Position Statement: Virology testing of Eye Donors in Australia – July 2009

The Eye Bank Association of Australia and New Zealand Inc. (EBAANZ) was formed to promote cooperation, communication, consistency and reliability of service between Eye Banks for the benefit of donors, donor families, ophthalmic surgeons and tissue recipients. All Eye Banks in Australia and New Zealand are members of the Association. Most importantly, EBAANZ and its member Eye Banks hold a strong commitment towards ensuring the safety and quality of transplanted eye tissue. We believe that our leadership in this field must be supported through the application of evidence-based medicine and scientific rigor, combined with effective and efficient administrative and management principles.

EBAANZ member Eye Banks and the associated ophthalmic profession have an enviable quality and safety record. No infectious communicable disease has ever been transmitted through the transplantation of eye tissue in Australia and New Zealand. In the early 1980’s Australian Eye Banks and ophthalmologists were among the first donation and transplant services in the world to introduce hepatitis B virology testing. This pre-dated the use of this screening in the Australian blood donor population. This experience was repeated in 1990 when Australian Eye Banks were among the first in the world to introduce hepatitis C testing, again pre-dating the blood donor screening in Australia. EBAANZ members continue to apply stringent criteria to donor acceptability through a thorough process of donor screening based on medical and social history, clinical status, physical assessment and testing.

It is in this context of bio-safety vigilance and overall responsibility to the community that EBAANZ considered Nucleic Acid Amplification Technology (NAT) testing of eye donors. NAT testing offers a reduced “window period” between infection and detection of virus. EBAANZ believes that for a test to be considered mandatory as part of an overall quality approach to safety and quality of transplant tissue there must be a consideration and evaluation of testing efficacy (in relation to efficiency, sensitivity, specificity and reliability), availability, significant risk reduction versus benefit and overall cost versus benefit. Within this framework consideration must be given to:

- Guidance based on data specific to the properties of the tissue being offered for transplant.
- A risk-based analysis on the number of tissues likely to be discarded versus the number of recipients likely to acquire the disease.
- A risk-based approach to transmission (evaluating the relevance of a disease to different types of tissues).
- A cost versus benefit analysis prior to the introduction of additional testing.

Conclusions

EBAANZ has produced accompanying documentation that provides both a risk analysis and a cost benefit approach to virology testing of eye donors in Australia and New Zealand. The Association concludes:

- In the Australian and New Zealand context mandatory NAT testing will provide no reduction in risk, either in relation to detection of eye donors with viraemia or in regard to the transmission of viruses through corneal transplantation.
- The low prevalence of the disease in the Australian and New Zealand eye donor population makes the risk/benefit ratio of loss of tissue as a result of NAT testing unacceptable.
- The significant increasing costs related to tests that have not been scientifically validated to significantly reduce risk cannot be justified.

Thus:

The Eye Bank Association of Australia and New Zealand does not support the mandatory NAT testing of eye donors in Australia or New Zealand until such a time when it is scientifically demonstrated that this type of testing is justifiable on a cost versus benefit and risk reduction basis.