



INTERNATIONAL COUNCIL
of OPHTHALMOLOGY



Cornea Society
Advancing the treatment of corneal disease

Donation, Processing, Allocation, Advocacy, and Legislation Supporting Human Corneal Tissue for Ocular Transplant

Position: The International Council of Ophthalmology, Cornea Society, and Global Alliance of Eye Bank Associations, encourage Custodians (ophthalmologists, eye banks, Ministries of Health, clinical service providers, and non-governmental advocacy groups) to promote national sustainable self-sufficient practice and policy, in relation to quality and safety, procedure, procurement, processing, and equitable distribution of human Corneal Tissue (CT), through implementing ethical, affordable, and standardized legislation, policy, best practices and service.

Goal: To ensure the respectful management of donation, strong infrastructure, and improved access to quality CT for waiting recipients - by working as a harmonized collective global sector, driving legislative change; standardization of sector expectation and policy; streamlining of existing services (inclusive of cost recovery systems; bioethical, procedural, safety and quality parameters); improved donation practices; maximizing utilization through innovation, research and development; and equitable and standardized access to CT for waiting recipients.

Background: Corneal blindness conditions, leading to corneal opacification, accounts for 4% of the world's 45 million blind (WHO, 2010), a large portion of which is treatable. Treatment for many people with these conditions can be provided via a corneal transplantation, making access to CT essential to prevent blindness and subsequent disability (Doughman & Rogers, 2012).

CT is donated as an end-of-life gift by the deceased and their next-of-kin, and is entrusted to sector Custodians, who have a collective responsibility to both the donor and recipient (Noel & Martin, 2009) to ensure ethical utilization.

CT is distinctly different from other tissues and organs, and requires a unique (AAO Statement, 2016) and individualized management and legislative plan (as CT is processed like other tissue yet transplanted relatively quickly, similarly to 'living organ' donation).

In 2012, while an estimated 184,576 corneal transplants were performed across 116 countries (Gain et al, 2015) through local recovery and importation processes, supply currently does not meet demand, particularly in lower resource locations. Gain et al (2015) estimate that there are 12.7 million people waiting for a corneal transplant.

Recommendations:

Custodians are encouraged to:

1. Collaborate with sector members, local, national, and international agencies, both governmental and non-governmental, to harmonize and support the development and implementation of eye banking programs and associated activities – aimed at the promotion of ethical recovery and improved ocular health and sight restoration. (EBAANZ, 2015).
2. Strive for long-term self-sufficient national service (Martin et al, 2017).
3. Support Sustainable Development and GAP2014-2019 Universal Eye Health strategies. (WHO, 2013).
4. Legislate for the clear distinction between human tissue for ocular application, and other tissues, organs (AAO statement, 2016) and human biologicals.
5. Develop services and legislation in accordance with the: *United Nations' 1948 Declaration of Human Rights; World Health Organization's 2010 Guiding Principles on human cell, tissue, and organ transplantation; and 2006 Aide-Memorie: Access to Safe and Effective Tissues for Transplantation;* national Tissue Acts (or support implementation if not already in place); sector bioethical frameworks; good manufacturing principles; and/or national trade practicing or proprietary laws.
6. Support the inclusion of corneal services within the wider short- and long-term national or regional *Eye Health Plans*.
7. Implement policy, tracking and surveillance, operating procedures, and quality systems, in accordance with local, regional, or global minimal practice standards.
8. Manage cost-recovery and distribution (allocation) - in accordance with sector bioethical principles and policy (GAEBA, 2017; WHO, 2010).

Professionalism

9. Collaborate harmoniously as sector Custodians.
10. Perform duties in dual consideration of donor and recipient.
11. Promote specialist professional qualifications and professional development.

Procurement

12. Implement public promotion programs to specifically address eye donation.
13. Encourage partnership with existing organ or tissue procurement agencies.
14. Work within national systems when establishing consent from donor/next-of-kin.

Registries

15. Maintain a national/pan-national donor registry.
16. Implement a national/pan-national corneal transplant register in conjunction with ophthalmology or corneal societies – inclusive of export and import tracking of donor and recipients.
17. Inform the sector of adverse events inclusive of transmission of disease, trafficking, or counterfeit activities via the national or regional corneal and eye

bank associations and/or the WHO's Project Notify Library system.

Recommended Readings:

1. World Health Organization. (2010). *Guiding principles on human cell, tissue, and organ transplantation*. www.who.int/entity/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf?ua=1
2. World Health Organization. (2006). *2006 Aide-Memoire: Access to Safe and Effective Tissues for Transplantation*. <file:///U:/Reference%20Library/WHO%20and%20DoI/WHO%20Aide-%20Memoire%20AM-HCTTServices.pdf>
3. United Nations. (1948). Universal Declaration of Human Rights. www.un.org/en/documents/udhr/
4. Project Notify Library. <https://protect-au.mimecast.com/s/rNKkB3t1oNJbcW?domain=notifylibrary.org><<https://protect-au.mimecast.com/s/ZXq6BmSQ9z5qFx?domain=notifylibrary.org>>

References:

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2. EBAANZ: Eye Bank Association of Australia and New Zealand. (2015). *Bioethical Framework for Policy and Procedure*. <http://www.ebaanz.org/wp-content/uploads/2016/05/EBAANZ-Bioethic-Framework-2015.pdf> Accessed 05.05.2017
3. Doughman, D, J., & Rogers, C, C. Eye Banking in the 21st Century: How far have we come? Are we prepared for what's ahead? *International Journal of Eye Banking*. 1, 1, Sept 2012. 1 - 15
4. Gain, P, Jullienne, R, He, Z, Aldossary, M, Acquart, S, Cognasse, F., Thuret, G. (2015). Global Survey of Corneal Transplantation and Eye Banking. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2015.4776 Published online December 3, 2015
5. Global Alliance of Eye Bank Associations. *Position Statement: Commodification and Profitization of human materials and ocular services*. August 2017. <http://www.gaeba.org/wp-content/uploads/2017/08/GAEBAPositionStatementCommodificationandprofitizationofhumanmaterialsandocularservices.pdf> Accessed 09.07.2017
6. Martin, D, Kelly, R, Jones, G, Machin, H., & Pollock, G. (2017). Ethical issues in transnational eye banking. *Cornea*. 36. (2). 252-257.
7. Noel, L., & Martin, D. Progress towards national self-sufficiency in organ transplants. *Bull World Health Organization*.2009:87:647

8. World Health Organization. (2010). *Action plan for the prevention of avoidable blindness and visual impairment 2009 – 2013*. http://www.who.int/blindness/ACTION_PLAN_WHA62-1-English.pdf
Accessed: 24.05.2017.
9. World Health Organization. (2013). *Universal Eye Health. A Global Action Plan. 2014-2019*. http://www.who.int/blindness/AP2014_19_English.pdf?ua=1
Accessed 29.05.2017