EBAA Major Guidance and Standards Changes

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As stated in the introduction of the standards themselves, the Eye Bank Association of America (EBAA) Medical Standards were developed to maintain acceptable levels of quality, proficiency and ethics in the handling of ocular tissue for transplantation.[1] They serve as the minimal standards for any and all eye bank functions including recovery, processing, storage, tissue evaluation, donor eligibility determination and distribution. They are reviewed at least annually by the EBAA Medical Advisory Board (MAB) and revised as necessary.

The purpose of this article is to review some of the major changes to the EBAA Medical Standards over the past few years.

EBTAG NOMENCLATURE AND ISBT 128

The Eye Bank Technical Advisory Group or EBTAG is an advisory group consisting of representatives from multiple national and international eye bank organizations including the EBAA, the European Eye Bank Association, the Eye Bank Association of Australia and New Zealand, the Eye Bank Association of India, the Asia Cornea Society, and the Pan-American Association of Eye Banks. The group began meeting in 2010 with the goal of creating and publishing a nomenclature that could be endorsed by all represented groups, agree on standardized labeling, and promote the use of Information Standard for Blood and Transplant (ISBT) 128 nomenclature, coding and labeling of ocular tissue.[2]

In June 2013, the MAB voted to adopt EBTAG nomenclature and the Medical Standards were rewritten to harmonize the language of the Medical Standards with EBTAG. Effective June 30, 2015, all EBAA member eye banks were required to utilize EBTAG nomenclature to describe ocular tissue classes and attributes.

Promoting the use of ISBT 128 nomenclature, coding and labeling for ocular tissue is, as mentioned above, another goal for EBTAG. ISBT 128 is the international standard for the identification, labeling and information transfer for medical products of human origin across different health care systems and globally.[3] It is meant to ensure accuracy, safety and efficiency in transferring information from one health system to another and features a unique code for every collected product.[4] A Code 128 bar code allows for unambiguity in the product code and for ease of transfer of the electronic information.

The use of the ISBT 128 Standard has been supported by numerous national and international organizations including the American Association of Blood Banks, the American Society for Apheresis, the American Society for Blood and Marrow Transplant, the European Group for Blood and Marrow Transplantation, the Foundation for Accreditation of Cellular Therapy, the International Society for Blood Transfusion, the International Society for Cellular Therapy, the Joint Accreditation Committee for ISCT and EBMT, the National Marrow Donor Program, and the World Marrow Donor Association. More than 77 facilities across six continents around the world have registered to use ISMT 128.[4]

The EBAA MAB has joined the international community in supporting the use of ISBT 128 Standards. A timeline has been given by the MAB for the implementation of ISBT 128 product codes and bar code labeling to help eye banks phase in ISBT 128. Eye banks were required to utilize standardized ISBT 128 terminology and register with the International Council for Commonality in Blood Banking Automation (ICCBBA) for a Facility Identification Number by June of 2015. Registering and licensing with the ICCBBA is required to use ISBT 128 labels. The second stage of implementation went into effect on January 1, 2016 with the requirement to utilize standard product codes. The final stage to be implemented by January 1, 2017 is the use of bar code labeling for eye banks that distribute tissue internationally. New guidance documents have been provided by the EBAA to help eye banks with the implementation of ISBT 128. Additionally, the EBAA has partnered with Digi-Trax,® a company that focuses on bar code modernization and ISBT 128 compliance, to provid an affordable labeling solution for eye banks.

FRAUDULENT ACTIVITY

The importance of having a system in place that allows for the safe and accurate transfer of donor tissue information was highlighted by a case of possible fraudulent activity that was brought to the attention of the eye banking community in late 2012.

In 2012, the EBAA was made aware of a situation in which there was possible falsification of documentation associated with an exported U.S. donor corneal tissue. The tissue was received by a corneal surgeon overseas via a third party distributor. Because of concerns regarding possible alteration and forgery of the Tissue Information Form, the corneal surgeon alerted the original distributing U.S. eye bank. Upon further review, it appeared that multiple changes had been made to the Tissue Information Form compared to the original documentation.

Potentially forged information included: donor age, ocular cooling time, time of death, time of in situ, time of preservation, endothelial cell density, slit lamp examination date and specular date and time. Additionally, the descriptions of the corneal epithelium and stroma had been altered.

As a direct result of this case, a new medical standard was added to address concerns surrounding the potential for future fraudulent activity. A new medical standard (K1.500) was set in place which requires eyes backs to report to the EBAA within 10 days of identification of fraudulent activity.[1]

UNIFORM DRAI

In addition to the EBAA's endorsement of EBTAG nomenclature and the ISBT 128 Standards, the EBAA also works closely with other donor organizations to improve and facilitate the process of donation. The uniform donor risk assessment interview (UDRAI), also known as the medical history interview, was a collaborative, coordinated effort involving eye, tissue and organ donation organizations in addition to government agencies. It was first conceptualized in 2006 with the goal to create a qualified, uniform donor history questionnaire for adults and for children under the age of 12 to determine donor eligibility. The UDRAI was finalized in September 2014 and the Eye Only UDRAI was endorsed by the EBAA MAB in October of the same year. Guidance documents have been added to the EBAA procedures manual to help eye banks with adoption and implementation of the Eye Only UDRAI forms.

OARRS

The adverse reaction reporting system was developed by the EBAA in 1990 with the current online adverse reaction reporting system (OARRS) beginning in 2004. Adverse reactions that are reportable to OARSS include: primary graft failure, ocular infections, systemic infection in a recipient, transmission of corneal dystrophy or ocular malignancy, and prior (unknown) refractive surgery in the donor tissue. The EBAA requires that each distributing establishment seek postop outcome information between 3 and 6 months. This 3 to 6 month timeframe for seeking adverse reactions was a new change as of June 2013. Previously, it was required that eye banks seek this information 6 to 12 months after transplant. This was changed in a way that better reflects the typical timeline for most adverse reactions.

Version 1 of the OARRS guidance document was published in 2009. Version 2 of the guidance document for OARSS was updated and published in September 2014. The major changes to OARRS include:

1. Standardization of surgical procedure and cause of death categories to match EBAA statistical reporting;
2. Harmonized adverse reporting categories with the European SOHO V&S (Vigilance and Surveillance of Substances of Human Origin)/WHO Project NOTIFY and the addition of a "possible" category;
3. Genus and species of culture positive organisms now captured;
4. Delineation between domestic- and internationally-placed tissue;
5. New reporting category called "Early Regraft" was added for regrafts prior to 8 weeks.

Additionally, a new guideline was adopted to the EBAA statistical reporting to provide information from the source eye bank on the surgical technique and indication for ocular transplantation surgery.

NEW CONTRAINDICATIONS FOR OCULAR TRANSPLANTATION

Finally, there have been several new additions to the EBAA contraindications for transplant over the pat several years. Parkinson, amyotrophic lateral sclerosis, multiple sclerosis and Alzheimer disease were added to the Medical Standards (D1.110.A.11) to help clarify what had already been an FDA regulation.[1] D1.110.A.10 was adjusted to active leukemia as a contraindication for transplant (previously contraindication was leukemia without indication regarding the status of the disease process).[1]

In reaction to the Ebola virus disease outbreak that began in December 2013 in Guinea[5] and spread rapidly in West Africa particularly to neighboring Sierra Leone and Liberia, donors with a history of Ebola virus disease was added as a contraindication to transplantation (D1.110.A.13).[1] At this time, it is not clear how long Ebola Virus persists within the eye. In the U.S., there is a known case of a pa-

tient who was found to have viable Ebola virus in the eye 9 weeks after clearance of systemic viremia.[6]

Finally, the issue of melanoma and metastatic disease. In February 2016, the EBAA MAB met urgently in response to reports of a potentially life-threatening adverse event related to keratolimbal allograft-donor recipient melanoma transmission. The donor had passed of metastatic melanoma. A moratorium was temporarily placed on ocular tissue from donors with any history of melanoma and on vascularized ocular tissue from donors with any history of metastatic solid tumors. A subcommittee was formed to address these new concerns.

As a result of the subcommittee discussions and the present literature on the topic, additions were made to the Medical Standards to address the donors with a history of malignant melanoma or metastatic tumors. On June 10, 2016, the EBAA MAB voted to include the following new contraindications for transplant in D1.110:[1]

1. For all ocular donors, a history of melanoma with known metastatic disease;

2. For scleral tissue donors and keratolimbal allograft tissue donors, a history of melanoma with or without known metastatic disease;

3. For scleral tissue donors and keratolimbal allograft tissue donors, a history of a solid, cancerous, non-melanoma tumor with metastasis.

Irradiated tissue is excluded from these contraindications.

CONCLUSIONS

The EBAA Medical Standards were originally adopted in 1980 to help standardize eye banking procedures and to provide a guide for eye banks to ensure acceptable standards for ocular tissue for transplantation.[7] As eye banking has evolved, the Medical Standards have been updated to reflect the current standards of care in medicine and eye banking. It is important for those of us in the eye banking community to keep abreast of all changes to the Medical Standards so that we may continue to provide the quality of tissue that surgeons and patients have come to expect.

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