy (Chair), Collin Ross, Tom Miller, Eric Meinecke, Dave Korroch, Michael Nordlund, MD, PhD, Brian Ha, and Paul Dubord, MD.

D. ISBT 128 Implementation Guide – Jennifer DeMatteo

Ms. DeMatteo shared the ISBT 128 Implementation Guide, reviewed highlights related to ocular terminology, tissue attributes, storage solutions, and processing facility code, and noted that future revisions will occur to accommodate portions of tissue to the coding system.

ACTION: A motion was made and seconded to adopt the implementation guide with the future revisions. <u>Motion passed.</u>

The ISBT 128 subcommittee was tasked with reviewing the medical standards related to tissue identification numbers and the implementation of the ISBT 128 coding system. The subcommittee includes the following members:

Pat Dahl (Chair), Beth Binnion, Jennifer Li, Donna Drury, Mike O'Keefe, Michael Tramber, Julie Frketich, and Jennifer DeMatteo

VI. Late Additions

Dr. Nordlund made a motion to add History of Ebola Virus Disease (EVD) as a contraindication to D1.100.

ACTION: A motion was made and seconded to add History of Ebola Virus Disease (EVD) as a contraindication. <u>Motion passed.</u>

Dr. Rhee sought feedback from the MAB and other physicians about altering the steroid regimen with vaccination and the use of Zostavax following ocular zoster.

Ms. DeMatteo requested guidance from MAB on revisions to the Uniform DRAI. The MAB recommended that the eye only subcommittee make the changes without explicit MAB approval and report changes at the MAB meeting.

VII. For Information and Review

As the new Editor, Ms. Ellen Heck requested submissions for the International Journal of Eye Banking, which was recently acquired by the EBAA.

Ms. DeMatteo referred to the ISBT 128 Registration FAQs and the Advisory Committee on Blood &Tissue Safety and Availability (ACBTSA)

recommendations to the Secretary of Health on tissue tracking and traceability, which are included for reference.

A brochure on the NOTIFY Library website was also included in the agenda packet to make members aware of this resource. Members were urged to publish interesting case reports of adverse reactions following corneal transplantation for inclusion in the database.

Dr. Nordlund announced that Matthew Kuehnert, MD was not able to be present.

VIII. Adjournment

ACTION: A motion was made and seconded to adjourn the Medical Advisory Board meeting at 3:18pm. <u>Motion passed.</u>