

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

Graeme Alfred Pollock, PhD, MPH

ABSTRACT

The Eye Bank Association of Australia and New Zealand is the peak body for eye donation and eye banking in Australia and New Zealand. It facilitates communication, cooperation, and the sharing of expertise between eye banks. It holds a strong focus on defining and implementing the profession's best practice, especially in regard to standards of quality and safety. The sound medical and scientific evidence base of the Association and its close ties with the ophthalmic profession have provided a strong foundation and allows it to speak with the confident and representative voice that is necessary to support many of its advisory and advocacy functions. Importantly, the uniqueness of eye banking in relation to other forms of donation has been foremost in the Association's approach, an approach that is necessary to ensure that national regulatory affairs and organisational models are designed appropriately for eye donation and eye banking as distinct from other forms of donation.

KEYWORDS: eye banks, corneal transplantation, medical standards, advocacy, biologicals regulation

The Eye Bank Association of Australia and New Zealand (EBAANZ) is the peak body for eye donation and eye banking in Australia and New Zealand. Currently every eye bank that operates in these two nations is a member. Through representation, cooperation, and education it works to support the Australian and New Zealand eye banks in delivering their services with consistently high levels of quality, safety, proficiency, and ethical standards.

The Association works in a number of key areas:

Quality: It promotes tissue safety through the setting of medical standards for eye donation and eye banking and by providing professional development.

Collaboration: It promotes communication, cooperation, collaboration, and sharing between eye banks.

Innovation: It encourages advancement in eye banking, eye donation, and eye tissue transplantation.

Advocacy: It communicates and advocates to government and regulatory agencies and with our partners in donation and transplantation (tissue banks and organ procurement agencies) to advance the restoration of sight.

Service: It provides a framework for sharing and distributing transplant tissue across Australia and New Zealand.

These values have helped guide the Association from its origins as a small forum with the objective of sharing information on eye banking, to its current status as an authority on eye banking medical and quality standards, and as a strong advocate for the profession.

Origins and History

EBAANZ traces its beginnings back to impromptu gatherings between eye bankers during the mid-1990s that were held during the annual Cornea and Eye Bank Meetings in Adelaide, Australia. While some eye banks in Australia were formed in the late 1950s as little more than a refrigerator in the corner of a hospital's ophthalmology department, the contemporary eye banks that we think of today first began to appear in 1982 with the establishment of the Lions South Australian Eye Bank. By 1991, five eye banks in Australia and one in New Zealand had been formally established—each with full-time staff, dedicated facili-

Author Affiliations: Lions Eye Donation Service, Centre for Eye Research Australia, The University of Melbourne.

Corresponding Author: Graeme Alfred Pollock, Lions Eye Donation Service, c/- RVEEH, Locked Bag 8, East Melbourne, Victoria 8002, Australia (graemeap@unimelb.edu.au).

Author Disclosure: The author reports no conflicts of interest.

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

ties, and its own set of Medical Standards. In their discussions, usually held over lunch or between sessions of the Cornea and Eye Bank Meeting, staff from these six now well-established eye banks began to identify a number of issues that were common to them all: new government regulations, the selection of donors, and reimbursement for services. In addition, a common and important thread in relation to all these issues began to emerge—the uniqueness of eye banking and the need to clearly articulate that reality to government agencies and regulatory authorities.

In this regard, the importance of clear, focused, and cohesive advocacy for the eye banks became readily apparent as the Therapeutic Goods Administration (TGA)—Australia's regulatory agency for drugs, medical devices, and biologicals—began rolling out its regulatory scheme for eye banks and tissue banks. (Under the framework, biologicals include tissue and cellular products, tissue and cell-based derivatives, and other emerging biological therapies.) The first iteration of this was the TGA's Australian Code of Good Manufacturing Practice (cGMP) for Therapeutic Goods: Human Tissues (September 1995). Eye banks and tissue banks were required to be licensed by the TGA and adhere to and be audited on the cGMP. Eye banks were caught up in a whirlwind of regulatory activity that was largely based on the code for Blood and Blood Products. Much of the code's embedded standards reflected those of blood banking and tissue banking (especially musculoskeletal tissue banking, the predominant form of tissue banking in Australia at the time). The failure to identify eye banking as a distinct entity, with its own unique standards, procedures, donation dynamics, and time constraints created a regulatory environment that was both divisive and ambiguous. The Australian eye banks were required to incorporate blood banking standards, alter existing procedures, and introduce new procedures, yet these provided no significant gains in risk reduction of eye tissue for transplantation. The opportunity cost was high; donation rates remained stagnant as limited resources were diverted from donor programs to unproductive and irrelevant work and re-work as dictated by the regulations.

Over the ensuing years the eye banks, sometimes acting in unison, managed to have some issues reviewed and resolved by the regulators. However, the release of a revised cGMP by the TGA, now the Code of Good Manufacturing Practice: Human Blood and Tissues (August 2000),¹ introduced a raft of new concerns for the eye banks. Once again these issues often arose due to the failure to provide good unified advocacy for the eye banking sector and to promote the unique requirements of eye banking as distinct from blood or tissue banking. Fortunately, through the collective efforts of the eye banks, a significant number of exceptions were introduced into the cGMP that accommodated the practice of eye banking.

It was this background of modestly effective joint advocacy that, during the Corneal and Eye Meeting held in Adelaide, Australia, in 2003, all six eye banks of Australia and New Zealand met to discuss the formation of what was to become EBAANZ. While advocacy and awareness was the initial impetus for the

formation, by 2003 the eye banks were also increasingly sharing information and expertise (and in many cases, corneas) among themselves. It was hoped that creation of an Association would facilitate this type of productive activity.

The first governance structure of the Association was deliberately designed to be simple and non-bureaucratic and would require only the enthusiasm and commitment of its members. Each eye bank would be considered a member of the Association and have an equal vote in the Association's affairs. The business of the Association would be carried out by a Chair and a Secretary; the Chair generally being the Medical Director of one of the eye banks and the Secretary usually the director/manager of a second eye bank. These responsibilities would rotate through each eye bank every two years. While this structure operated for a number of years with some significant results (including the production of Medical Standards and a framework for the sharing and distribution of tissue across Australia and New Zealand), it soon became apparent that EBAANZ required a more formal structure to allow it to operate more effectively. Thus in 2009 the Association legally became an Incorporated Association, adopted Rules of Incorporation (a Constitution), and created a democratically elected executive committee of Chair, Deputy Chair, and Secretary/Treasurer to carry out its business. Each eye bank in itself is a full member with full and equal voting rights regardless of size. Associate members, with no voting rights, are derived from the staff of each of the eye banks. All five eye banks in Australia and the one national eye bank of New Zealand are full members. During Incorporation the Association also officially adopted its name, abbreviation (EBAANZ), and logo (Fig. 1).



Fig. 1. Logo of the Eye Bank Association of Australia & New Zealand.

More recently this governance structure was strengthened through EBAANZ representation on the committee of the Australian and New Zealand Corneal Society. This Society constitutes a special interest group of the Royal Australian and New Zealand College of Ophthalmologists and provides a strong linkage and alliance between the professional standards of the eye banks and those of the ophthalmologists they serve.

Operationally, the elected executive committee members (Chair, Deputy Chair, and Secretary/Treasurer) are responsible for conducting most of the business of the Association. The Association's annual scientific meeting and Annual General Meeting is held in conjunction with the Australian and New Zealand Corneal Society meeting, and teleconferences are held three or four times a year to discuss the Association's activities, future plans, and sharing of information and ideas.

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

Medical and Quality Standards

A priority for the new Association was the development and publication of Medical Standards. It was important that standards of practice in the donation, retrieval, testing, preservation, and distribution of eye tissue were established by the experts of the two nations: the ophthalmological medical community and the eye banking community of Australia and New Zealand.

Prior to EBAANZ producing its medical standards, each eye bank operated through its own standards, which were largely based on those of the Eye Bank Association of America (EBAA). In most instances the in-house standards applied actually exceeded the requirements of the EBAA. In addition, the Australian eye banks had to adhere to the embedded standards within the regulatory agency's cGMP. So the impetus to develop medical standards was not driven by concerns of lack of safety or quality in practice, but more by the desire to discuss, analyse, and codify world's best-practice in eye donation and banking (and through an annual review to continue that process). The standards also had to encompass both hypothermic and organ culture storage of corneas in some detail and thus it was necessary to consult widely and to extensively examine the existing literature in the context of eye banking.

The authors of the first set of medical standards were also aided in their endeavours and drew heavily from a number of existing international standards, in particular those of the EBAA and those originating in the United Kingdom and Canada. Following a good deal of debate, review, and consensus among members, the first edition "EBANZ Medical Standards for Eye Donation and Ocular Tissue Banking" was published in August 2005. Some amendments were made over the ensuing few years (particularly to the Donor Screening and Contraindications Section) until a fully revised second edition, "EBAANZ Medical and Quality Standards for Eye Donation and Eye Tissue Banking," was published in April 2009.²

The authors of the first set of medical standards were also aided in their endeavours and drew heavily from a number of existing international standards, in particular those of the EBAA and those originating in the United Kingdom and Canada. Following a good deal of debate, review, and consensus among members, the first edition "EBANZ Medical Standards for Eye Donation and Ocular Tissue Banking" was published in August 2005. Some amendments were made over the ensuing few years (particularly to the Donor Screening and Contraindications Section) until a fully revised second edition, "EBAANZ Medical and Quality Standards for Eye Donation and Eye Tissue Banking," was published in April 2009.²

The Medical Standards have proved to be particularly important to the Association. Derived from world's-best medical and scientific practice, they provide a practical example of the Association's values; a de facto manifesto, if you will. Thus they are important in establishing a strong medical and scientific foundation from which most of our actions are directed. This is especially true in supporting the advocacy role of the Association and its members, as so much of our involvement and rhetoric in this field returns to ensuring the quality (primarily the safety and efficacy) of what we do. Importantly, the Standards also act as our professional statement and assurance to the government,

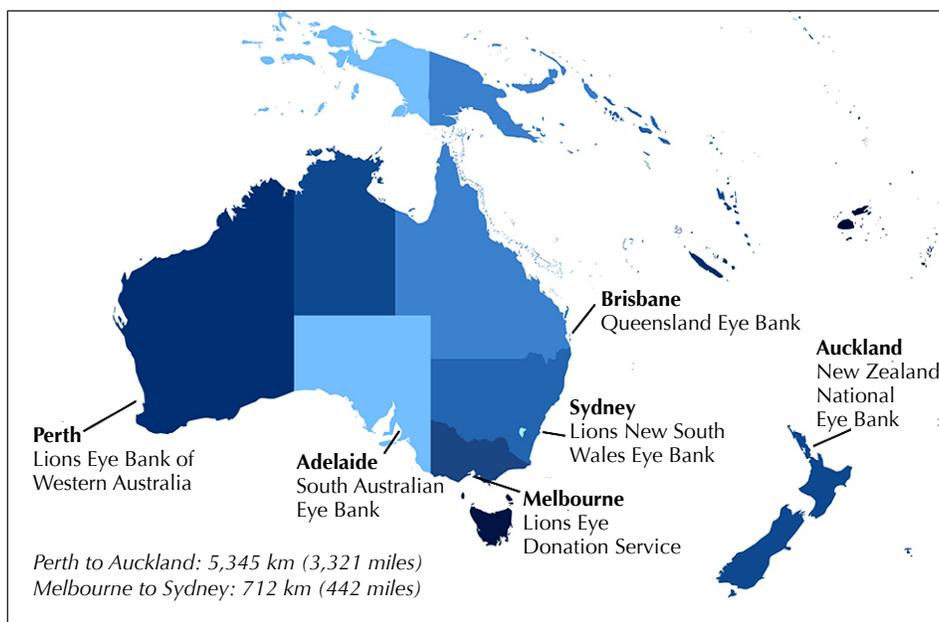


Fig. 2. Eye bank service delivery in Australia and New Zealand evolved to reflect their relatively small populations located in larger cities separated by vast distances.

the medical community, and the public so that they can place their faith and support in the practice of eye banking in Australia and New Zealand. Good evidence of this was shown when the TGA in 2010 included verbatim and referenced sections of the EBAANZ standards in its new Ocular Tissue Goods Orders (standards).^{3,4}

A Framework for Services

The eye banks in Australia and New Zealand were established and evolved through a combination of need, geography, available finances, and either partnership or agreement with Lions Clubs, university departments, regional governments, and health authorities. Acute care health delivery in Australia (in the public sector) is the immediate responsibility of each of the States and Territories, and in New Zealand it is the responsibility of the national government. The combined population of both nations is relatively small (26 million), but this population tends to live in large cities (1-5 million people) that are separated by vast distances (Fig. 2). Thus, the location and service delivery areas of the eye banks evolved to be aligned with government health care jurisdictions. Each eye bank is located in the largest city within its State or region (jurisdiction), and is primarily responsible for eye donation and distribution of corneas within that jurisdiction.

The growth of eye donation saw an increase in the degree of sharing of the available tissue between eye banks. This took into account corneas both in surplus and in deficit within a jurisdiction. However, while eye banks had always been sharing

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

corneas, the particular arrangements and requirements between eye banks differed. In order to improve and standardise these arrangements, and to facilitate a national exchange of corneas, EBAANZ developed a Service Agreement relating to the sharing of corneas between eye banks, to which all six member eye banks are signatories. The Agreement covers the information that is provided to a receiving eye bank regarding a cornea, financial arrangements relating to an exchange, and information regarding recipient and transplant information given to the receiving eye bank. Overall, eye donation and corneal transplantation activity in Australia and New Zealand is relatively small compared with other countries. However, the rates are healthy, and with 49.5 eye donors per million population in 2011, they compare favourably with overseas figures (Table 1). Thus, Australia and New Zealand have always been largely self-sufficient in donor cornea availability.

The Australian Corneal Graft Registry and the New Zealand Corneal Transplant Registry

Although not operated by EBAANZ, the eye banks give full support to the Australian Corneal Graft Registry and the New Zealand Corneal Transplant Registry (both outcome registries) by registering every corneal transplant that is performed in Australia

Table 1. Eye Donation and Corneal Transplantation Rates

Year	Eye Donors	Corneal Transplants
2008	1096	1696
2009	1032	1679
2010	1084	1668
2011	1288	1992

*Eye donation rate for 2011 is 49.5 per million population.

and New Zealand. (The Australian Registry is administered by the Ophthalmology Department of Flinders University in Adelaide and supported by Commonwealth Government grants; the New Zealand Registry is administered by the New Zealand National Eye Bank and the Ophthalmology Department of the University of Auckland.) It is understood that to receive a cornea from an EBAANZ member eye bank the ophthalmologist will supply details of the transplant and provide regular (yearly in the first few years) information on graft, patient, and centre outcome. This has allowed both Registries to amass a large and significant cohort relating to factors that influence the outcome of corneal transplantation, with (in 2012) some of this information now being analysed at 30-year graft outcomes.^{5,6}

Advocacy

Perhaps the most active role that EBAANZ has fulfilled in recent years is that of advocacy for the sector and the profession. This has taken the form of representation on technical and task force committees, through to review and consultation to government departments and regulatory agencies.

National Organ and Tissue Authority

The National Organ and Tissue Authority was established in 2009 by the Commonwealth Government of Australia as part of the Australian Government's new national reform package. The Authority is primarily involved in vascularised organ donation and transplantation and joint governance arrangements with State health departments of an Organ Donation Agency Network. However, one of its funded tasks is also the establishment of an Eye and Tissue Network. It is unclear what form such a Network will take given that eye banks and tissue banks in Australia operate under a number of different business and governance models, the majority of them being independent of government administration or direct funding. EBAANZ was represented on the Eye and Tissue Working Group that was tasked with making recommendations on the Network approach. The Association has been a strong advocate for recognising the uniqueness of eye banking and identifying and maintaining those organisational and operative elements of eye banking that have made it such a successful undertaking. Early indications are that initially a "network" will look at maximising and formalising shared collaborative efforts in operations, education, and communications, rather than introducing any national governance and funding structure. EBAANZ will play an important role in the collation, analysis, and interpretation of data in relation to eye donation rates, corneal distribution, and transplant outcomes that will inform the progression of the collaborative network.

In addition, the National Authority is responsible for an ongoing evidence-based national community awareness and education program for organ and tissue donation. The Association, in a consulting role, has been a strong advocate for the awareness of all the facts and figures of donation—not just the organ donation component.

The New Biologicals Framework (regulatory environment)

During 2011 and 2012 the TGA is introducing a new regulatory framework for biologicals in Australia.⁷ It is also planned that New Zealand and Australia will establish a joint regulatory agency by 2016, and thus New Zealand is likely to soon be subject to the same regulatory framework for biologicals as currently applies in Australia.

The new TGA Biologicals Framework retains the requirement for eye banks to be licensed as manufacturers and to comply with a cGMP for Blood and Tissues. It also introduces substantial additional requirements including the requirement for

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

each biological to comply with a product-specific standard (a Therapeutic Goods Order [TGO]) and to be registered on the table of Therapeutic Goods. The Association has been able to provide considerable feedback to the TGA during the development of the new cGMP and TGOs for biologicals. Our professional input and our published standards have been well considered by the TGA and, as noted above, some sections of the EBAANZ Standards have been incorporated into the Ocular Tissue TGO. This is in contrast to the original introduction of regulations in Australia when eye banks had no opportunity to consult with the TGA and had no professional organisation to represent the sector.

Funding and Reimbursement in Australia

Depending on the jurisdiction in which an eye bank operates, Australian eye banks are funded either through a combination of State government based grants, as a government funded and operated agency, or through fee-for-service contract arrangements with the State government. Importantly, though, in most cases the major component of income for an eye bank is the collection of service fees levied in the private health sector. Since the early 1990s service fee levels have been formally set through applications to the Commonwealth Government's Private Health Insurance Branch.⁸ A negotiated fee-per-service for each eye bank is established and published by the Commonwealth. This fee becomes the minimum amount health insurance companies must pay on behalf of their policy-holders for the service provided by the eye bank. Legislation across Australia (and New Zealand) dictates that trade (profit) in human tissue is illegal. Therefore the fee must be set at a not-for-profit level; the eye bank must demonstrate that the expected income derived from service fees does not exceed the expenditure involved in providing the service.

Over the past year the Commonwealth Government has been reviewing these arrangements. Given that eye banks in Australia derive the majority of their income from private service fees it is important that any new arrangements or alterations are formulated with a thorough understanding of eye banking practices and sources of income. EBAANZ has played an important role in advising the Commonwealth Government on the intertwined issues of donation rate, transplantation rate, required infrastructure, and staffing levels, public funding, support services, regulatory imposts, and costs, and their combined effect on service fee levels now and into the future. In this respect it has become important for EBAANZ to more fully understand the unique aspects of the "business" of eye banking and to clearly convey this understanding to public and private health administrators and governments alike.

Conclusions

The Eye Bank Association of Australia and New Zealand has over the past decade established itself as the peak body for eye

donation in Australia and New Zealand. Formed primarily in response to a difficult regulatory environment and the need for a professional body to provide expert and considered advice to regulators and government, the Association has ensured continued tissue safety and supply by setting the profession's medical standards for eye donation and eye banking. The sound medical and scientific evidence base of the Association, promoted by both its collegial culture and collaboration with the ophthalmic profession, have provided the strong foundation necessary to support many of its advisory and advocacy functions. Importantly, the uniqueness of eye banking in relation to other forms of donation has been foremost in the Association's approach. This approach is necessary to ensure that the regulatory affairs, medical standards, and organisation models are designed appropriately for eye donation and eye banking as distinct from other forms of donation. All of these activities have helped to ensure the continued success and viability of the eye banking sector in Australia and New Zealand.

References

1. Therapeutic Goods Administration. Australian Code of Good Manufacturing Practice – Human Blood and Tissues. August 2000. Therapeutic Goods Administration website. <http://www.tga.gov.au/pdf/manuf-cgmp-human-blood-tissues.pdf>. Accessed 15 February, 2012.
2. EBAANZ Medical and Quality Standards for Eye Donation and Eye Tissue Banking. Edition 2; 2009. EBBANZ website. <http://ebaanz.org/doc/EBAANZMedical&QualityStandards2ndEditionApril2009.pdf>. Accessed 15 February, 2012.
3. Therapeutic Goods Administration. Therapeutic Goods Order No. 85 Standards for Human Ocular Tissue. July 2011. Therapeutic Goods Administration website. <http://www.comlaw.gov.au/Details/F2011L01491>. Accessed 15 February, 2012.
4. Therapeutic Goods Administration. Australian Regulatory Guidelines for Biologicals, Appendix 5—Guidance on TGO 85 (Standards for human ocular tissue). Version 1; June 2011. Therapeutic Goods Administration website. <http://www.tga.gov.au/pdf/biologics-argb-app05.pdf>. Accessed 15 February, 2012.
5. Williams KA, Lowe MT, Bartlett L, et al, eds. Australian Corneal Graft Registry 2007 Report. Adelaide, Aust: Flinders University Press, 2007. Department of Ophthalmology, Flinders University website. https://dspace.flinders.edu.au/jspui/bitstream/2328/1723/3/FINAL_COMPILED_REPORT_2007.pdf. Accessed 15 February, 2012.
6. Patel HY, Ormonde S, Brookes NH, et.al. The New Zealand National Eye Bank: Survival and Visual Outcome 1 Year After Penetrating Keratoplasty. *Cornea* 2011; 30(7):760-764. doi:10.1097/ICO.0b013e3182014668.
7. Therapeutic Goods Administration. Australian regulatory guidelines for biologicals (ARGB). August 2011. Therapeutic Goods Administration website. <http://www.tga.gov.au/industry/biologics-argb.htm>. Accessed 15 February, 2012.

GLOBAL PERSPECTIVES

The Eye Bank Association of Australia and New Zealand: Origins, History, Activity, and Future

8. Australian Government Department of Health and Aging. Private Health Insurance—Prostheses List, Guides and Application Forms. Department of Health and Aging, Commonwealth of Australia website. <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheselistforms#HumanTissueList>. Accessed 15 February, 2012.