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The Evolution of Eye Banking in the United States: Landmarks in the History of the Eye Bank Association of America

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ABSTRACT

Established in 1961, the Eye Bank Association of America (EBAA) was not only the first eye bank association in the world but also the first association to represent any group of organ or tissue transplantation professionals. Its history is one of additional “firsts”: setting medical standards to ensure tissue safety, establishing an accreditation process for individual eye banks, and developing a certification program for eye bank technicians, among others. To accomplish these initiatives, the EBAA has fostered collaborations with diverse communities, including government officials, corneal surgeons, Lions Clubs members, researchers, tissue and organ banks, and international organizations, thus continuing to evolve its role in pursuit of an unchanging mission: to champion the restoration of sight.

KEYWORDS: corneal transplantation, Eye Bank Association of America (EBAA), eye bank methods, eye banks, history of eye banks

The Preamble to Eye Banking

A date familiar to ophthalmologists and eye banking professionals alike is December 7, 1905, when Karl Edward Zirm, a young physician in Moravia, performed the first successful penetrating graft into his patient.¹ This single event catalyzed renewed enthusiasm for the feasibility of penetrating keratoplasty. (See the related article in this issue, “Eye Banking in the 21st Century: How Far Have We Come? Are We Prepared for What’s Ahead?”) What ensued was the elaboration and articulation of the principles of patient selection, surgical management, and postoperative care. Newly refined techniques and protocols brought legitimate success to keratoplasty.² (See the EBAA’s “Wall of History.”) The migration of Ramon Castroviejo from Spain to the United States in 1929 effectively moved the center of modern kerato-

plasty development to North America. He became the chief proponent of penetrating keratoplasty and developed basic surgical techniques and instrumentation, many of which remain the basis of contemporary surgery.³

From the beginning, what distinguished keratoplasty from other ophthalmic procedures was the requirement for donor tissue, a need that added a unique dimension to the surgery. In 1933, Richard Townley Paton (1901–1984) (Fig. 1), an ophthalmology resident at the Wilmer Eye Institute, became intensely interested in the potential of the procedure utilized

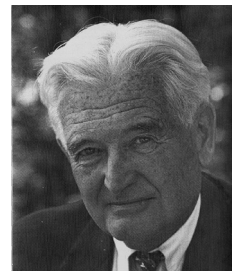


Fig. 1. Richard Townley Paton, MD, founder of the first eye bank in the United States, the Eye-Bank for Sight Restoration in New York, NY.

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In early eye bank history, Eastern Airlines transported corneas from the Red Cross.

to restore sight. When he began practicing ophthalmology in New York City, Paton recognized the need for an infrastructure for the collection of suitable donor tissue that would support the development of corneal transplantation. Together with Aida da Costa Breckenridge, a former patient of William Holland Wilmer who had helped to raise funding for the establishment of the Wilmer Institute, Paton established the Eye-Bank for Sight Restoration in New York City, chartered on February 21, 1945.

It was this singular alliance between a physician and a layperson that set the stage for the intrinsic partnership that would propel American eye banking forward. Upon this stage the premier eye banking organization in the world developed, setting the bar for similar national and international support organizations. Its history presents a marvelous story, with many chapters, the overriding theme being the establishment and operation of an infrastructure to provide the corneas needed for transplantation—what we know today as the eye bank.



Volunteers such as Mrs. Gison (K7UJV) of Phoenix, Arizona, responded via radio to urgent calls for tissue. Here she readies her daughter for school. *Newsight*, August 1964.

During the 1940s and 1950s, a proliferation of new eye banks occurred across the country. These were typically not the formal organizations we know today, but rather services most often adjunct to a local department of ophthalmology and operated under the auspices of the ophthalmologist who performed corneal transplants in the host institution. The proponents of corneal transplantation, now completely dependent on tissue availability, began to realize that separate and independent eye banks, each following its own mission and working in isolation, would not achieve consistent national success unless United States eye banks joined to promote tissue donation and their mutual interests as transplant support organizations.

By the mid 1950s, a number of prominent leaders in the field recognized the need to establish uniform medical standards and practices that would “govern” the emerging subspecialty and provide an adequate supply of corneas to meet the growing demand for tissue as keratoplasty became more successful and more commonly performed in the United States. These experts met during the annual meeting of what was then the American Academy of Ophthalmology and Otolaryngology (AAOO). During that meeting in 1955, 27 ophthalmologists, representing 11 eye banks (Table 1), formed a Committee on Eye Banks, which still functions today under the sponsorship of the American Academy of Ophthalmology (AAO). During meetings over several years, the

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Table 1. Founding Eye Banks of the EBAA

Buffalo Eye Bank
Colorado Eye Bank
The Eye-Bank for Sight Restoration
Eye Foundation of Delaware Valley
Hawaii Eye Bank
Iowa Eye Bank
Lions of District 22-C of Washington, DC
Minnesota Lions Eye Bank
North Carolina Eye Bank
Rochester Eye Bank
Southern Eye Bank

form of their vision took shape. They identified and agreed upon establishing an “association” of affiliated but separate eye bank organizations. As the concept matured, all eye bank representatives were invited to an open meeting, where the resolution was approved and forwarded for approval to the Council of the AAOO. The Eye Bank Association of America (EBAA), born in 1961, emerged from this approval (Fig. 2). Forty-six member banks joined the new association by 1964, representing all American eye banks that were then qualified to join.

Fig. 2. Official EBAA logo



The governance of the new organization was immediately identified, with the appointment of a Board of Directors and a House of Delegates, with the AAOO Committee on Eye Banks acting as a medical advisory board. A formal infrastructure would follow in 1985, almost 25 years later, when a national office opened in Washington, DC. Until that time, the EBAA office had operated as an adjunct to or within a member organization.

The Formation of the EBAA

The formation of the EBAA has brought eye banking to the highest level through an evolving combination of leadership and advocacy, an unflinching insistence on medical standards, community service, and innovation, and a fostering of best practices. A review of the history of the association to date reveals how the

EBAA’s vision, mission, and values produced a national cooperative that has inspired respect among wide-ranging constituencies and transformed the lives of countless cornea recipients.

The EBAA was both the first eye bank association and the first organization of its kind within the larger organ and tissue community. It was the first organization to establish medical standards, accreditation procedures, and technician certification for its members—elemental actions that have helped differentiate the eye banking community as a unique enterprise.

Reviewing the history of the EBAA to date, several practices that stem from eye banking values have been formally institutionalized or informally nurtured. These practices have provided the bedrock that has inspired the subsequent respect and success that are widely recognized as the hallmarks of today’s EBAA. An overview of these factors will reflect the story of EBAA’s vision, mission, and values.

The Development of a National Cooperative

Throughout the 1960s, 70s, and 80s, eye banks were established in many communities, with more than 1 eye bank in some, and the number of United States member organizations participating in the EBAA totaled more than 120 by 1990. After a period of consolidation, the number is currently 85—some of which are umbrella organizations with multiple sites.⁴ Although eye bank membership in the EBAA remained completely voluntary, the vast majority of American eye banks became active and supportive members, establishing the EBAA as their official professional organization. Currently, the EBAA represents all eye banks in the United States as well as a number of organizations that perform some, but not all, eye bank functions; the EBAA also sets and monitors the standards to which all members adhere. Membership in the EBAA is not restricted to banks within the United States, but also includes eye banks in Canada and abroad.

One of the hallmarks of the EBAA has been its ability to adapt and evolve, innovate and improve. Regional representation serves as an example: Beginning in the 1970s, EBAA member organizations were grouped into regions, based on the country’s geography. Each region engendered loyalty and commitment, fostering tissue sharing and regional meetings, most often held during the national EBAA meeting. As eye banking evolved, the EBAA adapted an organizational system based on size of banks. Regions still meet informally during the annual meeting, but a new voting structure has been adopted to mirror the further evolving composition of its members.

Standards Setting, Implementation, and Review

The Development of Medical Standards

Early in the history of the EBAA, leaders recognized that uniform medical standards for the collection, preservation, and equitable

distribution of donor tissue were required, and they set about developing the first set of national medical standards.⁵⁻⁷ This effort during the 1980s became one of the cornerstones of the EBAA's achievements, along with the accreditation of banks and certification of technicians. The Medical Advisory Board (originally called the Medical Standards Committee) was established to set community standards for eye banking; it was populated by eminent corneal surgeons and has continued to flourish over 4 decades of increasingly complex and sophisticated activity. In the last decade, with the addition of international members and a larger number of certified eye bank technicians as fully participatory members, the Medical Advisory Board has reinforced and strengthened the peer-to-peer relationship of technicians, administrators, and corneal surgeons that has characterized American eye banking from its beginnings. The EBAA medical standards have remained a living and constantly evolving document that reflects a delicate balance between science and practice, always placing patient safety as top priority.

Accreditation System

To ensure uniform application of its standards throughout the eye banking community, the EBAA established inspections of member banks. Teams of physicians and technicians, who performed site visits and constructive critique of eye bank practices, implemented this system of critical peer review. The inspection and accreditation program was voluntarily adopted by member eye banks as a form of quality control self-governance and assured member banks that participating accredited banks provided uniformly high standards of tissue acquisition, processing, and distribution. The professionalism of the practice has been recognized by the United States Food and Drug Administration (FDA), which oversees the transmission of communicable disease through transplantation of tissue and eyes.

Technician Certification

A natural outgrowth of the accreditation program was the standardization of requirements for eye bank technicians. Certification and recertification programs for technicians were introduced in the 1980s. At first a modest and straightforward program, 2 important actions occasioned the jump from simple standardization of technical practices to formal professional recognition of technicians: contracting out the certification exam and establishing a "Certification Board" to set requirements for the certification and recertification of technicians. The result has been a recognized "profession" (Certified Eye Bank Technician, CEBT), which has greatly enhanced both the quality of eye banking practice as well as the retention and advancement of the technical force in American eye banking. Recently, the EBAA introduced an electronic examination administered at designated centers that is offered both nationally and internationally.

The Development of a Self-Sustaining National System

As charitable organizations, eye banks were originally completely dependent on volunteerism and philanthropy. In the 1970s and 80s, eye banks began to adopt a "processing fee" to cover costs related to providing tissue. These fees varied depending on a number of factors related to each eye bank. When the National Organ Transplant Act (NOTA)⁸ was passed in 1984, it allowed reimbursement for costs associated with providing tissue and organs for transplantation; eyes and tissue were considered "organs" for the purposes of this section of the act. Today, eye banks function as not-for-profit organizations, largely self-sustaining and staffed by paid professional administrators and technicians. Indeed, all EBAA members must be not-for-profit organizations established under state law.

Eye banks, operating as separate entities, have historically depended on each other to meet requests for tissue. Today's umbrella organizations, which own and operate more than 1 eye bank under a comprehensive structure, represent formalized collaboratives that are expected to increase. From the outset of American eye banking, the need for tissue sharing was obvious. This was especially true prior to legislation that greatly expanded the tissue available for transplantation. Passed in 1975 in Maryland, and thereafter in more than 30 additional states, the laws, known as "Medical Examiners" ("ME") laws, allowed for the recovery of corneal tissue with "no known objection" by next of kin.⁹ The underlying impetus for this was based on the public policy of the "common good." Eye banking is no longer dependent on tissue recovered under the provisions of "ME" laws; some of the laws have been revoked and most are in disuse.

NOTA awakened lawmakers to the transplant field and the challenges that existed at the time (and remain). In the late 1980s, following its move to Washington, DC, the EBAA foresaw the likelihood of eventual federal oversight. The EBAA and its members had been quietly and effectively providing corneas for transplantation for decades with an emphasis and reliance on strict medical standards and regular review of practice, but with attention on organ transplantation, human tissue—including corneal tissue—was swept into a larger net. (Eye banking has generally flown under the radar of legislative proposals but at times has been included in a definition, most often referencing organs and other tissues, which is meant specifically but applied broadly). EBAA leaders identified a regulatory vehicle that was in draft formation as an appropriate "fit" for federal oversight: the Clinical Laboratories Improvement Act of 1988 (CLIA),¹⁰ administered by the Department of Health and Human Services (HHS). However, when the regulations were published in proposal form, an eye bank was considered a "laboratory" under its definition; with an emphasis on large laboratories rather than small entities such as eye banks, it became quickly apparent that eye banks were a "square peg in a round hole." The EBAA submitted formal comments that made the case for excluding eye

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banks, and in the final regulations, eye banks were removed from the requirements of the Act.

The EBAA then turned its focus to the FDA as a potential vehicle for appropriate regulatory oversight. In December 1993, the FDA, acting on information of potential transmission of communicable disease through tissue transplantation, issued its first “Interim Final Rule” to regulate transmission of communicable disease through tissue transplantation.¹¹ Corneal tissue was included in the reach of this regulation as well as the FDA regulations and guidances that followed, some of which the Association deemed inapplicable to eye banking. EBAA members had historically relied on a record of no reported transmission of systemic disease resulting from corneal transplantation since the implementation of medical standards in the 1980s, but the FDA was not satisfied that this guaranteed safety or that it would satisfy public perception of safety. In late 1990, the EBAA had led the transplantation arena in its development (its implementation strengthened in 1991 by adding it as a requirement for accreditation) of an extremely effective adverse reaction reporting system. This stringent self-regulation, coupled with a 100-percent compliance in voluntary accreditation measures by the eye bank community, quelled FDA concerns regarding the safety and efficacy of eye banking and introduced an era of candid dialogue, comity, and partnership between the agency and the EBAA. The EBAA also reached out to the agency by creating a committee slot on its Medical Advisory Board for an FDA representative.

Two other seminal actions during the 1990s preserved EBAA’s independence and reinforced the Association’s standing with federal regulators on behalf of eye banks. In one, the EBAA actively pursued and was granted an exception to a legislative proposal that was originally part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, more commonly called the “Privacy Rule,”¹² thus allowing eye bank and other transplant technicians unfettered access to private health information that was necessary for informed decision making for transplant purposes. In the other, EBAA won a “pass through” designation, announced in 2000, from the Health Care Financing Administration, a division of HHS, that to this day allows for full reimbursement for corneal tissue provided for transplant at a “reasonable rate,” effectively reimbursing the cost of providing the tissue.¹³

A Community Builder

From its beginnings, the EBAA’s decision makers recognized the need to join and collaborate with other constituencies to achieve goals that would be difficult to reach alone. In addition to working with government officials, the EBAA has fostered crucial relationships with corneal surgeons, members of Lions Clubs, researchers, the broader organ and tissue transplant community, and the international community.

Corneal surgeons. The most obvious relationship has been between the EBAA and the broader ophthalmology community and the AAO. From the outset, the EBAA stressed the impor-

ance of surgeon involvement in eye banking, consistent with the legacy of R. Townley Paton. Under EBAA bylaws, an applicant could not open as an eye bank without the approval of the local ophthalmological community. In the first Constitution & Bylaws, drafted in the 1960s (a constitution was adopted in 1962 and bylaws followed shortly), each bank was required to appoint an ophthalmologist with special interest or expertise in corneal transplantation as its medical director. The surgeon/medical director remains one of the required centerpieces of every eye bank in the country, with corneal surgeons sharing the duties of governance with their eye bank colleagues. This relationship is mirrored by the association itself; physicians and eye bank professionals share its governance.¹⁴

Eye bank administrative, technical personnel, and surgeons—all working together—have forged a unique relationship: one of comity, cooperation, and collegiality. The dynamics of such mutual regard and respect have attracted volunteers to the association from across all communities, provided the impetus for collaborative research that has advanced the field of ophthalmology, and broadened public support for the eye banking community. The cultivation of young corneal surgeons, the “seed corn” for leadership of the future, led to the establishment of a Young Physician’s Leadership Program in 2011, created by the EBAA with the support and commitment of The Cornea Society,¹⁵ to attract and commit the physician leaders of tomorrow.

Lions Clubs. The EBAA has also enjoyed a special relationship with Lions Clubs International.¹⁶ In the early days of eye banking, every aspect of eye banking was local. Eye banks served their local corneal surgeon(s) and their geographical community. Eye banking proved a favorite charity of local Lions Clubs, which became active in the volunteer effort surrounding eye banks based on a speech Helen Keller gave to a 1925 Lions convention, in which she charged members to become “Knights of the Blind.” Many early eye banks were initially “Lions” banks, with Lions sitting on the board, raising funds to support the bank, and assuming a number of different roles from procurement through governance. As eye banks became professionalized, particularly in the technical area as required by EBAA medical standards, the direct operational involvement of Lions has lessened, although there is still strong community support of eye banks by Lions organizations.

Research community. While recovering and distributing tissue for transplantation are two of the six primary functions of the eye bank (Table 2), the provision of tissue for research has always assumed an important role in most member banks.¹⁷ Many banks, particularly

Table 2. Functions of Eye Banking

- Donor Eligibility Determination
- Recovery
- Storage
- Evaluation
- Processing
- Final Distribution

those housed in or associated with university-based departments of ophthalmology, have committed to research as part of their mission and service to the research community. In the world of medicine, ophthalmology stands out as a leader in innovation, with the provision of ocular tissue for research a significant component in its forward strides.

Starting in 1990, the EBAA became the recipient of funds from various manufacturers of corneal storage media; these monies allowed the EBAA to build a corpus of funds for the purpose of supporting grants for research related to eye banking and corneal surgery. At first, capital was committed to awarding small grants, each totaling up to \$5,000. As funds accumulated, the EBAA was able to commit more significant amounts to projects such as the Cornea Donor Study¹⁸⁻²⁰ and the ongoing Corneal Preservation Time Study. The Richard Lindstrom/EBAA Research Fund²¹ (named after one of the developers of the product) has been reestablished and amounts to more than \$1.2 million, and interest monies are targeted for awarding grants of up to \$15,000 each. These grants have been awarded both nationally and internationally.

Although not provided solely for research, an annual statistical report was introduced by the EBAA, based on the information collected and voluntarily provided by eye bank members since the late 1980s. It has identified the amount of tissue provided for transplantation, education, and research, as well as a breakdown of donation patterns. In the report for the year 2011,²² eye banks provided 19,230 tissues for research and 63,181 tissues for transplantation. The report's data collection tool was redesigned in 2010 to elicit more specific information to aid corneal surgeons and researchers by accumulating a history and specific profile of new surgical procedures that have been introduced over the past 5 years. The new system is vastly more sophisticated and will allow banks to see trends, compare data, and identify issues of importance to transplantation, providing fertile ground for eye bank research. These reports are updated online monthly and will result in the immediate availability of graphs and data.

Broader transplant community. When the EBAA was established in 1961, it was the first and only national association representing any kind of transplant organization in the world. Corneal transplantation preceded other human tissue transplants by decades, so perhaps it is not surprising that no associations had yet been dedicated to other types of tissues or organs. By the 1970s, EBAA, among other groups, recognized the need for a formal system of tissue banks, similar to the model that thrived within the eye banking community. The EBAA was instrumental in the founding of what became the American Association of Tissue Banks (AATB)²³ in 1976 and was a member "section" of that organization until the early 1990s. (The federal government institutionalized a system of organ banks in the 1980s in response to NOTA of 1984.⁸) By the time that other transplant organizations were founded, however, eye banking was a fairly dynamic system, enjoying a separate and historically unique sta-

tus. It had established ties in the community and relationships with hospitals, donor families, and recipients over the decades of its existence. Thus, individual eye banks resisted efforts to be subsumed by transplant organizations whose focus and interests were less well established. As a result, there has been both some competition and tension at the local level between eye banks, tissue banks, and organ procurement organizations (OPO)s. Whenever transplant organizations have joined together, whether under a single umbrella or in a collaborative fashion, to promote geographical interests, even within the auspices of an OPO, the eye bank retains membership in the EBAA and participates with its association colleagues in maintaining EBAA standards and procedures.

International community. International eye banking was not on the minds of the founders of the EBAA in 1961, but as the association and its community prospered and institutionalized policies and practices that could be shared, eye banks formed "sister" relationships with their international counterparts. These most often began as informal agreements to provide ocular tissue to a site in need; however, one United States banking system formed a federation of international eye banks in 1989. Under the aegis of the International Federation of Eye Banks (IFEB), Tissue Banks International (TBI)²⁴ opened multiple centers abroad throughout the 1990s. TBI established the eye banks, provided equipment, and employed staff, but often still found it necessary to use ocular tissue from the United States for transplantation. The most pressing need for the international community was an inadequate supply of tissue largely due to the absence of regionally based eye banks without an overseeing organization. With an adequate supply of tissue in the United States to meet its need, the number of tissues distributed abroad in the 2000s increased steadily. It is clear, however, that American eye banks cannot sustain the costs necessary to provide tissue outside this country at past levels. Reimbursement is tightening, as is philanthropy, and eye banks cannot afford to support such a vast need. Moreover, there is recognition that a more effective mode of outreach is to equip local international banks with the knowledge and infrastructure that will lead to independence, rather than reliance on exported tissue.

Funding to implement goals that could move international efforts forward in a shared trajectory has been and remains elusive. Over the past 15 years, there have been a number of formal and informal meetings among members of interested eye bank communities. In 1996, the EBAA hosted the Forum on World Eye Banking in Orlando, Florida, inviting international leaders in eye banking and corneal transplantation to discuss issues of mutual interest. This effort produced a set of draft medical standards for the international community, and an updated version served as guidelines when the European Union adopted international standards in 2004. In 2011, another group oriented toward raising the level of eye banking around the world was formed; The Global Alliance of Eye Banking brings together regional eye

bank associations, and its objectives appear to be more practical, as do the strategies for implementing them. The EBAA is an enthusiastic supporter of this alliance.

The association pursues its own programs to share its expertise with communities abroad. The Mary Jane O'Neill Fellowship in International Eye Banking, for example, was established in 2001 with joint funding from the EBAA and the Eye-Bank for Sight Restoration.²⁵ The fellowship brings an eye banking professional (physician or technician) most often to the United States for practical study with an Association member organization. Learning from early experience, the association has refined its requirements to focus on individuals who hail from an actual eye bank and whose command of English is sufficient to meet his or her needs and that of the banks. Fellows have visited from Vietnam, India, South Africa, and South America.

Additionally, the EBAA provided a pathway to international membership within its own organization by formally broadening its membership categories to include eye banks outside United States borders and by identifying different levels of membership—depending on accreditation status—recognizing that some of its standards are only relevant for American practice. International eye bank members enjoy the variety of services offered to American members: medical and regulatory alerts, position and policy papers, and access to research grants, as well as education through annual meetings, video conferencing, newsletters, leadership forums, and networking grants that allow bank staff to visit a member bank for the specific purpose of sharing information and practice.

Conclusions

The driving force behind eye banking is the restoration of sight. Corneal transplantation produces miracles, and will produce all the more as surgical procedures such as endothelial keratoplasty, deep anterior lamellar keratoplasty, and prosthokeratoplasty continue to evolve. These new surgical procedures have both altered the way in which eye banks function and have made the eye bank an even more intimate partner in the surgical event.

In 2009, the EBAA Board of Directors approved a revised mission statement intended to update its commitment to the values that have guided and sustained the association for more than 50 years: “The EBAA champions the restoration of sight through core services to its members which advance donation, transplantation and research in their communities and throughout the world.” Thus, as the association itself continues to evolve, facing whatever new challenges lie ahead, it will forever stay focused on its history. Additional information about programs and activities of the Eye Bank Association of America are available on its website (www.restoresight.org).

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