

EBAA Medical Standards, an Evolving, Living Document

Joel Sugar, David Glasser, Mark Mannis

The Medical Standards of the Eye Bank Association of America (EBAA), as stated in the “introduction and purpose,” “have been developed to assure consistently acceptable levels of quality, proficiency, and ethics in dealing with ocular tissue for transplantation; and to define the minimum standards of practice for eye bank functions, as determined by the ophthalmological medical community.” The Medical Standards of the Eye Bank Association of America evolved over a period of several years prior to actual codification and adoption in 1980.¹ There was spirited debate over the necessity of these standards. Moreover, there was discussion that these standards might eliminate certain eye banks for what was perceived as their inability to comply with these standards. Nonetheless, the Standards were adopted by the association due, in no small part, to the persistence and guidance of ophthalmologists including Frederick Brightbill, Jay Krachmer, and Donald Doughman, the expressed interest of the American Academy of Ophthalmology and the collaboration with lay leaders among association membership.

The Standards became and remain a living document, subject to review and change on a semi-annual basis. There have been multiple additions over time as disease transmission from pathogenic microorganisms heightens the concern for public health. While well codified and time-tested, these standards have not been and cannot become static. Challenges continually arise in our medical and regulatory environment. As medicine has evolved and new diseases have been recognized, the Standards have been changed to reflect this. Examples include the emergence of HIV/AIDS, hepatitis, Creutzfeldt-Jakob disease (CJD), rabies, West Nile virus, vaccinia, Ebola, Zika,² and others that have become public health issues.

Serologic tests, when available, either approved for cadaveric blood samples or not per FDA guidance; have rapidly been incorporated in the Standards.³ The EBAA enacted standards for serologic testing and other screening procedures well before FDA requirements or in tandem with these regulations. Moreover, additional specific measures for tissue quality determination such as specular microscopy, and environmental controls have been codified.

An immediate concern over melanoma donor tissue led to a Standards change. This was prompted by a recent case, later reported formally at the EBAA Medical Advisory Board (MAB) and the EBAA/Cornea Society symposium in Chicago in October 2016, of the transmission of melanoma from a donor to a recipient through keratolimbal allograft. This triggered the exclusion of all ocular donor tissue from patients with metastatic malignant melanoma. The MAB also established a Scientific Review Committee to evaluate issues affecting tissue safety and suitability, questions that arise and constitute potential concerns for patient outcomes. Government regulations have, in turn, both been influenced by and have influenced the modification of the Standards. Although adherence to and compliance with government regulations must occur, the Standards are independent, and modifications remain science-based, not governmentally mandated.⁴ Even as these standards are published, additional concerns are under evaluation, for example, fungal contamination and the potential for changes in tissue storage media.^{5,6} Recommendation for the culturing of donor tissue for fungus, especially in relation to DSAEK and DMEK laboratory preparation procedures, has been discussed.⁷

Eye bank processes, stimulated by newer surgical techniques, have led to incorporation of newer standards, including newer methods of assessing tissues processed in the eye bank as well as pre-surgical preparation of tissues. Future techniques for processing ocular tissues and cells will undoubtedly lead to additions to and/or modification of the Standards. The Medical Advisory Board has had as its Chair many in the practice of ophthalmology, included among these have been Drs. Mark Mannis, William Reinhart, Joel Sugar, Wing Chu, Edward Holland, Marian Macsai, David Glasser and Michael Nordlund. The Standards remain a vibrant and living document, an essential to patient safety in an ever-changing environment.

The document contained in this publication represents the most recent edition of the EBAA Medical Standards and represents the commitment of the Association and its members to provide the safest possible transplantable tissues for recipients of ocular tissue.

The Medical Standards include:

- Personnel and governance
- Training, certification and competency review
- Facilities
- Donor eligibility screening and testing
- Recovery, processing and preservation
- Tissue evaluation
- Quality assurance
- Non-surgical donor tissue
- Tissue storage
- Labeling
- Tissue distribution
- Documentation
- Packaging

REFERENCES

1. Mannis MJ, Reinhart WJ. Medical standards for eye banks. In Brightbill FS (ed) Corneal Surgery, Mosby, St. Louis, 1993. pg 531-548
2. FDA. Guidance for industry: donor screening recommendations to reduce risk of transmission of Zika virus by human cells, tissues, and cellular and tissue-based products. March, 2016
3. Mannis MJ, Sugar J. Syphilis, serologic testing, and the setting of standards for eye banks. *Am J Ophthalmology* 1995;19:93-95
4. FDA. Guidance for industry: eligibility determination for donors of human cells, tissue, and cellular and tissue-based products. 2007
5. Duncan K, Parker J, Hoover C, et al. The effect of light exposure on the efficacy and safety of amphotericin B in corneal storage media. *JAMA Ophthalmology* 2016;134:432-436
6. Aldave AJ, DeMatteo J, Glasser DB, et al. Report of the Eye Bank Association of America medical advisory board subcommittee on fungal infections after corneal transplantation. *Cornea* 2013;32:149-154
7. EBAA Medical Advisory Board Minutes, June, 2016