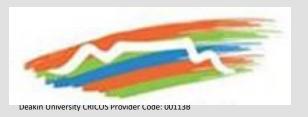
Ethical aspects of transnational eye banking

A/Prof Dominique Martin, MBBS, PhD

Dominique.martin@deakin.edu.au



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Disclosures



I have no conflicts of interest with regards to this presentation.

All opinions expressed in this presentation are my own and do not necessarily reflect those of any of the organizations with which I have been or am currently affiliated.

Ethical Issues in Transnational Eye Banking

Martin, Dominique E. PhD, MBBS, BA (Hons); Kelly, Richard MD, BBiomed; Jones, Gary L. A. BSc (Econ); Machin, Heather RN, MBA; Pollock, Graeme A. PhD, MPH, BSc (Hons)



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Review

Purpose: To review ethical issues that may arise in the setting of transnational eye banking activities, such as when exporting or importing corneal tissue for transplantation.

Methods: A principle-based normative analysis of potential common dilemmas in transnational eye banking activities was performed.

Results: Transnational activities in eye banking, like those in other fields involving procurement and use of medical products of human origin, may present a number of ethical issues for policy makers and professionals. Key ethical concerns include the potential impact of export or import activities on self-sufficiency of corneal tissue supply within exporting and importing countries; potential disclosure requirements when obtaining consent or authorization for ocular tissue donation when donations may be exported; and difficulties inherent in assuring equity in the allocation of tissues available for export and in establishing and respecting standards of safety and quality across different jurisdictions.

Conclusions: Further analysis of specific ethical issues in eye banking is necessary to inform development of guidelines and other governance tools that will assist policy makers and professionals to support ethical practice.

Overview



- Ocular tissue as a medical product of human origin
- Transnational eye banking
- Key ethical concerns and current dilemmas in transnational eye banking

Ocular tissue as a medical product of human origin (MPHO)



MPHOs:

"substances derived wholly or in part from human biological materials and intended for clinical application" (Noël and Martin 2015)

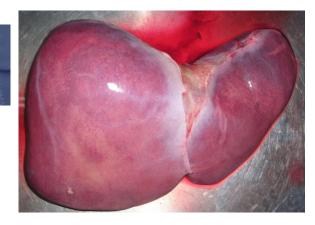
Which MPHO raises ethical concerns?











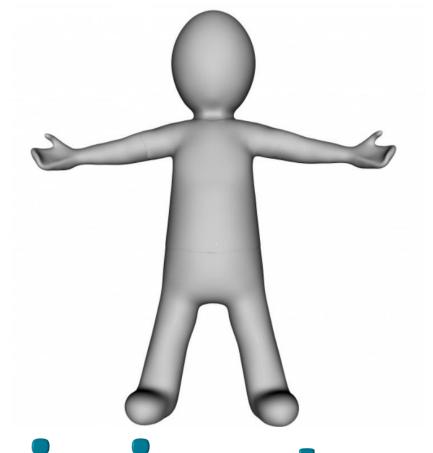






Ethical implications of MPHOs





Ethical concerns common to all MPHOs:

- sufficiency and quality of supply
- risks and benefits for recipients
- equity of access and allocation

Recipient needs

Ethical implications of MPHOs





Ethical concerns common to all MPHOs:

- Consent of donors/donor families
- Risks and benefits of donation
- Equity in donation
- Equity of access to MPHOs for donor populations
- Commodification of MPHOs and donation

Transnational eye banking impacts many countries



In 2012, an estimated 11% of corneal transplants performed worldwide used imported tissue, with 27 countries wholly dependent and 43 countries partially dependent on imported tissue.⁴ Eight percent of corneal tissue procured annually was reportedly exported, primarily from the United States, which accounted for 85% of corneal exports, Sri Lanka (9%), and Italy (3%).⁴ Thus, of the 116 countries currently active in corneal transplantation, at least 70 of these are directly involved in transnational eye banking activities.⁴

Martin et al. 2017 (data from Gain et al. 2016)

1700 corneas imported by Sth Africa in 2017!

Key ethical concerns arising in the context of transnational eye banking



- Implications for consent to/authorization of donation
- 2. Equity in allocation of donated tissues
- 3. Impact on self-sufficiency
- 4. Economic implications and financial neutrality of donation

1. Implications for consent to/authorization of donation



Respecting autonomy in donation decision-making:

- Can consent to export be presumed?
- Should the possibility of export be routinely disclosed?
- How much information about export practices is sufficient?
- Should conditional donation excluding export be permitted?

LAS VEGAS REVIEW-JOURNAL

But when she learned from a network representative in an exchange But when she learned from a network representative in an exchange following the post that her son's corneas had been sent overseas, her donation pain was too raw for her to remain silent.

"I would love to know how much money you guys got for my son's Leaves he corneas that I gave to you guys — for free — to help a kid in the

United States — for free," she asked in a video posted on Instagram last week. LiCari, who started a foundation to assist children with cancer or sickle cell anemia and their families, has 316,000 Instagram followers.



https://www.reviewjournal.c om/local/local-las-vegas/lasvegas-womans-donation-ofsons-corneas-leaves-herangry-1832635/

2. Equity in allocation of donated tissues



Promoting justice in the local and global context:

- Should domestic needs be prioritized (export only when "surplus" available)?
- Should higher quality tissues be prioritized for domestic use?
- Which criteria should guide selection of export destinations? E.g. ability to cover costs, generate profit, or maximise utility for recipients?

3. Impact on self-sufficiency



Promoting self-sufficiency such that populations are able to sustainably meet their own needs for corneal transplants.

- Is continued generation of tissue surplus to domestic needs a justifiable demand upon domestic donor populations?
- Should export activities be conditional upon complementary interventions to support development of sustainable eye banking activity in importing destinations?
- Is long term reliance on imports of tissue preferable to development of domestic eye bank programs if the former is more cost-effective?

4. Economic implications and financial neutrality of donation



Respecting altruism and solidarity in donation and the principle of financial neutrality:

- How should we determine reasonable fees for products and services in the context of transnational eye banking?
- To what extent is generation of profit via export activities
 justifiable? E.g. if profits are used to sustain generation of surplus
 tissue, research and development, etc?
- When does cost-recovery become undue profit generation?

Ethical guidance for eye banking





WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION¹



GLOBAL ALLIANCE

Barcelona EPrinciples

An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies[©].

www.gaeba.org/publications

Thank you!

Dominique.martin@deakin.edu.au



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