

The Dynamic Relationship: The Accreditation Process and Medical Standards

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EBAA instituted a program of eye bank accreditation in 1981 to assist with and document compliance to EBAA Medical Standards. The Accreditation Committee was created as a subcommittee of the EBAA Medical Standards Committee to oversee the accreditation process. In 1993, the Medical Standards Committee was renamed the EBAA Medical Advisory Board (MAB), and the Accreditation Committee became a separate entity, later to become the EBAA Accreditation Board (AB) in 2000.

Accreditation inspections were initially intended to occur every 4 years and were to be conducted by a single site visitor. Inspections would include review of donor charts, inspection of the physical facilities, interviews with the Executive Director and Medical Director, and observation of technicians performing corneal excisions. Standardized questionnaires were developed by the Accreditation Committee and used by site inspectors to assure consistent inspections. This core process has remained intact throughout the years; however, the specifics of the inspection process have evolved along with the EBAA Medical Standards.

The EBAA Medical Standards and accreditation have a dynamic relationship; changes to the Standards impact the accreditation process, and often, the accreditation process results in changes to the Standards. The Medical Standards are reviewed at least annually by the EBAA MAB, and have been revised many times since their initial publication to keep pace with changes in scientific knowledge, medical practice and governmental regulations. The EBAA AB must, in turn, assess the impact of these Standards changes and adjust the accreditation process accordingly.

Many changes made to the Medical Standards, such as revisions to exclusionary criteria, are straightforward and simply require the Accreditation Board inspectors to assure that a bank's policies and procedures have been updated and that donor records reflect the revision. Other changes,

however, are more complex; two examples are highlighted in this document.

EARLY EBAA ACCREDITATION COMMITTEE INSPECTIONS

The first round of inspections was declared complete at the November 1984 EBAA Medical Standards Committee meeting, and a plan for recertification of member eye banks was discussed. At its June 1986 meeting, the Medical Standards Committee discussed the fact that many banks throughout the U.S. had satellite laboratories that received, processed and distributed tissue without sending it to the parent laboratory. The Medical Standards were amended to read, "Satellite laboratories that procure, process and distribute tissue must have a certified technician and be supervised by and have access to a qualified Medical Director or his delegate. Satellite laboratories must be inspected with a site visit as part of the certification process of the parent bank." While records from this time are somewhat scarce, the Accreditation Committee would have had to gather additional information about each bank, and increase the number of inspectors and time spent on inspections in response.

The early inspections also resulted in proposals for additional Medical Standards from the Accreditation Committee members. In the document outlining the Revisions to Medical Standards for May 1989, it is stated, "The definition of the Eye Bank Laboratory has been expanded to cover those items that our site inspectors have insisted on to certify a laboratory." The definition included having a separate area with limited access, a refrigerator with mechanism for recording temperature variations, a sink with a drain and running water and adequate table space for preparation of donor material. All of these requirements remain intact in the current EBAA Medical Standards, although the section has been further modified many times since the initial definition of an Eye Bank Laboratory.

EYE BANK PROCESSING FOR ENDOTHELIAL KERATOPLASTY

The rise in the popularity and performance of Descemet's Automated Stripping Endothelial Keratoplasty (DSAEK) in the early 2000s led to a new type of service provided by eye banks. In 2005, the first eye banks began providing pre-cut corneal tissue for DSAEK surgery. The EBAA MAB, at its June 2006 meeting, revised the Medical Standards to include new requirements for endothelial keratoplasty tissue in general and for banks providing the processing (pre-cut) service. Additional requirements included contraindications for use of tissue for endothelial keratoplasty, necessary documentation following processing, the need for a validated process to be used, and post-cut tissue evaluation.

As more banks began providing pre-cut tissue for DSAEK, the EBAA Accreditation Board formed a sub-committee in June 2007 to create a tool for the practical demonstration of lamellar tissue preparation during site inspections. A list of AB inspectors familiar with the pre-cut process was drawn up for initial inspections, and it was agreed that all other AB inspectors should be trained. Following a round of feedback from AB inspectors using the practical tool, it went into use during the Spring 2009 inspection cycle, and questions were added to the Site Inspection Questionnaire to document the practical demonstration of a bank's pre-cut processing.

AREAS OF ACCREDITATION INSPECTION

Currently, the EBAA Accreditation Board accredits establishments that perform any or all of the following functions: Recovery, Processing, Storage, Distribution, Tissue Evaluation and Donor Eligibility Determination. The inspection process is designed to focus on the bank's

performance in these areas to ensure the function and safety of the tissue provided, adherence to EBAA Medical Standards and compliance with FDA regulations. The areas of inspection are:

- Policies and Procedures
- Director
- Medical Director
- Quality Assurance Director
- Technical Staff
- Observation of Recovery / Processing Techniques
- Physical Inspection of Eye Bank Laboratory
- Review of Eye Bank Records (includes, but is not limited to: Donor/Recipient records; Laboratory Environmental Cleaning/Monitoring; Laboratory Equipment Cleaning, Monitoring and Calibration/Certification; Personnel Orientation, Training, and Continuing Education; Quality Assurance records; Medical Director meeting minutes)

Any items of non-compliance are presented to the bank immediately following the conclusion of the inspection. The bank has 10 business days in which to provide appropriate corrective actions for any items found to be non-compliant.

CONCLUSION

EBAA's accreditation process meets or exceeds most state and national regulations, and encourages public confidence in eye banking. The dynamic relationship between Medical Standards and the Accreditation Board will continue to provide assurance that member banks provide safe and quality ocular tissue for transplantation.