MEDICAL ADVISORY BOARD MEETING MINUTES
Eye Bank Association of America
Thursday, November 12, 2015
1:00pm – 4:00pm
Caesar’s Palace, Las Vegas, NV

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
Victoria Adler
Anthony Aldave, MD
Tony Bavuso, Secretary
Beth Binnion, Ex-Officio
Jason Brosious
Scott Brubaker, AATB Liaison, Ex-Officio
Winston Chamberlain, MD
Brychan Clark, MD, FDA Liaison, Ex-Officio
Kevin Corcoran, EBAA President/CEO, Ex-Officio
Patricia Dahl
Jennifer DeMatteo, EBAA Director, Ex-Officio
Donna Drury
Paul Dubord, MD
Sean Edelstein, MD
W. Craig Fowler, MD
David Glasser, MD, EBAA Chair, Ex-Officio
Kenneth Goins, MD
Sadeer Hannush, MD
Holly Hindman, MD
Bernie Iliakis
Bennie Jeng, MD
Stephen Kaufman, MD, PhD
David Korroch
William Barry Lee, MD, Accreditation Board Chair
Thomas Lindquist, MD, PhD
Jay Lugo, Certification Board Chair
Marian Macsai, MD
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. Graphical data is now being shown as incidence per 10,000 grafts. It was noted that the relative prevalence of fungal infections going back to the early 2000’s represents a significant portion of endophthalmitis cases.

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

No report.

**C. Accreditation Board – Barry Lee, MD**

Dr. Lee reported that 9 banks were inspected this cycle. Two banks received a 100% score, and of the remaining 7 banks, 6 banks received a 3-year accreditation and 1 bank received a 1-year accreditation.

The Accreditation Board formed a subcommittee to discuss and develop policies for accrediting international eye banks outside of North America.
D. Certification Board – Jay Lugo

Mr. Lugo reported that 27 people sat for the Fall CEBT exam cycle. Twenty-one people passed and 6 failed for a passing rate of 77.8%. Five of the 6 who failed were repeat test-takers. The next exam cycle will take place March 19-April 2, 2016.

The Certification Board approved a change in the certification criteria proposed by the Continuing Education Committee. The change redefines the number of CEUs awarded for self-study, and will allow for a journal article or self-study submission to be eligible for ¼ CEU with a maximum of 1 CEU to be earned per cycle with Continuing Education Committee approval.

E. Technician Education Committee – Kristen McCoy

Ms. McCoy reported that the committee held 2 EEI’s in August and October 2015. Additional EEI’s are planned for the coming months. The second slit-lamp course was held successfully on October 8-10 at the Minnesota Lions Eye Bank with 17 attendees. The next TES will be held in Tampa and hosted by the Lions Eye Institute for Transplant and Research on January 20-23, 2016. The selection committee for the Jachin Misko Memorial Scholarship will announce this year’s recipient of the scholarship in the next couple of weeks.


No report.

IV. Old Business

A. ISBT 128 Subcommittee – Pat Dahl

Ms. Dahl highlighted the proposed changes to the Medical Standards to comply with ISBT 128 standards. The proposed changes are as follows:

B1.000 Active Membership

In order for an eye bank to become an active member of the Eye Bank Association of America (EBAA), it must comply with the EBAA Bylaws and the following:

1. Demonstrate compliance with EBAA Medical Standards.
2. Maintain accreditation status by passing the site inspection as administered by the EBAA Accreditation Board.
3. Demonstrate proficiency in any aspect of eye banking including recovery, processing, tissue storage, evaluation, donor eligibility determination and distribution.
4. Proficiency shall be demonstrated by providing documentation, at the time of completing the application, of the handling of at least 25 surgical corneas for each eye bank function for which it is seeking accreditation.

5. Certify compliance with applicable Federal and State regulations.

6. Register with ICCBBA for a Facility Identification Number (FIN). This is required for all eye banks that assign a DIN or apply an ISBT 128 label to ocular tissue, by June 30, 2015.

Once accredited, an eye bank must be inspected and reaccredited at least every three years to maintain active membership in the EBAA.

E1.300 Use of Short or Intermediate Term Storage Solution

Eye banks shall use an appropriate corneal storage solution that has been manufactured in accordance with FDA Good Manufacturing Practices. The solution shall be used and stored according to the manufacturer’s recommendations for temperature, date and other factors. The manufactured solution purchased and shipped to the eye bank shall be inspected for damage upon arrival. The lot number of storage solution used for each cornea shall be recorded on the tissue report containing the ISBT 128 tissue unique identification number of the tissue to allow tracking and recall.

J1.000 Labeling

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labeled to include at least the information below.

All tissues:

1. Name of source eye bank.
2. ISBT 128 Tissue identifier. The ISBT 128 tissue identifier includes the Donation Identification Number (DIN), Product Code, and Processing Facility Information Code (if applicable). There must be a unique identification number for each ocular tissue or fraction thereof.
3. Type of tissue (e.g. cornea, whole eye, sclera).
4. If cornea has had additional processing (e.g. lamellar, laser shaped), clearly indicate this on the label.
5. If the Product Code and the Donation Identification Number are not assigned by the same entity, then the label must include the Processing Facility Information Code (FINP).
6-6 Expiration date of tissue, in the international format (YYYY-MM-DD).
6-7 A statement that the tissue is intended for single patient application only.
7-8 A statement that the tissue is not to be considered sterile unless tissue has been subjected to a validated process to ensure sterility.
8-9 Type of storage solution.
9. Utilize ISBT-128 identifiers to label ocular tissue products, effective January 1, 2016. These identifiers include the Donation Identification Number (DIN), Product Code, and all dates.
10. ISBT 128 data structures shall be used within two-dimensional (2-D) symbols (Data Matrix) to label ocular tissue products distributed internationally, effective January 1, 2017.

Short and intermediate term preserved tissues:

1. Date and time of donor’s death \((YYYY-MM-DD HH:MM)\).
2. Date and time of initial corneal/scleral preservation \((YYYY-MM-DD HH:MM)\).

L1.000 Documentation to Accompany Donor Tissue

L1.100 Tissue Report Form

For special research studies, by recommendation of the Medical Advisory Board and approved by the EBAA Board of Directors, certain specific data may be masked on the tissue report form and label. A copy of the tissue report form shall accompany the tissue. The tissue report shall contain the following:

All Tissues:

1. Name of (Source) eye bank
2. Location of eye bank
3. Telephone number of eye bank
4. **Eye bank ISBT 128 Tissue Identification number unique to each tissue graft. Effective January 1, 2016, utilize ISBT 128 Donation Identification Number (DIN) and Product Code.**
5. Type of storage solution
6. If cornea is processed, clearly indicate the type of processing performed or the indicated use (e.g. endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty, etc.).
7. Report requirements by processing type according to Matrix II.
8. Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, storage, evaluation, donor eligibility determination and distribution.
9. A summary of records reviewed regarding the eligibility of tissue for transplant.

Short and intermediate term preserved tissues:

1. Age of donor
2. Cause of death
3. Death date and time \((YYYY-MM-DD HH:MM)\)
4. Preservation date and time \((YYYY-MM-DD HH:MM)\)
5. Additional tissue processing date and time \((YYYY-MM-DD HH:MM)\)
6. The date and time that cooling of ocular tissues and/or refrigeration of the body was begun
L1.200  Package Insert Form

A “Package Insert” form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole eye). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
3. For corneas in intermediate-term storage solution, a color change per the manufacturer’s guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank.
5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
6. The form shall advise the consignee that they are responsible for tracking of
   • the tissue recipient’s name and unique identification number,
   • age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery,
   • and the name of the transplanting surgeon when the tissue is transplanted, and
   • the ISBT 128 tissue identifier.
6. This information is required to track the tissue from the donor to consignee and from the consignee to the recipient.
7. Infectious disease tests were performed by a CLIA certified and FDA registered laboratory.
8. That FDA approved tests were used for infectious disease testing as required by the FDA and EBAA, some of which are approved for pre-mortem blood and that FDA approved tests for cadaveric blood were used where available.
9. A list of infectious disease test results for that specific donor.

This information may be included on the eye bank’s donor screening form as long as it is easily noticed; otherwise a separate package insert form is advised.

M1.000  Eye Bank Records
Eye banks shall utilize ICCBBA Eye Bank Technical Advisory Group (EBTAG) nomenclature to describe ocular tissue classes and attributes, effective June 30, 2015.

All records shall utilize ISBT 128 tissue identifiers, effective January 1, 2016. This includes the Donation Identification Number (DIN) and Product Code.

M1.400 Minimum Information to Be Retained

Forms for retaining donor and recipient or consignee information shall be established and shall be readily accessible for inspection by the EBAA Accreditation Board. Eye bank records shall include the following minimum information:

See Section L1.000 for information to be included on the Tissue Report Form.

1. **ISBT 128 Tissue Identifier** - Eye bank identification number unique to each tissue graft
2. Name of eye bank
3. Type of storage solution
4. Storage solution lot numbers
5. Unique donor identification number
6. Name of donor (or if import tissue, name of importing eye bank and their unique ID number)
7. Age of donor
8. Cause of death
9. Death date and time
10. Enucleation or in situ excision date and time
11. Preservation date and time
12. The date and time that cooling of ocular tissues and/or refrigeration of the body was begun
13. Additional tissue processing date and time
14. Slit lamp report(s)
15. Endothelial cell density(ies) (if applicable)
16. Name of enucleator/processor/evaluator/technician
17. Name of surgeon or consignee receiving tissue
18. Tissue readily traceable from donor to consignee for each ISBT 128 tissue identifier unique graft number (See Section M1.500)
19. Date, time, method of transportation
20. Utilization of tissue: i.e., surgical, research, training
21. Printed results of all EBAA required and non-required infectious disease screening tests
22. Microbiologic screening results if performed
23. Microbiologic reports of positive donor rim cultures from the receiving surgeon if reported
24. Adverse reactions if reported
25. Documentation that post-operative outcome information from the transplanting surgeon has been requested
M1.500  Recipient Follow-Up Information

1. Each distributing eye bank shall obtain consignee name and address information for each eye tissue used for human transplantation distributed by the bank.

2. Each distributing eye bank shall seek:
   - Patient’s name (if allowed by law)
   - Unique recipient identification, such as according to the following order of preference:
     a. Social security number
     b. Driver’s license number
     c. Medical record Hospital information number
     d. Alien identification
     e. Passport number
     f. Other unique identifier appropriate to the health care delivery system where surgery is performed
   - Age and/or Date of Birth
   - Diagnosis
   - Name of surgeon receiving transplanting tissue
   - Date of surgery
   - Location of surgery
   - Post-operative complications (tissue related)
   - Type of surgery performed, e.g. penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, keratolimbal allograft, and/or tectonic

Glossary

**DIN.** An abbreviation for **Donation Identification Number.**

Donation Identification Number (DIN). A unique identification of a donation/recovery event. The DIN contains three elements: the Facility Identification Number (FIN); a two-digit year code; and a unique six-digit sequence number assigned by the facility.

**FIN(P).** An abbreviation for **Processing Facility Information Code.**

**ICCBBA.** An abbreviation for **International Council for Commonality in Blood Banking Automation.** The international standards organization responsible for managing the ISBT 128 Information Standard for the terminology, identification, coding and labeling of medical products of human origin.

**Identification Number.** A unique numeric or alphanumeric designation assigned to, and thus associated with, a donor or recipient, a specific establishment (or facility) and tissues for the purpose of tracking and confidentiality. If donated ocular tissue is divided, a unique donor identification number is distinctly assigned to each part.
ACTION: A motion was made and seconded to adopt the proposed changes with a six-month grace period* for implementation. Motion passed.

* The six-month grace period will end July 1, 2016, after which banks are required to have implemented the ISBT 128 labeling changes.

B. Distribution Compliance Subcommittee – Paul Dubord, MD

Dr. Dubord presented the subcommittee’s proposed changes to the definition of Distributing Eye Bank as follows:

**Distributing Eye Bank.** The entity that is reimbursed for or invoices for providing tissue to a consignee, such as an eye banking intermediary, transplantation surgeon (whether agency, institution, organization or researcher) 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. A process must be in place to ensure the principles of tracking, traceability and adverse event reporting.

**ACTION:** A motion was made and seconded to adopt the proposed
changes with the typographic correction. Motion passed.

C. Globalization of Medical Standards Subcommittee – Brian Philippy

Mr. Philippy presented the subcommittee’s proposed changes to the Medical Standards as follows:

C1.300 **Staff Performing Eye Banking Functions** Staff (Technical and Supportive)

Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.

The Director shall appoint technical and supportive staff and ensure that this staff has the appropriate qualifications and training for the performance of their job responsibilities. The Director shall ensure that there are a sufficient number of qualified eye bank technicians and supportive staff to perform all eye bank laboratory tests and procedures at a level of proficiency established by the bank. The eye bank Medical Director or Medical Director’s designee must document in writing those eye bank tasks in which each staff member is qualified and released to perform independently.

Each eye bank must employ at least one EBAA CEBT in a supervisory and training role(s).

If the only function the establishment performs is recovery and/or storage, a documented contractual, consultative relationship with a CEBT and the accredited organization in which the CEBT is employed may be an acceptable alternative to having a CEBT on staff.

An eye bank or other establishment which performs eye banking functions has six months in which to replace their required EBAA CEBT(s) provided that:

1. The establishment notifies the EBAA office in writing that it does not meet this standard.
2. The establishment submits appropriate evidence of its intent to comply with the “required CEBT” standard.
3. A documented interim consultative relationship is established with a CEBT and the accredited organization in which the CEBT is employed.
D1.000  **Donor Eligibility Determination**

Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible person. Reference Appendix II for requirements related to the donor eligibility process. **Eye banks outside of the United States should reference Appendix V for requirements related to the donor eligibility process.**

Prior to making an eligibility determination, the donor must be screened according to D1.200. In addition to donor eligibility determination, tissue must be evaluated for suitability per F1.000.

All donors must be identified by name. All prospective donors shall undergo a physical examination as close as possible to the donation with special attention to physical signs of HIV disease, infectious hepatitis, and injecting drug use. Each eye bank shall have a consistent policy for conducting and documenting this examination. Each eye bank shall also have a consistent policy for examination and documentation of the prospective donor’s available medical record and death investigation. Review of all available records on each donor shall be performed by an individual who is qualified by profession, education, or training to do so, and who is familiar with the intended use of the tissue.

Medical and social histories are important aspects of donor eligibility. Adequately determining eligibility includes, but is not limited to:

1. Infectious disease testing (see G1.200)
2. Physical assessment of the donor (see above paragraph)
3. Tissue evaluation (see F1.000)
4. Donor history evaluation: this must include the donor’s name, social history and donor information obtained from at least one of the following:

   a. Pathologist or medical examiner physical assessment of death report
   b. Police investigation report accompanied by (a) and/or (c)
   c. Medical examiner’s investigative report
   d. Donor risk assessment interview
   e. Medical record or hospital chart
   f. Treating physician interview
   g. Medical director oversight to review any donor information where questions arise in the above areas (see C1.200). This shall be documented.
D1.100 Donor Screening

The eye donor’s relevant medical records must be reviewed for (Reference Appendix III for FDA requirements related to review of relevant medical records):

- EBAA-specific contraindications (Ref. D1.110); and
- (Eye banks inside the United States only): FDA-defined relevant communicable disease agents and diseases (Ref. D1.120); and
- (Eye banks outside of the United States only): relevant communicable disease agents and diseases as applicable (Ref. Appendix V); and
- Other diseases as required by the country of import, if exported outside of the United States

D1.120 Screening for FDA-Defined Relevant Communicable Disease Agents and Diseases

The FDA defines communicable disease agents and diseases considered relevant (Ref. Appendix I). Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behavior associated with relevant communicable disease must not be used for transplant purposes (Ref. Appendix II).

Eye banks outside the United States must screen for relevant communicable disease agents and disease according to applicable regulations (Ref. Appendix V).

D1.200 Donor Testing

The eye donor must be tested according to:

- EBAA testing requirements (D1.210)
- FDA testing requirements (D1.220). Eye banks located outside of the United States are not bound by FDA testing requirements, but must test in accordance with national and local regulations in the jurisdiction in which they are located (Ref. Appendix V).
- State requirements, if applicable
- Other testing requirements of the country of import, if exported outside of the United States
G1.000  Quality Assurance

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness

The quality assurance program shall address applicable requirements relating to the following areas of eye bank functions:

1. Facilities
2. Environmental control
3. Equipment
4. Supplies and reagents
5. Recovery
6. Processing and processing controls
7. Labeling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing
11. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.
The Quality Assurance Program shall establish a system for reporting, documenting, and investigating deviations. Deviations for distributed tissue relating to core CGTPs must be reported to the federal regulators and EBAA.

The eye bank’s quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with FDA 1271.350, adverse reactions involving a relevant communicable disease must be reported to the FDA within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention. Eye banks outside of the United States must report adverse reactions/events to the EBAA and to appropriate agencies within their region (Ref. Appendix V). Any deviations reported to a regulatory public health authority will also be reported to EBAA.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director’s investigation determines to be possibly, likely/probable or definitely due to donor tissue must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.
L1.200  Package Insert Form

A “Package Insert” form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole eye). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
3. For corneas in intermediate-term storage solution, a color change per the manufacturer’s guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank.
5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
6. The form shall advise the consignee that they are responsible for tracking of the tissue recipient’s name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, and the name of the transplanting surgeon when the tissue is transplanted. This information is needed to track the tissue from the donor to consignee and from the consignee to the recipient.
7. Infectious disease tests were performed by a CLIA certified and FDA registered laboratory. Eye banks outside of the United States, see Appendix V.
8. That FDA approved tests were used for infectious disease testing as required by the FDA and EBAA, some of which are approved for pre-mortem blood and that FDA approved tests for cadaveric blood were used where available. Eye banks outside of the United States, see Appendix V.
9. A list of infectious disease test results for that specific donor.

This information may be included on the eye bank’s donor screening form as long as it is easily noticed; otherwise a separate package insert form is advised.
**Recall.** An action taken to locate and retrieve tissue from distribution and dispensary inventories. Removal or correction of a marketed product that the FDA/other governmental or regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recalls may be conducted on a firm’s own initiative, by FDA regulatory agency request, or by FDA order under statutory authority. (Reference: EBAA Tissue Recall Guidance Document)

**Relevant Communicable Disease.** Any communicable disease relevant to transplantation of tissue in humans as defined by FDA regulations, FDA guidance documents or US law. Eye banks outside the United States may refer to Appendix V for definition.

**Withdrawal (or Market Withdrawal).** Removal or correction of a distributed product by an eye bank that involves a minor violation that would not be subject to legal action by the FDA/other government or regulatory agency, or that involves no violation. Does not involve a relevant communicable disease. No notification to FDA or EBAA is required. (Reference: EBAA Tissue Recall Guidance Document)

**EBAA Medical Standards Appendix V:** Accredited Eye Banks Not Located in the United States

**Introduction**

This appendix establishes the requirements for each country or region in which eye banks are subject to EBAA accreditation. The sections are written to address each Medical Standard that is otherwise written for eye banks within the United States. The determination of which regulations apply (e.g. FDA, foreign federal, foreign state, or other) may be made by the Accreditation Board and submitted to the Medical Advisory Board for inclusion in the appendix.

**Medical Standards Specific to Canada**

**D1.100**

The eye donor’s relevant medical records must be reviewed for:

- EBAA-specific contraindications (Ref. D1.110): and
- Health Canada-defined relevant communicable disease agents and diseases: and
- Other diseases as required by the country of import, if exported outside of the United States

**D1.120**

Health Canada defines communicable disease agents and diseases considered relevant. Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behavior associated with relevant communicable disease must not be used for transplant purposes.
D1.200

The eye donor must be tested according to:

- EBAA testing requirements (D1.210)
- Health Canada testing requirements (D1.220).
- Provincial requirements, if applicable
- Other testing requirements of the country of import, if exported outside of Canada

A review of written results of infectious disease testing shall be received by the eye bank prior to releasing tissue designated for surgical use.

The infectious disease testing laboratory and test kits used must meet Health Canada’s regulatory requirements.

If plasma dilution sufficient to affect the results of communicable disease testing is suspected, the donor should be considered ineligible, unless a pre-transfusion or infusion sample drawn up to 7 days before recovery is tested; or an algorithm designed to evaluate volumes administered in the 48 hours before specimen collection is used, showing that plasma dilution sufficient to affect the results has not occurred.

Eye banks shall use a plasma dilution algorithm which meets Health Canada requirements.

D1.220

Refer to Canadian National Standards and CTO Guidance for donor testing requirements and recommendations. Results must be negative or non-reactive for the tissue to be eligible for transplant except as indicated for syphilis.

G1.000

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness
The quality assurance program shall address applicable requirements relating to the following eye bank functions:

1. Facilities
2. Environmental control
3. Equipment
4. Supplies and reagents
5. Recovery
6. Processing and processing controls
7. Labeling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing
11. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.

The Quality Assurance Program shall establish a system for reporting, documenting, and investigation of deviations (read as “errors or accidents,” as defined by Health Canada). Deviations for distributed tissue relating to eye bank functions must be reported to the federal regulators and EBAA.

The eye bank’s quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with Health Canada, adverse reactions involving a relevant communicable disease must be reported to Health Canada within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director's investigation determines to be possibly, likely/probable or definitely due to donor tissue must be
communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

**L1.200**

A “Package Insert” form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole eye). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
3. For corneas in intermediate-term storage solution, a color change per the manufacturer’s guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank.
5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
6. The form shall advise the consignee that they are responsible for tracking of the tissue recipient’s name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, and the name of the transplanting surgeon when the tissue is transplanted. This information is needed to track the tissue from the donor to consignee and from the consignee to the recipient.
7. “Infectious disease testing has been performed by a laboratory that meets the applicable requirements of the authority having jurisdiction over that laboratory,” as required by Health Canada.
8. That Health Canada approved tests were used for infectious disease testing as required by the Health Canada and EBAA, some of which are approved for pre-mortem blood and that Health Canada approved tests for cadaveric blood were used where available.
9. A list of infectious disease test results for that specific donor.
This information may be included on the eye bank’s donor screening form as long as it is easily noticed; otherwise a separate package insert form is advised.

**Glossary**

*Relevant communicable disease*: Any communicable disease relevant to transplantation of tissue in humans as defined by Health Canada regulations, Health Canada guidance documents or Canadian law.

**Canadian References**


*National Standard of Canada CAN/CSA Z900.2.4 Ocular Tissues for Transplantation, updated August 2015.*


**ACTION:** A motion was made and seconded to adopt the proposed changes with a friendly amendment to G1.000. Motion passed.

**D. Tissue Report Form Subcommittee – Tom Miller**

Mr. Miller reported that the subcommittee will present the proposed changes to MAB members by email for review, and a vote will then be taken by email to accept the changes.

**E. Pre-Operative Culture Subcommittee – Anthony Aldave, MD**

Dr. Aldave reported that 29% of donor rims were cultured, and of those 0.7% were culture positive for fungal organism, and of those 17% transmitted infection to the patient in the form of endophthalmitis or keratitis. Rates of infection were significantly higher with EK than with PK.

There was discussion about whether routine donor rim cultures should be recommended, but there was no consensus for a particular recommendation.
Dr. Elmer Tu was invited to share the results of his study (New Business Agenda Item B) as it was relevant to the discussion. Dr. Tu shared that corneal tissue being processed for EK is exposed to ambient temperature far longer than tissues being provided for PK or DALK. The data showed that fungal contaminants can be amplified by more than 100 times by routine warming cycles, which is reflective of current eye bank protocols for the preparation of tissue for EK, as compared to a single warming cycle simulating the handling of unprocessed corneal tissue for PKP and DALK.

A Medical Advisory will be sent out to make eye banks aware of the results of Dr. Tu’s study and encourage eye banks to minimize to the extent possible the amount of time corneas are kept unrefrigerated.

Much interest still remains in the possibility of adding an antifungal agent to the corneal storage media. This may be possible by having eye banks add the antifungal under the order of a Medical Director, but more investigation will need to be done before any recommendations or changes to the Medical Standards are made.

V. New Business

A. Stem Cell Transplants from Outside U.S. – George Rosenwasser, MD

Dr. Rosenwasser share a recent case where a donor received a stem cell transplant while abroad. Consensus was that donors should be deferred when they have received stem cells from an unknown source.

B. The Effect of Temperature on Fungal Contamination of Optisol-GS – Elmer Tu, MD

Dr. Tu presented the results of his study in Old Business Agenda Item E.

VI. Late Additions

Ellen Heck put out a call for submissions to the International Journal of Eye Banking.

Jennifer DeMatteo shared that the FDA released a new draft Guidance on Homologous Use of Human Cells, Tissues, and Cellular and Tissue Based Products. The FDA has also scheduled a 1-day public hearing on April 13, 2016 to obtain input on four recently issued draft guidance documents relating to the regulation of HCT/Ps. Eye banks should forward comments to EBAA so that they can be represented at the hearing.
VII. For Information and Review

Updated ISBT 128 documents were included in the agenda packet for reference. This included the *Implementation Guide: Use of ISBT 128 in North American Eye Banks, v1.2.0* and *Standard Terminology for Medical Products of Human Origin, v6.9.0.*

VIII. Adjournment

**ACTION:** A motion was made and seconded to adjourn the Medical Advisory Board meeting at 2:55pm. **Motion passed.**